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BTEC

Edexcel Level 3 BTEC National Certificate in Pharmacy Services

For first teaching September 2007

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Specification

Edexcel Level 3 BTEC National Certificate in Pharmacy Services

QCA
Qualifications and Curriculum Authority

Llywodraeth Cynulliad Cymru
Welsh Assembly Government

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Rewarding Learning

Edexcel, a Pearson company, is the UK's largest awarding body offering academic and vocational qualifications and testing to more than 25,000 schools, colleges, employers and other places of learning here and in over 100 countries worldwide. We deliver 9.4 million exam scripts each year, with 3 million marked onscreen in 2005. Our qualifications include GCSE, AS and A Level, GNVQ, NVQ and the BTEC suite of vocational qualifications from entry level to BTEC Higher National Diplomas and Foundation Degrees. We also manage the data collection, marking and distribution of the National Curriculum Tests at Key Stages 2 and 3, and the Year 7 Progress Tests.

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Contents

Ten principles for delivering an Edexcel Level 3 BTEC National qualification

This specification contains the rules and regulations, along with the units and associated guidance, to enable centres to design and deliver a programme of learning for the Edexcel Level 3 BTEC Nationals in Pharmacy Services. The qualification structures set out the permitted combination of units learners need to complete the qualification. Each unit sets out the learning outcomes and grading criteria along with content, advice and guidance regarding appropriate delivery and assessment strategies. The following generic principles need to be adhered to so that a BTEC qualification is delivered to the appropriate standard.

1 **The specification:** The specification gives the information needed for the successful delivery and achievement of the units and the qualification as a whole. The specification is of importance to the learner and the tutor alike. Individual units can be delivered and studied in isolation but the learner and the deliverer should have access to the full information provided to support the programme of learning.

2 **The website**: Centres need to make regular use of the Edexcel website (www.edexcel.org.uk) to ensure that they have the most up-to-date information. In particular, the requirements for the external verification of the qualification receive regular updates, and appropriate information for centres is posted on the website. It is the responsibility of the centre to ensure that they are familiar with the latest BTEC NQF Level 2/3 (including Short Courses at Levels 1–3) Handbook and that they implement any related policy documentation which may have been posted on the website.

3 **Policy:** This specification gives details of our assessment and quality assurance procedures. It includes advice about our policy regarding access to our qualifications, the design of programmes of study and delivery modes. Centres must ensure that they follow the procedures and conform to the policies outlined.

4 **Recruitment:** Centres are required to recruit learners with integrity. A fundamental aspect of this integrity is that centres take appropriate steps to assess each applicant's potential and make a professional judgement about the applicant's ability to be able to successfully complete the programme of study and achieve the qualification. Centres should ensure that applicants have appropriate information and advice about the qualifications and that the qualification will meet their needs.

5 **Assessment:** Centres are required to use this specification to design and deliver a programme of learning that will enable learners to achieve the grading criteria stipulated in the unit grading grids. The programme of learning should consist of assignments which provide the opportunity for coverage of all grading criteria as set out in the grading grid for each unit. Assignments must be reliable and fit for purpose, giving learners every opportunity to generate evidence which satisfies the grading criteria. Centres should use a variety of assessment methods, including case studies, assignments and work-based assessments, along with projects, performance observation and time-constrained assessments where appropriate.

6 **Assignments:** Centres are encouraged to apply the grading criteria in a practical way. They should provide, wherever possible, a realistic scenario for learners to work with, and make maximum use of practical activities and work experience. The creation of assignments that are fit for purpose is vital to the learner's achievement.

7 **National Qualifications Framework (NQF):** These qualifications have been accredited to the NQF and are eligible for public funding as determined by the DfES under Sections 96 and 97 of the Learning and Skills Act 2000. Details of the qualification units can be seen on the QCA OpenQuals database (www.openquals.org.uk).

8 **Qualification Accreditation Numbers (QANs):** The qualification titles feature in the funding lists published annually by the DfES and on the regularly updated website www.dfes.gov.uk/. The NQF QANs should be used by centres when they seek public funding for their learners. The QANs are listed in *Annexe A*.

9 **Accreditation**: This specification is accredited by the Qualifications and Curriculum Authority (QCA) until 31/08/2009 and for certification of learners until 31/08/2012. This specification may be updated during its period of accreditation and centres should refer to our website for the latest issue.

10 **Approval:** Centres that have not previously offered BTEC qualifications must apply for, and be granted, centre approval before they can apply for approval to offer the programme. When a centre applies for approval to offer a BTEC qualification they will be required to enter into an 'approvals agreement'. The approvals agreement is a formal commitment by the head or principal of a centre to meet all the requirements of the specification and any linked codes or regulations.

What are BTEC Nationals?

BTEC Nationals are qualifications that are designed to provide specialist work-related qualifications in a range of sectors. They give learners the knowledge, understanding and skills that they need to prepare them for employment. The qualifications also provide career development opportunities for those already in work. Consequently they can provide a course of study for full-time or part-time learners in schools, colleges and training centres.

The family of BTEC Nationals includes Awards, Certificates and Diplomas which offer opportunities for nested provision and flexibility of delivery.

BTEC Nationals are designed to relate to the National Occupational Standards for the sector, where these are appropriate, and are supported by the relevant Standards Setting Body (SSB) or Sector Skills Council (SSC). Some BTEC Nationals form the Technical Certificate component of Apprenticeships and all attract UCAS points that equate to similar-sized general qualifications.

On successful completion of a BTEC National qualification, learners can progress into or within employment and/or continue their study in the same vocational area.

BTEC National Award

The 360 guided learning hours (GLH) (usually six units) BTEC National Award offers a specialist qualification that focuses on particular aspects of employment within the appropriate vocational sector. The BTEC National Award is a qualification which can extend a learner's programme of study and provide vocational emphasis for learners following an Applied GCE or GCE route or a combination of both in their main programme of study. The BTEC National Award is especially suitable for more mature learners, who wish to follow a shorter programme of study directly related to their work experience or to an area of employment that they wish to move into.

BTEC National Certificate

The 720 GLH (usually 12 units) BTEC National Certificate provides a specialist work-related programme of study that covers the key knowledge and practical skills required in the appropriate vocational sector. The BTEC National Certificate offers flexibility and a choice of emphasis through the specialist units. It is broadly equivalent to two GCEs or the full award AVCE.

The qualification offers an engaging programme for those who are clear about the area of employment that they wish to enter. These learners may wish to extend their programme through the study of a related GCE, a complementary NVQ or another qualification. These learning programmes can be developed to allow learners to study complementary qualifications without duplication of content.

For adult learners the BTEC National Certificate can extend their experience of work. It is a suitable qualification for those wishing to change career or move into a particular area of employment following a career break.

BTEC National Diploma

The 1080 GLH (usually 18 units) BTEC National Diploma extends the specialist work-related focus available from the BTEC Certificate. There is potential for the qualification to prepare learners for employment in the appropriate vocational sector and is suitable for those who have decided that they wish to enter a particular area of work.

Some adult learners may wish to complete this qualification in order to enter a specialist area of employment or progress into higher education. Other learners may want to extend the specialism that they followed on the BTEC National Certificate programme.

Progression from the BTEC National Diploma could be into employment where learners might take professional body examinations or complete NVQs. Alternatively, learners could continue to degree or other higher-education programmes in the same vocational sector or in a related sector.

National Occupational Standards (NOS)

BTEC Nationals are designed to relate to the National Occupational Standards in the sector which in turn form the basis of the National Vocational Qualifications (NVQs). BTEC Nationals do not purport to deliver occupational competence in the sector, which should be demonstrated in a work context. However, the qualifications provide much of the underpinning knowledge for the National Occupational Standards, as well as developing practical skills in preparation for work and possible achievement of NVQs in due course.

Each unit identifies relevant aspects of the National Occupational Standards that are addressed by the outcomes and content of the unit. These BTEC Nationals in Pharmacy Services relate to:

- NOS Level 3 in Pharmacy Services: 3.01 to 3.12.

A mapping of these NOS is available in *Annexe D*.

Key features of the BTEC Nationals in Pharmacy Services

The BTEC National Certificate in Pharmacy Services has been developed to focus on:

- education and training for pharmacy technicians who are employed in the pharmacy sector, eg hospital, community or industry or Primary Care Trusts
- providing opportunities for pharmacy technicians to achieve a nationally recognised Level 3 vocationally specific qualification
- providing opportunities for full-time learners to gain a nationally recognised vocationally specific qualification to enter employment as a pharmacy technician or to progress to higher education vocational qualifications such as a full-time degree in pharmacy (provided that any additional requirements have been met, such as learners achieving a GCE in Chemistry)
- developing learners' knowledge, understanding and skills from a pharmacy technician's viewpoint

- the role of the pharmacy technician, their relationship within the section/department in which they work and how their role and their department/section fit into the organisational structure and the other pharmacy sectors and local community
- giving learners opportunities to develop the major key skills and wider key skills such as improving own performance, working with others and problem solving, in a science and technological context
- providing opportunities for learners to develop a range of skills and techniques, personal qualities and attitudes essential for successful performance in working life.

These qualifications provide underpinning knowledge for NOS Level 3 in Pharmacy Services and make a contribution to the Technical Certificate/Modern Apprenticeship for pharmacy technicians.

Rationale of the BTEC Nationals in Pharmacy Services

This qualification allows learners to develop the skills required to enable them to make an effective contribution within the pharmacy sector.

Learners could come to this qualification from a standard secondary school education or from a more vocationally related background within the pharmacy sector.

The BTEC National Certificate in Pharmacy Services prepares the learner for employment in the pharmacy sector. Learners could also use this qualification to progress to a higher education qualification, such as an undergraduate degree in pharmacy (provided that any additional requirements have been met, such as learners achieving a GCE in Chemistry).

Because of the skills, knowledge and understanding learners need for employment or progression to higher education, the qualification consists of nine core units and five specialist units. The learners must complete all core units and three of the specialist units. This allows centres to choose which specialist units are most suitable to deliver, based on the teaching strengths of their staff and the learning requirements of the learners.

The core units of the BTEC National Certificate in Pharmacy Services include the skills, knowledge and understanding required by all pharmacy technicians. However, the content of the specialist units is more specific, as required by particular learners in preparation for employment in a specific job role.

There is opportunity for innovative, imaginative and creative curriculum planning and delivery in all of the units of this qualification, in both delivery of the content and the assessment of each unit.

Registration of Pharmacy Technicians

Learners who are seeking employment in the pharmacy sector, as a pharmacy technician, will soon be required to register with the Royal Pharmaceutical Society[1]. Registration requirements are the completion of the BTEC National Certificate in Pharmacy Services (or similar qualification meeting technical certificate requirements) and the Level 3 NVQ in Pharmacy Services. For more information on the registration of pharmacy technicians please see the Royal Pharmaceutical Society website (www.rpsgb.org.uk).

To meet the requirements of the Royal Pharmaceutical Society of Great Britain for the Technical Certificate in Pharmacy Services a learner must:

- achieve a pass (or above) grade for the nine core units plus three specialist units
- be undertaking work experience of not less than 14 hours a week. This must be under the supervision, direction or guidance of a practicing pharmacist.

[1] The Pharmacists and Pharmacy Technicians Order 2006 is expected to come into force at the end of 2006 or early in 2007 making registration statutory for pharmacy technicians in England and Wales.

Structure of the qualification

Edexcel Level 3 BTEC National Certificate in Pharmacy Services

The Edexcel Level 3 BTEC National Certificate in Pharmacy Services consists of nine core units **plus** three specialist units that provide for a combined total of 720 guided learning hours (GLH) for the completed qualification.

Edexcel Level 3 BTEC National Certificate in Pharmacy Services			
Unit	**Core units**	**GLH**	**Level**
1	Scientific Principles for Pharmacy	60	3
2	Pharmacy Law, Ethics and Practice	60	3
3	An Introduction to Action and Uses of Medicines	60	3
4	Cytotoxic, Endocrine and Nutritional Medicines	60	3
5	Central Nervous System, Eyes, ENT, Skin and Gynaecological Medicines	60	3
6	Cardio-respiratory and Genito-urinary Medicines, and Medicines Management	60	3
7	Pharmaceutics	60	3
8	Human Physiology for Pharmacy	60	3
9	Microbiology for Pharmacy	60	3
Unit	**Specialist units — choose three**		
10	Pharmacy Practice	60	3
11	Pharmacy Production	60	3
12	Chemistry for Pharmacy	60	3
13	Scientific Method for Pharmacy Technicians	60	3
14	Information and Automation Technology for Pharmacy	60	3

These units are not listed in teaching order. Centres can teach these units in the order that they feel is best.

Unit format

All units in Edexcel Level 3 BTEC National qualifications have a standard format. The unit format is designed to give guidance on the requirements of the qualification for learners, tutors, assessors and those responsible for monitoring national standards.

Each unit has the following sections.

Unit title

The unit title is accredited by QCA and this form of words will appear on the learner's Notification of Performance (NOP).

NQF level

This is the level of the unit within the National Qualifications Framework (NQF). The level of the unit has been informed by the NICATs level descriptors and, where appropriate, the NOS and/or other sector/professional benchmarks.

Guided learning hours (GLH)

In BTEC National qualifications each unit consists of 30, 60, 90 or 120 GLH. Guided learning hours are 'a notional measure of the substance of a unit'. GLH include an estimate of time that might be allocated to direct teaching, instruction and assessment, together with other structured learning time such as directed assignments or supported individual study. It excludes learner-initiated private study. Centres are advised to consider this definition when planning the programme of study associated with this qualification.

Unit abstract

The unit abstract gives the reader an appreciation of the value of the unit in the vocational setting of the qualification as well as highlighting the focus of the unit. It gives the reader a snapshot of the aims of the unit and the key knowledge, skills and understanding developed while studying the unit. The unit abstract also highlights any links to the appropriate vocational sector by describing how the unit relates to that sector.

Learning outcomes

Learning outcomes state exactly what a learner should 'know, understand or be able to do' as a result of completing the unit.

Unit content

The unit content gives centres the substance to devise and plan the programme of learning needed for the learning outcomes to be successfully achieved. Evidence to meet the grading criteria will include relevant areas of the unit content as described in the assessment section of the unit. Where appropriate, this is informed by the underpinning knowledge and understanding requirements of the related National Occupational Standards (NOS).

The unit content sets out each learning outcome with prescribed key phrases or concepts listed in italics followed by the range of related topics. Detailed lists provide an indicative range to support the specific topic item. Not all of the unit content is expected to be assessed in every unit.

Grading grid

Each grading grid contains statements of the assessment criteria used to determine the evidence that each learner must produce in order to receive a pass, merit or distinction grade. It is important to note that the merit and distinction grading criteria refer to a qualitative improvement in the learner's evidence, and not a quantitative one.

Essential guidance for tutors

This section is designed to give tutors additional guidance and amplification in order to provide understanding and a consistent level of delivery and assessment. It is divided into the following sections:

- *Delivery* — explains the content's relationship with the learning outcomes and offers guidance about possible approaches to delivery. This section is based on the more usual delivery modes but is not intended to rule out alternative approaches.
- *Assessment* — gives amplification about the nature and type of evidence that learners need to produce in order to pass the unit or achieve the higher grades. This section should be read in conjunction with the grading criteria.
- *Links to National Occupational Standards, other BTEC units, other BTEC qualifications and other relevant units and qualifications* — sets out links with other units within the qualification. These links can be used to ensure that learners make connections between units, resulting in a coherent programme of learning. The links show opportunities for integration of learning, delivery and assessment.
- *Essential resources* — identifies any specialist resources needed to allow learners to generate the evidence required for each unit. The centre will be asked to ensure that any requirements are in place when it seeks approval from Edexcel to offer the qualification.
- *Indicative reading for learners* — provides a short list of learner resource material that benchmarks the level of study.

Key skills

This section identifies any opportunities in the unit for learners to generate evidence to meet the requirements of key skills units. Assessors should take care to become familiar with the key skills specifications and evidence requirements and not to rely solely on this section when presenting key skills evidence for moderation. Centres should refer to the QCA website (www.qca.org.uk) for the latest version of the key skills standards.

Units

Unit 1: Scientific Principles for Pharmacy

NQF Level 3: BTEC Nationals

Guided learning hours: 60

Unit abstract

In order for pharmacy technicians to practise safely they need to have a good understanding of scientific principles. This unit is designed to give learners knowledge of the fundamental principles of biology and chemistry essential for all units in this qualification.

In learning outcome 1 learners will study cellular structure and function. Understanding of these concepts is an essential prerequisite for the study of the actions and use of medicine units (*Units 3, 4, 5 and 6*), *Unit 8: Human Physiology for Pharmacy* and *Unit 9: Microbiology for Pharmacy*.

Learning outcomes 2 and 3 show the relevance of atomic structure and they introduce learners to a quantitative approach to chemical reactions. These fundamental concepts should be linked to the relevant knowledge and skills of a pharmacy technician, for example in calculating drug dosage. They also provide underpinning knowledge for *Unit 7: Pharmaceutics* and for *Unit 12: Chemistry for Pharmacy*.

Learning outcome 4 gives learners the opportunity to study the major biological chemicals that make up living organisms. This unit specifically links to *Unit 3: An Introduction to Action and Uses of Medicines*, *Unit 4: Cytotoxic, Endocrine and Nutritional Medicines, Unit 5: Central Nervous System, Eyes, ENT, Skin and Gynaecological Medicines* and *Unit 6: Cardio-respiratory and Genito-urinary Medicines, and Medicines Management*.

Learning outcomes

On completion of this unit a learner should:

1 Understand cellular structure and function

2 Know how physical and chemical properties of elements are dependent on their atomic structure and how this influences chemical reactions

3 Be able to balance chemical equations and carry out calculations involving quantities and concentrations

4 Understand the structure and functions of the major biological chemicals.

Unit content

1 **Understand cellular structure and function**

Structure of cells: views from light and electron microscopes; use of slides; illustrations and electron micrographs

Structure and function of cell organelles: plasma membrane; mitochondria; ribosomes; rough and smooth endoplasmic reticulum; Golgi apparatus; lysosomes; cytosol; nucleus

Transport in cells: diffusion; osmosis; active transport

2 **Know how physical and chemical properties of elements are dependent on their atomic structure and how this influences chemical reactions**

The nuclear model of the atom: protons; neutrons and electrons; atomic number; mass number

The electronic structures of atoms: arrangement of electrons around the nucleus; s, p, d notation; electronic configurations of the first 20 elements

The periodic table: organisation of elements in the periodic table; periodicity of physical properties

Bonding: ionic compounds (electron transfer common examples, common properties); covalent compounds (electron sharing common examples, common properties); hydrogen bonding

Experimental investigation: physical properties of selected elements

Chemical reactions: basic principles

3 **Be able to balance chemical equations and carry out calculations involving quantities and concentrations**

SI and metric units used in pharmacy: weights (kg, g, mg, mcg); volumes (l, ml); concentrations (g/l, mg/l, mg/ml etc); percentages (%w/w, %w/v, %v/v)

Chemical quantities: relative atomic mass and relative molecular mass; relationship between atomic quantities and grams

Molar quantities: the mole concept; molarity; calculation of amounts of substance in moles using equations such as moles = mass/relative molecular mass

Molar concentrations: mol/l; mmol/l; mmol/ml

Proportions in chemical reactions: balanced equations for chemical reactions; reacting masses

4 **Understand the structure and functions of the major biological chemicals**

Structure of carbohydrates: simple ring and straight chain forms of monosaccharides; formation of glycosidic bonds to form disaccharides; formation of polysaccharides

Function of carbohydrates: source of energy; structural

Structure of proteins: amino acids; formation of peptide bonds to form polypeptides; primary, secondary and tertiary structure of proteins including enzymes

Function of proteins: enzymes; transport proteins; contractile proteins; immunoproteins; membrane proteins; structural proteins; hormones

Structure of lipids: structure of glycerol; saturated and unsaturated fatty acids; triglycerides; phospholipids

Function of lipids: source of energy; structural; insulation; physical protection

Structure of nucleic acids: nucleotides; deoxyribonucleic acid (DNA); ribonucleic acid (RNA)

Function of nucleic acids: storage and transmission of genetic information; protein synthesis

Structure of water: polarisation of the water molecule; hydrogen bonding in water

Functions of water: solvent; lubricant; temperature buffer

Enzymes: structure (globular proteins, active site); action (catalysts, simple lock and key); properties (specificity, optimum conditions, denaturation)

Metabolism: definition of metabolism, anabolism (such as synthesis of protein or polysaccharides) and catabolism (such as aerobic and anaerobic respiration)

Grading grid

In order to pass this unit, the evidence that the learner presents for assessment needs to demonstrate that they can meet all of the learning outcomes for the unit. The criteria for a pass grade describes the level of achievement required to pass this unit.

Grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P1 explain cellular structure and the function of cells and cell organelles	M1 compare the main types of cellular transport, with reference to cellular activity	D1 relate the structure of cellular organelles to their function
P2 describe the electronic structure of the first 20 elements in the periodic table and identify trends in physical and chemical properties	M2 predict physical properties of elements from their atomic number and position in the periodic table	D2 relate the chemical and physical properties of an element to its electronic structure and position in the periodic table and its reactivity
P3 identify ionic, covalent and hydrogen bonding from diagrammatical representations of molecules	M3 explain ionic, covalent and hydrogen bonding	D3 relate the type of bonding formed by common elements to their position in the periodic table and bulk properties of their compounds
P4 balance simple chemical equations and carry out mole/mass conversions	M4 write balanced equations to solve problems involving mole/mass conversions	D4 carry out complex calculations involving the conversion of different concentration units
P5 identify the structure and function of the main types of biological chemicals	M5 relate the structure of the main types of biological chemicals to their function	D5 investigate the factors affecting enzyme activity

Grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P6 distinguish between anabolic and catabolic reactions.	M6 explain how glucose undergoes both anabolic and catabolic reactions in the cell.	D6 explain the main metabolic pathways involved in cellular respiration.

Essential guidance for tutors

Delivery

The fundamental concepts in this unit should be introduced through a programme of tuition, guided learning, practical work in the laboratory and problem solving.

The most should be made of any opportunity to gather information from part-time learners or from visits to relevant workplaces to relate fundamental concepts to applications in the pharmacy sector. This will put into context the knowledge and understanding of this unit for the pharmacy sector and will make essential links between this unit and other units in this programme.

Learning outcome 1 is likely to involve practical work, with learners using the light microscope and electron photomicrographs to study cellular structure.

Learning outcomes 2 and 3 are likely to be delivered via formal lectures, supplemented by independent research, problem-solving exercises and practical work. Activities related to atomic structure and periodicity should concentrate on the first 20 elements. The balancing of chemical equations and the correct use of different units should be applied to pharmaceutical applications whenever possible.

Learning outcome 4 covers a wide range of biological chemicals and so tutors must allow sufficient time for the delivery of this section. The emphasis should be on learners understanding the structure and function of the various chemicals, as opposed to memorising chemical names and structures. This section is likely to involve practical laboratory investigation, for example in investigating the factors which affect enzyme activity.

Assessment

This unit is broad in its content and learners are likely to produce a number of assignments as evidence of achievement.

In such a broad unit, there are opportunities for learners to work individually or in groups to investigate different aspects of an outcome. Evidence can be presented in a range of formats, for example posters or oral presentations, as alternatives to written reports.

Pass

For a pass grade, learners must achieve the five pass criteria listed in the grading grid provided.

To achieve P1, learners must explain cellular structure and function. For P2, they must give the electronic structure (without sub-shells) for the first 20 elements and identify trends in physical and chemical properties from periodic table data. For P3, they must identify ionic, covalent and hydrogen bonding from given examples. To achieve P4, learners must balance simple chemical equations and carry out mole/mass calculations. To meet P5, learners must identify the structure and function of the main types of biological chemicals. For P6, they must distinguish between anabolic and catabolic reactions.

Merit

For a merit grade, the learner must achieve **all** of the pass grade criteria **and** the six merit grade criteria.

For M1, it is necessary to compare diffusion, osmosis and active transport with regard to cellular function.

To achieve M2, learners must predict physical properties of elements from their atomic number and position in the periodic table. To meet M3, they must explain ionic, covalent and hydrogen bonding.

To meet M4, the learner must be able to write balanced equations in solving problems involving mole/mass conversions. For example, in the synthesis of aspirin, the theoretical yield in grams could be calculated from a given weight of starting material.

For M5, learners must relate chemical structure to biological function for the main biological chemicals. To meet M6, learners must explain the anabolic and catabolic conversions of glucose within the living cell.

Distinction

For a distinction grade, the learner must achieve **all** of the pass and merit grade criteria **and** the six distinction grade criteria.

For D1, the learner must relate the structure of cellular organelles to their function.

To meet D2, it is necessary to relate the chemical and physical properties of an element to its electronic structure and position in the periodic table. For D3, learners must relate the type of bonding formed by common elements to their position in the periodic table and to the bulk properties, such as melting point, conductivity, etc of their compounds.

To achieve D4, the learner must be able to competently use different concentration units.

To achieve D5, learners must investigate the factors affecting enzyme activity. For D6, they must explain the main metabolic pathways involved in cellular respiration.

Links to National Occupational Standards, other BTEC units, other BTEC qualifications and other relevant units and qualifications

Unit 1: Scientific Principles for Pharmacy may be linked with other units in the programme because the outcomes underpin the knowledge and understanding of other units.

The content is specifically linked to the following core and specialist units:

- *Unit 3: An Introduction to Action and Uses of Medicines*
- *Unit 4: Cytotoxic, Endocrine and Nutritional Medicines*
- *Unit 5: Central Nervous Systems, Eyes, ENT, Skin and Gynaecological Medicines*
- *Unit 6: Cardio-respiratory and Genito-urinary Medicines, and Medicines Management*
- *Unit 7: Pharmaceutics*
- *Unit 8: Human Physiology for Pharmacy*

- *Unit 9: Microbiology for Pharmacy*
- *Unit 12: Chemistry for Pharmacy*
- *Unit 13: Scientific Method for Pharmacy Technicians.*

This unit provides opportunities for learners to gather evidence towards key skills in application of number, communication, information and communication technology, improving own learning and performance and problem solving.

Essential resources

All learners will need access to appropriate laboratory facilities, and to library and information technology resources. They will also need access to a range of general AS/A2 Chemistry, Physics and Biology/Human Biology books.

Relevant information is also available on CD ROMs such as those available from:

- Plato Learning (www.new-media.co.uk).

Indicative reading for learners

Textbooks

Eroschenko V P — *Di Fiores Atlas of Histology* (Lippincott Williams & Wilkins, 2004) ISBN 0781750210

Fry M and Page E — *Catch Up Chemistry* (Scion Publishing Ltd, 2005) ISBN 1904842100

Hames B D and Hooper N M — *Instant Notes in Biochemistry* (Bios Scientific Publishers Ltd, 2005) ISBN 0415367786

Jones A et al — *Practical Skills in Biology* (Pearson Higher Education, 2002) ISBN 013045141X

Jones M et al — *Biology 1* (Cambridge University Press, 2000) ISBN 052178719X

Junqueira et al — *Basic Histology* (McGraw-Hill Publishing Co, 2005) ISBN 0071440917

Sackheim G I — *An Introduction to Chemistry for Biology Students* (Pearson Higher Education, 2004) ISBN 0805339701

Timberlake K — *An Introduction to General, Organic, and Biological Chemistry* (Pearson Higher Education, 2005) ISBN 0805377565

Websites

The Association for Science Education	www.ase.org.uk
Biochem4schools	www.biochem4schools.org
Biochemical Society	www.biochemistry.org
Biology4all	www.biology4all.com
Exams tutor	www.examstutor.com/chemistry/resources
Royal Society of Chemists	www.rsc.org
The Science Consortium	www.scienceconsortium.co.uk
S-Cool!	www.s-cool.co.uk
Sheffield College Science Web Links	www.sheffcol.ac.uk/links/science
Testandcalc.com	www.testandcalc.com

Key skills

Achievement of key skills is not a requirement of this qualification but it is encouraged. Suggestions of opportunities for the generation of Level 3 key skill evidence are given here. Tutors should check that learners have produced all the evidence required by part B of the key skills specifications when assessing this evidence. Learners may need to develop additional evidence elsewhere to fully meet the requirements of the key skills specifications.

Application of number Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• selecting and using appropriate methods to process experimental and secondary data obtained during an investigation	N3.2 Use this information to carry out multi-stage calculations to do with: a amounts or sizes b scales or proportion c handling statistics d using formulae.
• drawing and presenting conclusions drawn from processed experimental and secondary data, and linking to the action plan.	N3.3 Interpret the results of your calculations, present your findings and justify your methods.
Communication Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• taking part in group discussions about a complex subject such as electronic configurations of atoms of elements	C3.1a Take part in a group discussion.
• presenting the results and conclusions of an investigation about a complex subject	C3.1b Make a formal presentation of at least eight minutes using an image or other support material.
• using literature sources to develop familiarity with the technological methods to be used in an investigation	C3.2 Read and synthesise information from at least **two** documents about the same subject. Each document must be a minimum of 1000 words long.

Communication Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• preparing the report of an investigation.	C3.3 Write **two** different types of documents, each one giving different information about complex subjects. One document must be at least 1000 words long.
Information and communication technology Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• planning and carrying out a search for experimental methods appropriate to an investigation to be undertaken	ICT3.1 Search for information, using different sources, and multiple search criteria in at least one case.
• preparing the report of an investigation.	ICT3.2 Enter and develop the information and derive new information.
Improving own learning and performance Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• developing the plan for an investigation and consulting and gaining the agreement of their tutor or workplace supervisor	LP3.1 Set targets using information from appropriate people and plan how these will be met.
• implementing the plan and modifying it in accordance with results obtained and constraints and problems encountered	LP3.2 Take responsibility for your learning, using your plan to help meet targets and improve your performance.
• evaluating the plan at frequent intervals and refining it in accordance with the conclusions reached.	LP3.3 Review progress and establish evidence of your achievements.

Problem solving Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• formulating the plan for an investigation	PS3.1 Explore a problem and identify different ways of tackling it.
• identifying and evaluating alternative methods of approach to an investigation, and deciding on the approach to be adopted	PS3.2 Plan and implement at least **one** way of solving the problem.
• developing a plan for an investigation, using the preferred option	PS3.3 Check if the problem has been solved and review your approach to problem solving.
• evaluating the plan continuously during an investigation, on the basis of the results and conclusions produced.	

Unit 2: Pharmacy Law, Ethics and Practice

NQF Level 3: BTEC National

Guided learning hours: 60

Unit abstract

In order to practise safely and legally it is crucial for the pharmacy technician to understand the law relating to pharmacy and the place of pharmacy within the NHS, the private sector and industry. This has become even more important as pharmacy technicians assume greater responsibility and autonomy. As they become registered professionals, it is vital that they realise the obligations and responsibilities which registration brings. Implicit in this is the ability to make reasoned judgements, taking into account legal and ethical considerations.

This unit provides the necessary knowledge and application to practise within the law and regulatory framework so that pharmacy technicians can work safely, whilst acknowledging their responsibilities to patients, the public and other healthcare workers. This unit, in conjunction with *Unit 7: Pharmaceutics*, provides the pharmacy-specific knowledge for the day-to-day practice of the pharmacy technician.

The first three learning outcomes give the learner knowledge of the laws relating to, or affecting, the practice of pharmacy in the UK. Laws relating to medicines, controlled drugs and dangerous substances are covered in depth. Other non-pharmaceutical legislation can also impact on pharmacy and a selection of these Acts is also mentioned. Learners will be encouraged to relate their knowledge to their workplace in order to further their understanding.

The final learning outcome covers the NHS with particular reference to the pharmaceutical service. The major UK pharmacy organisations and associations the learner is likely to come across are also covered. Finally, the professional roles of the pharmacist and the pharmacy technician are covered with respect to regulation of the profession. Learners need to be aware of their responsibilities and obligations following successful registration with the Royal Pharmaceutical Society, and these are covered in the final learning outcome in order to prepare learners for registration.

Learning outcomes

On completion of this unit a learner should:

1 Understand legislation relating to drugs and medicines

2 Understand legislation relating to dangerous substances

3 Know about non-pharmaceutical legislation affecting pharmacy

4 Know about the structure and organisation of the NHS and professional organisations which affect pharmacy.

Unit content

1 **Understand legislation relating to drugs and medicines**

The Medicines Act 1968: aims; purposes; administration and enforcement of the Act

The licensing system: its application to medicinal products; marketing authorisations; exemptions for pharmacists; 'special' dispensing; parallel importing; counterfeit medicines

Sales promotion of medicinal products: the marketing, advertising, promoting and sale of medicinal products to the public and health professionals; monitoring of advertising; ethical concerns regarding promotion; Association of British Pharmaceutical Industry Code of Practice, workplace codes and guidance; substances liable to misuse

Retail pharmacy businesses: regulations applying to pharmacies for the sale of medicines; registration of pharmacy premises; restricted titles, eg pharmacist, pharmacy

General sales list (GSL) medicines: definition; conditions applying to retail sale or supply; product types not on the GSL; pack size restrictions

Pharmacy medicines: definition; conditions applying to retail sale or supply; supervision; medicine sales protocols

Prescription-only medicines (POM): definition; exemption from POM classification, eg due to strength, pack size; administration of POMs; independent and supplementary prescribing; types of prescriptions; prescription requirements; dispensing POMs (standard operating procedures); forged prescriptions; supply of a POM without a prescription (emergency supply, patient group directions, requisitions); records; exemptions for hospitals and health professionals

Containers and packaging: the labelling of medicinal products (general labelling provisions, standard labelling requirements, GSL, pharmacy, POM, dispensed medicines and other, eg pre-packs and chemist's nostrums); patient information leaflets; use of fluted bottles; child-resistant closures (legal and ethical considerations)

Wholesale dealing: definition; sale and supply of pharmacy medicines and POMs; records

Homeopathic medicines and herbal remedies: definitions; classification; sale and supply

The Veterinary Medicines Act 2005: classification; prescription requirements; labelling dispensed medicines; records

The Misuse of Drugs Act and associated controlled drug legislation: classification (classes and schedules); production; possession and supply; prescription requirements; requisitions; labelling; registers; destruction; safe custody; controlled drugs in hospitals; treatment of addicts (drug dependence, tolerance, prescriptions, instalment dispensing); sale of paraphernalia to addicts; needle and syringe exchange schemes

2 **Understand legislation relating to dangerous substances**

CHIP2 regulations: objectives; classification; indications of danger (symbols, risk and safety phrases); containers; packaging (child-resistant closures and tactile danger warnings); labelling; safety data sheets; restrictions to professional users; application to pharmacy; inspection and enforcement

COSHH: definitions of risk and hazard; identification of hazardous substances; COSHH assessments; control measures; application to pharmacy (especially risk assessment and management); inspection and enforcement

The Poisons Act 1972: definitions; poisons list; poison rules (schedules); labelling; sale and supply of poisons; inspection and enforcement

Schedule 1 poisons: sale and supply; storage; records; signed orders; exemptions from requirements

3 **Know about non-pharmaceutical legislation affecting pharmacy**

Acts: dealing with trade descriptions; consumer protection; weights and measures; environment (waste disposal); data protection; health and safety; equal opportunities; disability discrimination; etc

Laws relating to spirits and methylated spirits: retail sale and supply of spirits

4 **Know about the structure and organisation of the NHS and professional organisations which affect pharmacy**

Organisation of the NHS: structure of the NHS; function and purpose of NHS organisations, eg strategic health authorities, NHS trusts, primary care trusts

Other NHS bodies and organisations: special health authorities, eg NHS Direct, Prescription Pricing Authority, National Institute for Health and Clinical Excellence; Local Pharmaceutical Committees; Pharmaceutical Services Negotiating Committee

Royal Pharmaceutical Society of Great Britain: the objectives and roles of the Society; structure; membership; registration requirements

The profession of pharmacy: roles of pharmacists and support staff; professional ethics and law; code of ethics; practice guidance; council statements; professional decision making; confidentiality; continuing professional development; clinical governance

Professional discipline: duty of care; misconduct; fitness to practise; the concept of 'double jeopardy'; statutory committee, disciplinary committee, health committee, investigating committee; registers, practising and non-practising

Other pharmacy organisations: National Pharmacy Association; Guild of Healthcare Pharmacists; Association of Pharmacy Technicians

Other professions: the organisation and responsibilities of other healthcare professions, eg medical, veterinary, dental, nursing

Legislation relating to medicines, the NHS and the regulation of health professionals changes frequently, and tutors must keep learners informed of any relevant changes as they occur. Pharmacy practice is also constantly evolving and tutors may wish to incorporate additional material relevant to current pharmacy practice.

Grading grid

In order to pass this unit, the evidence that the learner presents for assessment needs to demonstrate that they can meet all of the learning outcomes for the unit. The criteria for a pass grade describes the level of achievement required to pass this unit.

Grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P1 describe the main provisions of current legislation relating to the use of drugs and medicines	M1 apply the provisions of current legislation relating to the use of drugs and medicines to pharmacy practice	D1 explain how the legislation relating to drugs and medicines is complied with in the workplace, through methods of work
P2 describe the main provisions of current legislation relating to the use of controlled drugs	M2 apply the provisions of current legislation relating to the use of controlled drugs to pharmacy practice	D2 explain how the legislation relating to controlled drugs is complied with in the workplace, through methods of work
P3 describe the provisions of legislation relating to dangerous substances	M3 apply dangerous substance legislation to a product stocked in the pharmacy	D3 appraise a COSHH assessment using safety data sheets
P4 summarise examples of non-pharmaceutical legislation which may affect pharmacy	M4 explain how the provisions of non-pharmaceutical legislation can affect pharmacy	D4 assess how non-pharmaceutical legislation affects the pharmacy workplace, through methods of work
P5 describe the current structure and function of the NHS and professional pharmacy organisations.	M5 explain how current changes in the NHS are affecting pharmacy.	D5 discuss the requirements of professional regulation for pharmacy technicians and assess the impact on the pharmacy workplace and profession.

Essential guidance for tutors

Delivery

Laws relating specifically to pharmacy and those aspects of law that affect pharmacy are published in great detail. Learners should have an understanding and overview of these laws. The tutor should constantly consider the level and depth of knowledge the learner will need to work safely and effectively in the workplace.

Tutors delivering this unit have opportunities to use as wide a range of techniques as possible. Lectures, discussions, case studies, 'real-life' anecdotes, research using the internet and/or library resources and the use of personal experience would all be suitable. Delivery should stimulate, motivate, educate and enthuse the learner. Throughout the unit the tutor should stress the importance of a sound understanding of the law to enable the learner to practise legally, and the responsibilities and behaviour expected of a healthcare professional.

It is essential that learners are undertaking relevant pharmacy work experience whilst studying this unit. Integration of the unit with tasks carried out in the workplace is considered essential since the learner should be able to demonstrate how the laws relating to pharmacy affect day-to-day work.

Work placements should be monitored regularly in order to ensure the quality of the learning experience. It would be beneficial if learners and supervisors were made aware of the requirements of this unit prior to any work-related activities so that naturally occurring evidence could be collected at the time.

This unit will have considerable overlap with the Dispensing unit in the Level 3 NVQ in Pharmacy Services. Delivery should ensure good tie-in with learners' workplace NVQ assessments.

Staff delivering this unit should be experienced registered pharmacists or pharmacy technicians. This will ensure they can provide case-studies and relate the law to the practice of pharmacy. Ideally, they should be practicing practitioners.

Learning outcome 1 covers medicine legislation. This is likely to be delivered through formal lectures, discussions and case studies. Learners will soon become aware of the vast range of medicines legislation in the UK. The key point here is that this should always be kept relevant to the practice of pharmacy and to the learners' workplaces. Some areas are undoubtedly more important than others (eg prescription requirements and controlled drugs) and these should be emphasised and explained in great detail. Less important areas must still be covered, more briefly perhaps, but signposting may be useful to direct the learner to further sources of information about these areas.

Learning outcome 2 looks at legislation relating to dangerous substances. It may be appropriate to relate this part of the unit to *Unit 7: Pharmaceutics*. For example, the use of personal protective equipment and the use of chemicals during extemporaneous dispensing are good examples of application of the legislation. Explanation of safety data sheets and COSHH assessments can be made in the context of previous preparations for Unit 7. This outcome also provides the opportunity to

consider general health and safety considerations and the meaning of risk. The use of poisons, although rare, should be covered.

Learning outcome 3 covers non-pharmaceutical legislation. Careful selection of the most appropriate and relevant Acts is necessary to ensure that this part of the unit remains relevant and manageable. Where possible, Acts should be described and then general examples of application to pharmacy practice provided.

Learning outcome 4 covers the NHS, regulation of healthcare professionals and also the professional responsibilities of pharmacists and pharmacy technicians. A consideration of ethics, professional disciplinary procedures and decision making is also included. Delivery techniques can be varied, and this part of the unit lends itself to discussions of real-life case studies and ethical dilemmas, building on the legal knowledge acquired at the start of the unit.

Assessment

In the grading grids we use the word discuss to mean: *to put forward both sides of an argument, identifying salient points and exploring solutions.*

Pass

For a pass grade learners must achieve the five pass criteria listed in the grading grid. For P1 and P2 learners will be expected to describe legislation relating to medicines (excluding controlled drugs) and controlled drugs, respectively. Learners will be expected to cover the range of topics listed in the unit content, although guidance should be given on which are the important and relevant sections to concentrate on.

P3 requires learners to describe the legislation relating to dangerous substances. This should include a full review of the legislation, including poisons.

For P4, learners need to summarise a range of non-pharmaceutical legislation which can affect pharmacy.

P5 requires learners to describe the structure and function of the NHS and professional pharmacy organisations. For the latter part of the task, it is appropriate to concentrate on the Royal Pharmaceutical Society and mention a couple of other organisations.

Merit

For a merit grade, the learner must achieve all of the pass grade criteria and the five merit grade criteria. For M1 and M2 they should provide a more detailed and comprehensive review of the legislation (including, for example, exceptions, such as supply of a POM without a prescription etc). They should also relate the Acts to pharmacy in general and give examples where applicable (eg examples of medicines which are GSL, pharmacy medicines and POM etc). This grade could be covered through a range of case studies, prescriptions and questions provided by the tutor.

M3 requires learners to apply the legislation to a product stocked in the pharmacy. This could include a cytotoxic or a chemical used in extemporaneous dispensing. This could be achieved by reviewing the labelling, packaging and handling of the product, taking into account CHIP and COSHH requirements.

For M4, learners need to relate the legislation covered in P4 to pharmacy in general and explain why it can affect pharmacy. A range of different Acts should be covered.

M5 requires learners to consider changes in the NHS and how they affect pharmacy. National Service Frameworks, NICE guidance and Government policy can all be considered here. Learners may well be able to get ideas from their workplaces regarding changes in working practices, organisation and so forth. Professional pharmacy journals, such as the *Pharmaceutical Journal*, will be a useful resource for this.

Distinction

For a distinction grade the learner must achieve all of the pass and merit grade criteria and the five distinction grade criteria. For D1 and D2, learners need to apply the legislation directly to their workplaces and assess how the legislation is put into practice. Plenty of examples will be needed, including copies of documentation (with confidential aspects removed), to show that a full assessment of work-based practices has been attempted.

For D3 learners need to select a dangerous substance and appraise a COSHH assessment by reviewing the product's safety data sheet. As for M3, this could be a product used in the workplace or during an extemporaneous dispensing exercise.

D4 requires learners to consider the impact of non-pharmaceutical legislation on their workplace. Learners should give a number of examples, together with explanations, of the impact the legislation has had on their workplace and, perhaps, on themselves as workers.

For D5, learners need to discuss the requirements of registration for pharmacy technicians. This would be best approached from a personal perspective, ie what it will mean to them. In addition, learners need to assess the impact that regulation of pharmacy technicians has on pharmacy as a whole, which will include the Pharmaceutical Society and pharmacy workplaces/pharmacists in general.

Links to National Occupational Standards, other BTEC units, other BTEC qualifications and other relevant units and qualifications

This unit provides opportunities for learners to gather evidence towards key skills in communication and information and communication technology.

Essential resources

Learners will need access, via the library or in the workplace, to a number of pharmacy reference texts and the internet. Staff delivering this unit should be experienced registered pharmacists or pharmacy technicians. This will ensure they can provide case studies and relate the law to the practice of pharmacy. Ideally, they should be practising practitioners. In addition, they should ensure they remain up to date regarding changes in the law and pharmacy practice, and inform the learners of these changes as they occur. Support from the workplace will be essential in ensuring that the learner meets the requirements of this unit. Ideally, the learner should be working on the Level 3 NVQ in Pharmacy Services concurrently.

Indicative reading for learners

Textbooks

Applebe G E and Wingfield J — *Pharmacy Law and Ethics, Eighth Edition* (Pharmaceutical Press, 2005) ISBN 3769215907

Merrill J and Fisher J — *Pharmacy Law and Practice, Third Edition* (Blackwell Science, 2001) ISBN 0853696047

Royal Pharmaceutical Society — *Medicines, Ethics and Practice* (Pharmaceutical Press, current, published annually in July)

Stone P and Curtis S J — *Pharmacy Practice, Third Edition* (Pharmaceutical Press, 2002) ISBN 3769218159

Websites

Department of Health	www.dh.gov.uk
Medicines and Healthcare Products Regulatory Agency	www.mhra.gov.uk
National Health Service	www.nhs.uk
Pharmaceutical Journal	www.pjonline.com
Royal Pharmaceutical Society of Great Britain	www.rpsgb.org.uk

Key skills

Achievement of key skills is not a requirement of this qualification but it is encouraged. Suggestions of opportunities for the generation of Level 3 key skill evidence are given here. Tutors should check that learners have produced all the evidence required by part B of the key skills specifications when assessing this evidence. Learners may need to develop additional evidence elsewhere to fully meet the requirements of the key skills specifications.

Communication Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• taking part in group discussions about a complex subject, eg the NHS, legislation relating to the use of drugs, etc	C3.1a Take part in a group discussion.
• presenting the results and conclusions of an investigation into, eg the NHS, legislation relating to the use of drugs, etc	C3.1b Make a formal presentation of at least eight minutes using an image or other support material.
• using literature sources to develop familiarity with the technological methods to be used in an investigation into, eg the NHS, legislation relating to the use of drugs, etc	C3.2 Read and synthesise information from at least **two** documents about the same subject. Each document must be a minimum of 1000 words long.
• preparing the report of an investigation into, for example, the NHS, legislation relating to the use of drugs, etc.	C3.3 Write **two** different types of documents, each one giving different information about complex subjects. One document must be at least 1000 words long.
Information and communication technology Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• planning and carrying out a search for information on, eg the NHS, legislation relating to the use of drugs, etc.	ICT3.1 Search for information, using different sources, and multiple search criteria in at least one case. ICT3.2 Enter and develop the information and derive new information.

Unit 3: An Introduction to Action and Uses of Medicines

NQF Level 3: **BTEC National**

Guided learning hours: 60

Unit abstract

Much of a pharmacy technician's role is concerned with dispensing medicines and advising patients on their correct use. This unit, along with *Unit 4: Cytotoxic, Endocrine and Nutritional Medicines, Unit 5: Central Nervous System, Eyes, ENT, Skin and Gynaecological Medicines, Unit 6: Cardio-respiratory and Genito-urinary Medicines, and Medicines Management*, covers all the sections found in the British National Formulary (BNF). This means that in studying all these units pharmacy technicians will cover all the categories of medicines they are likely to encounter in their professional lives.

The aim of this unit is for the learner to develop an understanding of the underlying principles behind the way medicines work on the human body. The unit extends the learner's knowledge from physiology in health to disease processes. It explains the appropriate use and limitations of therapeutic agents. The role of the pharmacy technician is expanding so learners will require a good knowledge of therapeutics and must be able to demonstrate good communication skills.

The unit develops general concepts around knowledge of disease states and the principles of drug action in these conditions. The fundamental principles are expanded so that the learner can apply the concepts of drug action in their workplace to provide appropriate dispensing, counselling and over-the-counter sales. This unit also forms the basis for other medicine management training. The pharmacy technician should also demonstrate that they are aware of their own limitations and when they need to refer to a pharmacist, senior pharmacy technician or prescriber.

Learning outcomes

On completion of this unit a learner should:

1 Understand the basic principles of drug action

2 Know about the use and limitations of medicines used in the treatment of gastro-intestinal disorders

3 Know about the use and limitations of medicines used in the treatment of musculo-skeletal and joint diseases

4 Be able to use standard pharmacy resources to research answers to pharmaceutical queries.

Unit content

1 **Understand the basic principles of drug action**

Disease: its nature and causes

Routes of drug delivery: routes by which drugs are delivered to the body (oral, rectal, injectable, transdermal, inhaled); advantages and disadvantages of all routes

Fate of medicines: route by which drugs travel through the body to the site of action; factors that influence the amount of drug that reaches the site of action and the final fate of therapeutic agents; influence of absorption, metabolism, excretion,

Basic principles of action of medicines in the body: drugs as receptor agonists and antagonists; drug action on enzymes; drug influence on ion channels; non-specific drug action; the concept of evidence-based practice

Medical terminology: introduction to medical terminology and drug nomenclature

Mechanisms of medicines interactions: chemical incompatibilities; pharmacokinetic and pharmacodynamic interactions

Adverse drug reactions (ADR): predictable and idiosyncratic; yellow card scheme

2 **Know about the use and limitations of medicines used in the treatment of gastro-intestinal disorders**

Antacids and ulcer healing agents: the nature of dyspepsia, peptic ulceration, helicobacter pylori eradication and gastro-oesophageal reflux disorders (GORD); drug treatment of the conditions, their benefits and limitations; non-prescription medicines treatment of indigestion and heartburn

Diarrhoea and constipation: gut motility; causes of diarrhoea and constipation; drug treatment of the conditions (agents and their actions, side effects, contra-indications); non-prescription medicines treatment of diarrhoea and constipation and its limitations

Inflammatory bowel disease: irritable bowel syndrome and inflammatory bowel disease; drug treatment of the conditions (agents and their actions, side effects, contra-indications)

Miscellaneous GI conditions: haemorrhoids; stomas care; anal fissures; emesis and antiemetics; diet and gastro-intestinal health

3 **Know about the use and limitations of medicines used in the treatment of musculo-skeletal and joint diseases**

Drugs used in rheumatic diseases: arthritis and rheumatic diseases; drug treatment of such diseases; non-steroidal anti-inflammatory agents (NSAIDs); comparative potencies and side effect profiles; corticosteroids and disease modifying anti-rheumatic agents (DMARDs)

Drugs used in the treatment of gout: acute gout (NSAIDs) and colchicine; side effects and limitations; long-term management of gout

Muscle relaxants: drugs used for the relief of chronic muscle spasm or spasticity

Rubifacients and topical anti-rheumatics: rubifacients and topical treatment of minor soft tissue injuries; topical NSAIDS and capsaicin

Drugs used in the treatment of miscellaneous skeletal disorders: osteoporosis; Paget's Disease; osteoarthritis; rheumatoid arthritis

Patient counselling: for patients with musculo-skeletal disorders

4 **Be able to use standard pharmacy resources to research answers to pharmaceutical queries**

British National Formulary: be able to retrieve information quickly and accurately

Other pharmaceutical texts: *Martindale*, *British Pharmacopoeia*, *Pharmaceutical Codex*, *Pharmaceutical Journal*, medical journals; be able to search for information and evaluate it as to usefulness in the particular context necessary

Online resources: eg Medline, eBNF; retrieval and evaluation of information found on the internet

Grading grid

In order to pass this unit, the evidence that the learner presents for assessment needs to demonstrate that they can meet all of the learning outcomes for the unit. The criteria for a pass grade describes the level of achievement required to pass this unit.

Grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P1 a) describe agonists and antagonists action b) list the routes of administration c) show how the route of administration can affect drug action d) recall the common drug/drug and drug/food interactions e) identify the main types of adverse drug reaction	M1 a) explain agonists and antagonists and identify examples b) illustrate with examples drugs acting on enzymes and ion channels c) explain the mechanism of drug/drug and drug/food interactions	D1 a) evaluate the advantages and disadvantages of the different routes of administration b) explain zero-order and first-order pharmacokinetics and half lives of preparations c) discuss how pharmacokinetics can influence the dosage regime

Grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P2 a) list the common disorders affecting the gastro-intestinal tract b) name common drugs used in each of the disorders (including non-prescription medicines) c) list the common side effects of these medicines d) describe the information given to the patient about their treatment	M2 a) describe how each medicine listed works b) discuss the problems with long-term laxative use c) deduce how the side effects of the medicines listed arise and relate them to their therapeutic action	D2 a) recommend ways in which patients can manage their conditions effectively
P3 a) list the common disorders affecting the musculo-skeletal system b) name common drugs used in each of the disorders (including non-prescription medicines) c) list the common side effects of these medicines d) describe the information given to the patient about their treatment	M3 a) describe how each medicine listed works b) deduce how the side effects of the medicines listed arise and relate them to their therapeutic action	D3 a) recommend ways in which patients can manage their conditions effectively

Grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P4 be able to retrieve the correct information from the British National Formulary for use in a work-related context.	M4 be able to select the correct information and retrieve it from the most appropriate source for use in a work-related context.	D4 evaluate the information retrieved to ascertain its usefulness for a particular work-related context.

Essential guidance for tutors

Delivery

The delivery of this unit requires a large degree of formal direction. There are opportunities for learners to take an active role in developing and demonstrating analytical and problem-solving skills. These opportunities can be found by using case studies, role play, patient counselling, the production of patient information leaflets and posters and links, where possible, to activities in the workplace. It is important that learners are aware of their own limitations and when they need to refer to a pharmacist or a prescriber.

This subject changes rapidly and the list of medicines covered should be updated regularly so that new developments are included and obsolete material removed.

This unit presents opportunities to demonstrate key skills at Level 3 in communication and information and communication technology.

This unit provides underpinning knowledge for the NVQ in Pharmacy Services at Level 3 in a number of units.

Although these units cover specific areas of therapeutics there needs to be an overarching theme for learners in terms of their role in the future of helping to manage a patient and their medicines and this needs emphasising in the method of delivery of this unit. Resources should be used to help learners glean information, particularly the BNF which will become their standby as they study these units and should feature throughout the delivery of Units 4, 5 and 6.

Assessment

In the grading grids we use the word discuss to mean: *to put forward both sides of an argument, identifying salient points and exploring solutions.*

Pass

To achieve a pass, learners will be able to link drugs with the treatment of specific diseases. They may require support in identifying diseases from symptoms and photographs. Learners will be able to briefly describe the drug action and list the most common side effects. They will be able to provide patient information but they may have to refer should the patient require detailed information or have a problem that needs solving.

Merit

To achieve a merit, learners will be able to identify diseases from case studies, photographs and descriptions in role play and prescriptions. Learners should be able to explain the pharmacological action of the drug and link this to the side effects. They should be able to apply their knowledge in identifying problems and solving them. Learners should be able to counsel patients and respond to requests for further/more detailed information.

Distinction

To achieve a distinction, learners should be able to understand how pathological changes produce the symptoms of the disease encountered in role play, case studies, photographs, prescriptions etc. Learners will have an understanding of complex issues and, by bringing together several areas of knowledge, will be able to present valid conclusions in explaining the choice of drugs used. Learners should be aware that in treatment of patients, compromises often have to be made between clinical factors and patients' abilities. They can give a detailed explanation of the pharmacological action of the drug and link it to side effects or required monitoring.

Learners should be able to analyse the information patients will require for optimum treatment and demonstrate that they can tailor this information to the patient's ability. If learners establish that other professionals should be involved, they should demonstrate that they have sufficiently deep knowledge and communication skills to approach them with suitable suggestions. Learners should be able to predict any problem or difficulty likely to occur with the treatment and make suitable suggestions as to how these should be solved.

Links to National Occupational Standards, other BTEC units, other BTEC qualifications and other relevant units and qualifications

This unit is one of four units on the action and use of medicines and it is necessary to study all four units to develop a comprehensive knowledge of drug use. The knowledge covered is linked closely with *Unit 8: Human Physiology for Pharmacy* and these units could be delivered in an integrated way. These units also build on knowledge gained in *Unit 1: Scientific Principles for Pharmacy* and *Unit 9: Microbiology for Pharmacy*. Knowledge of factors affecting disease states can be linked in with health promotion, counselling with effective supply and use of medicines found in the *Unit 10: Pharmacy Practice*.

This unit provides opportunities to gather evidence for key skills in communication and information and communication technology.

Essential resources

Staff delivering this unit should be experienced registered pharmacists or pharmacy technicians. This will ensure that the relevant knowledge and understanding needed in this unit is given. Centres will not be expected to supply the full range of resources but should provide an appropriate selection which learners should have easy access to. The British National Formulary (BNF) and a medical dictionary are regarded as essential. Access to the *Pharmaceutical Journal* would be an advantage.

Indicative reading for learners

Pharmacology and clinical pharmacology textbooks

Clayton B and Stock Y — *Basic Pharmacology for Nurses, Thirteenth Edition* (Mosby, 2004) ISBN 0323023592

Laurence D R, Bennett P N and Brown M J — *Clinical Pharmacology, Eighth Edition* (Churchill Livingstone, 1997) ISBN 0443049904

Minneman K P and Wecker L — *Brody's Human Pharmacology, Fourth Edition* (Mosby, 2005) ISBN 0323032869

Neal M J — *Medical Pharmacology at a Glance, Fifth Edition* (Blackwell Science, London 2005) ISBN 1405133600

Rang H P, Dale M M and Ritter J M — *Pharmacology, Fifth Edition* (Churchill Livingstone, Edinburgh, 2003) ISBN 0443071454

Stringer J — *Basic Concepts in Pharmacology* (McGraw-Hill Co Inc, 2001) ISBN 0071356991

Walker R and Edwards C (Editors) — *Clinical Pharmacy and Therapeutics, Third Edition* (Churchill Livingstone, Edinburgh, 2002) ISBN 0443071373

Drug use textbooks

Blenkinsopp A, Blenkinsopp J and Paxton P — *Symptoms in the Pharmacy, Fourth Edition* (Blackwell Science, 2005) ISBN 1405122226

Dodds L (Editor) — *Drugs in Use, Third Edition* (Pharmaceutical Press, 2004) ISBN 0853695415

Harman R J and Mason P (Editors) — *Handbook of Pharmacy Healthcare, Second Edition* (Pharmaceutical Press, 2002) ISBN 0853695075

Henry J A — *The British Medical Association's Concise Guide to Medicines and Drugs, Second Edition* (Dorling Kindersley, 2005) ISBN 1405306947

McGavock H — *How Drugs Work, Second Edition* (Radcliffe Medical Press, 2005) ISBN 1857756916

Nathan A — *Non-Prescription Medicines, Second Edition* (Pharmaceutical Press, 2002) ISBN 0853695067

Other useful publications

A medical dictionary — nursing level is suitable

MIMS (Monthly Index of Medical Specialities)

Websites

Electronic data sheet compendium	www.emc.vhn.net
Medicines Guides	www.medicines.org.uk

Key skills

Achievement of key skills is not a requirement of this qualification but it is encouraged. Suggestions of opportunities for the generation of Level 3 key skill evidence are given here. Tutors should check that learners have produced all the evidence required by part B of the key skills specifications when assessing this evidence. Learners may need to develop additional evidence elsewhere to fully meet the requirements of the key skills specifications.

Communication Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• taking part in group discussions about a complex subject, eg the action and use of medicines for any of the four learning outcomes, etc	C3.1a Take part in a group discussion.
• presenting the results and conclusions of an investigation into, eg the action and use of medicines for any of the four learning outcomes, etc	C3.1b Make a formal presentation of at least eight minutes using an image or other support material.
• using literature sources to develop familiarity with the technological methods to be used in an investigation into, eg the action and use of medicines for any of the four learning outcomes, etc	C3.2 Read and synthesise information from at least **two** documents about the same subject. Each document must be a minimum of 1000 words long.
• preparing the report of an investigation into, eg the action and use of medicines for any of the four learning outcomes, etc.	C3.3 Write **two** different types of documents, each one giving different information about complex subjects. One document must be at least 1000 words long.

Information and communication technology Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• planning and carrying out a search for information on, eg the action and use of medicines for any of the four learning outcomes, etc.	ICT3.1 Search for information, using different sources, and multiple search criteria in at least one case.

Unit 4: Cytotoxic, Endocrine and Nutritional Medicines

NQF Level 3: BTEC National

Guided learning hours: 60

Unit abstract

Much of a pharmacy technician's role is concerned with dispensing medicines and advising patients on their correct use. This unit, along with *Unit 3: An Introduction to Action and Uses of Medicines, Unit 5: Central Nervous System, Eyes, ENT, Skin and Gynaecological Medicines* and *Unit 6: Cardio-respiratory and Genito-urinary Medicines, and Medicines Management*, covers all the sections found in the British National Formulary (BNF). This means that in studying all these units pharmacy technicians will cover all the categories of medicines they are likely to encounter in their professional lives.

The aim of this unit is for the learner to develop an understanding of the underlying principles behind the way medicines work on the human body. The unit extends the learner's knowledge from physiology in health to disease processes. It explains the appropriate use and limitations of therapeutic agents. The role of the pharmacy technician is expanding so learners will require a good knowledge of therapeutics and must be able to demonstrate good communication skills.

The unit develops general concepts around knowledge of disease states and the principles of drug action in these conditions. The fundamental principles are expanded so that the learner can apply the concepts of drug action in their workplace to provide appropriate dispensing, counselling and over-the-counter sales. This unit also forms the basis for other medicine management training. The pharmacy technician should also demonstrate that they are aware of their own limitations and when they need to refer to a pharmacist, senior pharmacy technician or prescriber.

This unit examines the main medicine categories and their actions in the treatment of infection, on the endocrine system, in nutritional and blood disorders, malignant disease and immunosuppression and the use of immunological products.

Learning outcomes

On completion of this unit a learner should:

1 Understand the use and limitations of medicines in the treatment of infections

2 Understand the use and limitations of medicines affecting the endocrine system

3 Understand the use and limitations of medicines used in the treatment of nutrition and blood disorders

4 Understand the use and limitations of medicines of malignant disease and immunosuppression

5 Understand the use and limitations of commonly available immunological products in the prevention of infections.

Unit abstract

1 **Understand the use and limitations of medicines in the treatment of infections**

General principles: factors governing choice of anti-infective agents (spectrum of action, organism factors, disease factors, patient factors, drug factors, wider implications of use, resistance, World Health Organization (WHO) recommendations)

Resistance: mechanisms of resistance; innate and acquired resistance; avoiding resistance; problems of resistance

Antibacterials: blind therapy; samples of cultures; knowledge of prevalent organisms; mode of action, use, limitations of drugs; commonly used groups of antibacterial antibiotics, their target organisms

Tuberculosis: the phases of treatment; antitubercular drugs; difficulties of treatment (duration of treatment, patient compliance and resistance)

Antifungals: systemic infections; superficial infection; treatment of fungal infections; mode of action, use, limitations of drugs

Antivirals: herpes simplex; human immunodeficiency virus; viral hepatitis; influenza (severe acute respiratory syndrome (SARS), avian flu, respiratory syncytial virus); mode of action, use, limitations of drugs

Antiprotozoals: malignant malaria, benign malaria; prophylaxis; listed centres for advice; other protozoal infections (leishmaniasis)

Anthelmintics: roundworm, tapeworm and hookworm infestations; schistosomiasis; action, use, limitations

2 **Understand the use and limitations of medicines affecting the endocrine system**

Thyroid gland: hypothyroidism; hyperthyroidism; symptoms and treatment (thyroid replacement therapy, antithyroid drugs, radio-iodine therapy, surgery, symptomatic treatment)

Pancreas: diabetes; insulins; oral antidiabetics; complications of diabetes and their treatment; patient monitoring of the disease; treatment of hypoglycaemia; pancreatitis, symptoms and treatments

Sex hormones: oestrogens and anti-oestrogens; progesterones; male sex hormones and antagonists; hormone replacement therapy and the treatment of osteoporosis

Hypothalamic and pituitary hormones: corticotrophins and gonadotrophins; growth hormone; antidiuretic hormone analogues

Corticosteroids: mineralocorticoids; mode of action, use and limitations (replacement therapy); glucocorticoids; replacement; anti-inflammatory use; adverse effects; steroid warning cards; patient counselling; CSM advice; immunosuppressant use

3 **Understand the use and limitations of medicines used in the treatment of nutrition and blood disorders**

Deficiency anaemias: symptoms and treatment of iron deficiency anaemia and other anaemia (pernicious anaemia, megaloblastic, platelet disorders, idiopathic thrombocytopenia purpura)

Erythropoietin deficiency: in patients undergoing renal dialysis; in patients undergoing chemotherapy

Drugs used to treat neuropenia: use of recombinant human granuloyte-colony stimulating factor

Fluid and electrolyte imbalance: oral re-hydration therapy; intravenous fluids, reasons for and hazards of intravenous routes; uses of common infusion fluids and plasma substitutes

Intravenous nutrition: reasons for feeding intravenously; problems; methods; home care; constituents of fluids

Enteral nutrition: including PEGs (percutaneous endoscopic gastrostomy), nasogastric and sip feeds; reason for use and types of preparation

Dialysis: basic principles; haemodialysis; peritoneal dialysis and need of therapy for hormone deficiencies and metabolic disturbances

Vitamins and minerals: causes, symptoms and treatment of deficiencies

Special diets: coeliac and intolerance; other disorders (irritable bowel syndrome, weight reduction, food substitutes)

4 **Understand the use and limitations of medicines of malignant disease and immunosuppression**

Cancer: behavioural difference between normal cells and malignant cells, including metastasis

The general principles of cancer treatment: the necessity of often using a combination of techniques including surgery and radiotherapy rather than drug treatment alone; use of drugs pre-operatively to shrink tumours and post-operatively to deal with metastasis; the difficulty of killing cancer cells and the range of regimens used

Cytotoxic drugs: alkyalating agents; antimetabolites; cytotoxic antibiotics; platinum compounds; vinca alkaloids; other antineopastic drugs (taxenes, topoisomerase I inhibitors); actions and general toxicity

Hormone manipulation: use of in the treatment of hormone-dependent malignancies

Use of immunostimulants: uses and limitations

Immunosuppressants: uses and limitations

Monoclonal antibodies: uses and limitations

5 **Understand the use and limitations of commonly available immunological products in the prevention of infections**

Response to invasion: non-specific response; specific immune response; acquisition of immunity (natural, artificial, active, passive)

General principles of vaccination: vaccination and immune response; reasons for immunisation; immunisation schedule; immunisation of high-risk groups; immunisation procedures for international travel

Vaccines in common use: diseases; symptoms; reasons for vaccination; vaccines and antisera available and limitations for each disease; care of vaccines (records, storage, transport, disposal, cold chain)

Immunoglobulins: normal immunoglobulins; specific immunoglobulins; anti-D immunoglobulin; interferons; availability; reason for use

Grading grid

In order to pass this unit, the evidence that the learner presents for assessment needs to demonstrate that they can meet all of the learning outcomes for the unit. The criteria for a pass grade describes the level of achievement required to pass this unit.

Grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P1 a) list the different groups of antimicrobial treatments b) give examples of drugs within each of the named groups c) list the common side effects of these drugs d) describe information given to patients e) identify, with examples, the factors that influence the selection of antimicrobial drugs	M1 a) describe how antimicrobials achieve selective toxicity b) identify, with examples, the problems with antibiotic resistance c) explain how antibiotic resistance can be minimised	D1 a) discuss the factors that influence the choice of antimicrobial agents

Grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P2 a) list the common disorders affecting the endocrine system b) name common drugs used in each of the disorders c) list the common side effects of these drugs d) describe information given to patients e) give examples of the uses of corticosteroids f) discuss patient counselling required with corticosteroids	M2 a) describe how each drug listed works b) discuss problems associated with long-term steroid use c) outline how problems with long-term steroid use can be reduced	D2 a) recommend ways in which patients can manage their conditions effectively b) describe some other reasons steroids are used in clinical practice

Grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P3 a) list common disorders affecting the blood b) name common treatments of these disorders c) list common side effects of these treatments d) list the different types of dialysis e) outline the problems arising from nutritional deficiency f) give examples of routes used to provide artificial/supplementary nutrition	M3 a) identify, with examples, the treatments for renal failure b) compare the routes used to provide artificial/supplementary nutrition c) outline the main constituents of artificial/supplementary nutrition	D3 a) evaluate the advantages and disadvantages of each route used to deliver artificial/supplementary nutrition b) discuss the medical problems associated with renal failure
P4 a) list the different methods of treatment for cancer b) identify, with drug examples, the different groups of anticancer drugs	M4 a) outline the problems associated with anticancer drugs b) explain the use of combination chemotherapy	D4 a) describe the cell cycle for normal and cancerous cells b) evaluate, with examples, how anticancer drug choice and the cell cycle affect treatments for cancer

Grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P5 a) list common vaccines used b) identify vaccines in the current vaccination schedule c) describe the general principles of vaccination d) identify storage requirements for vaccines e) state why correct storage is vital.	M5 a) discuss the contraindications of vaccination b) explain why live vaccines can cause problems and outline how these can be reduced c) produce examples of when vaccination is used, apart from in the vaccination schedule.	D5 a) discuss natural, artificial, active and passive immunity in relation to vaccination.

Essential guidance for tutors

Delivery

The delivery of this unit requires a large degree of formal direction. There are opportunities for learners to take an active role in developing and demonstrating analytical and problem-solving skills. These opportunities can be found in the use of case studies, role play, patient counselling, the production of patient information leaflets and posters and links, where possible, to activities in the workplace. It is important that learners are aware of their own limitations and when they need to refer to a pharmacist, senior technician or prescriber.

This is a subject area that changes rapidly and the specifics relating to medicines and treatment schedules should be updated regularly so that new developments are included and obsolete material removed.

Although these units cover specific areas of therapeutics there needs to be an overarching theme for learners in terms of their role in the future of helping to manage a patient and their medicines and this needs emphasising in the method of delivery of this unit. Resources used to help learners glean information, particularly the BNF which will become their standby as they study these units and should feature throughout the delivery of Units 4, 5 and 6.

Assessment

In the grading grids we use the word discuss to mean: *to put forward both sides of an argument, identifying salient points and exploring solutions.*

This unit is broad in content and gives learners the opportunity to produce a number of assignments as evidence of achievement.

Assignments should be designed to be relevant to current and future workplace practices. They should encourage learners to demonstrate a clear understanding of drug usage rather than copying information directly from textbooks or the web.

Assignments that could meet these criteria are case studies, design of patient information booklets, role play in the sale of non-prescription medicines and patient counselling, information posters, demonstrations, talks and patient surveys followed by analysis and discussion groups with critical reporting.

Pass

To achieve a pass, learners will be able to link drugs with the treatment of specific diseases. They may require support in identifying diseases from symptoms/photographs. Learners will be able to briefly describe common drugs used and list the most common side effects. They will be able to provide patient information but they may have to refer should the patient require detailed information or have a problem that needs solving.

Merit

To achieve a merit, learners will be able to identify diseases from case studies, photographs and descriptions in role play and prescriptions. Learners should be able to explain the pharmacological action of the drug and link this to the side effects.

Learners should be able to apply their knowledge in identifying problems and solving them. Learners should be able to counsel patients and respond to requests for further/more detailed information.

Distinction

To achieve a distinction, learners should be able to understand how pathological changes produce the symptoms of the disease encountered in role play, case studies, photographs, prescriptions etc. Learners will have an understanding of complex issues and, by bringing together several areas of knowledge, be able to present valid conclusions in explaining the choice of medicines or treatment regimens used.

Learners should be able to analyse the information patients will require for optimum treatment and demonstrate that they can tailor this information to the patient's ability. Learners should be able to predict any problem or difficulty likely to occur with the treatment and make suitable suggestions as to how these should be solved.

Links to National Occupational Standards, other BTEC units, other BTEC qualifications and other relevant units and qualifications

This unit is one of four units on the action and use of medicines and it is necessary to study all four units to develop a comprehensive knowledge of medicines use. The knowledge covered is linked closely with *Unit 8*: *Human Physiology for Pharmacy* and these units could be delivered in an integrated way. The units also build on the learner's knowledge gained in *Unit 1*: *Scientific Principles for Pharmacy* and *Unit 9*: *Microbiology for Pharmacy*. Knowledge of factors affecting disease states can be linked in with health promotion, counselling with effective supply and use of medicines, found in *Unit 10*: *Pharmacy Practice*.

This unit presents opportunities to gather evidence towards key skills in communication and information and communication technology.

This unit will also form part of the underpinning knowledge component for the NVQ Level 3 in Pharmacy Services qualification.

Essential resources

Staff delivering this unit should be experienced registered pharmacists or pharmacy technicians. This will ensure that the relevant knowledge and understanding needed in this unit is given. Centres will not be expected to supply the full range of resources but should provide an appropriate selection which learners should have easy access to. The British National Formulary (BNF) and a medical dictionary are regarded as essential. Access to the *Pharmaceutical Journal* would be an advantage.

Indicative reading for learners

Pharmacology and clinical pharmacology textbooks

Clayton B and Stock Y — *Basic Pharmacology for Nurses, Thirteenth Edition* (Mosby, 2004) ISBN 0323023592

Laurence D R, Bennett P N and Brown M J — *Clinical Pharmacology, Eighth Edition* (Churchill Livingstone, 1997) ISBN 0443049904

Minneman K P and Wecker L — *Brody's Human Pharmacology, Fourth Edition* (Mosby, 2005) ISBN 0323032869

Neal M J — *Medical Pharmacology at a Glance, Fifth Edition* (Blackwell Science, London 2005) ISBN 1405133600

Rang H P, Dale M M and Ritter J M — *Pharmacology, Fifth Edition* (Churchill Livingstone, Edinburgh, 2003) ISBN 0443071454

Stringer J — *Basic Concepts in Pharmacology* (McGraw-Hill Co Inc, 2001) ISBN 0071356991

Walker R and Edwards C (Editors) — *Clinical Pharmacy and Therapeutics, Third Edition* (Churchill Livingstone, Edinburgh, 2002) ISBN 0443071373

Drug use textbooks

Blenkinsopp A, Blenkinsopp J and Paxton P — *Symptoms in the Pharmacy, Fourth Edition* (Blackwell Science, 2005) ISBN 1405122226

Dodds L (Editor) — *Drugs in Use, Third Edition* (Pharmaceutical Press, 2004) ISBN 0853695415

Harman R J and Mason P (Editors) — *Handbook of Pharmacy Healthcare, Second Edition* (Pharmaceutical Press, 2002) ISBN 0853695075

Henry J A — *The British Medical Association's Concise Guide to Medicines and Drugs, Second Edition* (Dorling Kindersley, 2005) ISBN 1405306947

McGavock H — *How Drugs Work, Second Edition* (Radcliffe Medical Press, 2005) ISBN 1857756916

Nathan A — *Non-Prescription Medicines, Second Edition* (Pharmaceutical Press, 2002) ISBN 0853695067

Other useful publications

A medical dictionary — nursing level is suitable

MIMS (Monthly Index of Medical Specialities)

Websites

Electronic data sheet compendium	www.emc.vhn.net
Medicines Guides	www.medicines.org.uk

Key skills

Achievement of key skills is not a requirement of this qualification but it is encouraged. Suggestions of opportunities for the generation of Level 3 key skill evidence are given here. Tutors should check that learners have produced all the evidence required by part B of the key skills specifications when assessing this evidence. Learners may need to develop additional evidence elsewhere to fully meet the requirements of the key skills specifications.

Communication Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• taking part in a group discussion, eg on the role of corticosteroids in the body, drugs used in hormonal disorders, the action and use of medicines for any of the five learning outcomes	C3.1a Take part in a group discussion.
• making a formal presentation of at least eight minutes using an image or other support material, eg on the role of corticosteroids in the body, drugs used in hormonal disorders, the action and use of medicines for any of the five learning outcomes	C3.1b Make a formal presentation of at least eight minutes using an image or other support material.
• reading and synthesising information from at least to documents about the same subject, each document being a minimum of 1000 words long, eg on the role of corticosteroids in the body, drugs used in hormonal disorders, the action and use of medicines for any of the five learning outcomes	C3.2 Read and synthesise information from at least **two** documents about the same subject. Each document must be a minimum of 1000 words long.

Communication Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• writing two different types of documents, each one giving different information about complex subjects, eg on the role of corticosteroids in the body, drugs used in hormonal disorders, the action and use of medicines for any of the five learning outcomes.	C3.3 Write **two** different types of documents, each one giving different information about complex subjects. One document must be at least 1000 words long.
Information and communication technology Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• planning and carrying out a search for information, eg on the role of corticosteroids in the body, drugs used in hormonal disorders, the action and use of medicines for any of the five learning outcomes.	IT3.1 Search for information, using different sources, and multiple search criteria in at least one case.

Unit 5: Central Nervous System, Eyes, ENT, Skin and Gynaecological Medicines

NQF Level 3: **BTEC National**

Guided learning hours: 60

Unit abstract

Much of a pharmacy technician's role is concerned with dispensing medicines and advising patients on their correct use. This unit, along with *Unit 3: An Introduction to Action and Uses of Medicines, Unit 4: Cytotoxic, Endocrine and Nutritional Medicines* and *Unit 6: Cardio-respiratory and Genito-urinary Medicines, and Medicines Management*, covers all the sections found in the British National Formulary (BNF). This means that in studying all these units pharmacy technicians will cover all the categories of medicines they are likely to encounter in their professional lives.

The aim of this unit is for the learner to develop an understanding of the underlying principles behind the way medicines work on the human body. The unit extends the learner's knowledge from physiology in health to disease processes. It explains the appropriate use and limitations of therapeutic agents. The role of the pharmacy technician is expanding so learners will require a good knowledge of therapeutics and must be able to demonstrate good communication skills.

The unit develops general concepts around knowledge of disease states and the principles of drug action in these conditions. The fundamental principles are expanded so that the learner can apply the concepts of drug action in their workplace to provide appropriate dispensing, counselling and over-the-counter sales. This unit also forms the basis for other medicine management training. The pharmacy technician should also demonstrate that they are aware of their own limitations and when they need to refer to a pharmacist, senior pharmacy technician or prescriber.

This unit examines the main medicines and their actions in the treatment of the central nervous system, eyes, ears, nose and throat, skin and gynaecological disorders.

Learning outcomes

On completion of this unit a learner should:

1 Understand and explain the use and limitations of medicines affecting disorders of the nervous system

2 Understand and explain the use and limitations of medicines used in disorders of the eye

3 Understand and explain the use and limitations of medicines used in disorders of the ear, nose, throat and mouth

4 Understand and explain the use and limitations of medicines used in common disorders of skin, hair and nails

5 Understand and explain the use and limitations of medicines used in gynaecological disorders and in obstetrics.

Unit content

1 **Understand and explain the use and limitations of medicines affecting the nervous system**

Chemical neurotransmitters: release and uptake; examples of neurotransmitters; ways in which drugs can interfere with chemical neurotransmitters

Hypnotics and anxiolytics: dangers of indiscriminate prescribing; actions, uses and limitations of prescribing (including use of sleep hygiene and relaxation techniques to reduce use); problems of dependence and methods of withdrawal

Antipsychotics: nature and symptoms of psychoses; uses and limitations of typical and atypical antipsychotic drugs (including problems of treating negative symptoms); the problems of compliance; methods of improving compliance; counselling use of depot injections

Lithium: bipolar affective disorder; lithium use; monitoring and patient counselling

Antidepressant drugs: depression symptoms; uses and limitations of each type of antidepressant

Stimulants and drugs used in the treatment of obesity: action and limitation of use

Nausea and vertigo: physiological mechanism causing nausea and vertigo; conditions for which anti-emetics are appropriate; choice and limitation of anti-emetic drugs

Analgesics: pain mechanism; psychological aspects of chronic pain and need to treat all aspects of pain (including the use of adjuvant drugs); the need for regular pain control and the analgesic ladder; non opioids (paracetamol, aspirin, NSAIDs and opioid analgesics); their uses and limitations; dangers and treatment of paracetamol overdose

Palliative care: drugs used in the treatment of terminal care; psychological and emotional support mechanisms available

Migraine: types, symptoms and trigger factors; use and limitation of drugs in treatment and prophylaxis

Anti-epileptics: types of epilepsy and their symptoms; general treatment of epilepsy (including first-aid measures); action and limitation of drugs

Drugs used in Parkinsonism: symptoms, uses and limitation of drugs

Substance dependence: drugs used in treatment of alcohol, opioid and nicotine dependence

Drugs used in the treatment of dementias: uses and limitations

General anaesthesia: modern anaesthetic technique and reasons for using drug combinations; intravenous anaesthetics; inhalation anaesthetics; antimuscarinics, anxiolytic and analgesic perioperative drugs; muscle relaxants and their reversal

Local anaesthesia: mode of action; routes of administration (epidural and intrathecal drugs and limitations)

2 **Understand and explain the use and limitations of medicines used in disorders of the eye**

Administration: counselling for safe and effective use of ophthalmic preparations; advice when referral is necessary

Common disorders: tired or dry eyes; contact lens care; infective conjunctivitis; allergic conjunctivitis (hay fever)

Diagnostic preparations: mydriatics; cycloplegics; stains

Glaucoma (closed and open angle, steroid induced): betablockers; anticholinergic miotics; carbonic acid anhydrase inhibitors; prostaglandin analogues

3 **Understand and explain the use and limitations of medicines used in disorders of the ear, nose, throat and mouth**

Administration: counselling for safe and effective use of ENT formulations; advice when systemic products are necessary

Drugs: anti-inflammatory drugs (corticosteroids, mast cell stabilisers, antihistamines, NSAIDs, sympathomimetic decongestants, local anaesthetics and counter irritants)

Antimicrobial: drugs (antiseptics, antibiotics, antiviral and antifungal)

Ear: ear wax; otitis externa and otitis media

Nose: allergic rhinitis (hay fever); rhinitis and nasal congestion (cold); staphlococcal infections

Mouth and throat: oral hygiene; dry mouth; teething; gingivitis; mouth ulcers; cold sores; oral thrush

4 **Understand and explain the use and limitations of medicines used in common disorders of skin, hair and nails**

Administration: counselling for safe and effective use of skin preparations; understand properties and uses of creams, ointments, gels, pastes, collodions, powders, lotions and applications

First aid, bites and stings, rashes: antiseptics and antipruritics; use and problems associated with antihistamines and local anaesthetics

Sun protection and treatment: importance and advice of use; protection rating

Dandruff: antiseptics; keratolytics; antifungals

Acne and rosaceae: skin hygiene; keratolytics (including benzoyl peroxide); antibiotics; retinoids

Dry skin, eczema and dermatitis: use of emollients and barriers; uses and problems of corticosteroids; 'fingertip method' for dosing; systemic treatment

Psoriasis: use and problems of keratolytics and antiproliferative drugs (calicipitriol, dithranol and coal tar, retinoids and cytotoxics and PUVA)

Bacterial infections (impetigo): antibiotics (including mupirocin)

Fungal infections (Tinea) athlete's foot/ringworm: antifungal drugs

Warts and veruccas: keratolytics

Lice and scabies: use and problems of organophosphate insecticides; bug busting for resistant lice

5 **Understand and explain the use and limitations of medicines used in gynaecological disorders and in obstetrics**

Reproductive system: hormonal contraception (combined oral contraceptives and progesterone only); alternatives to hormonal contraception and emergency contraception (hormonal and IUD)

Drugs used in obstetrics: induction of abortion; induction or augmentation of labour; prevention and treatment of haemorrhage; myometrial relaxants used to inhibit premature delivery

Grading grid

In order to pass this unit, the evidence that the learner presents for assessment needs to demonstrate that they can meet all of the learning outcomes for the unit. The criteria for a pass grade describes the level of achievement required to pass this unit.

Grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P1 a) identify the symptoms of common diseases of the nervous system b) give examples of the main drugs used in each of the above conditions c) list the main limitations and side effects d) show how analgesics are grouped according to their potency e) describe what role adjuvant drugs play in pain control f) provide basic patient counselling for all medicines listed g) identify the different roles of local and general anaesthetics h) list examples of local and general anaesthetics	M1 a) describe the action of drugs used in the nervous system b) discuss reasons why side effects may occur in the various drug therapies c) show how pain is controlled by good management in relation to good diagnosis, use of the analgesic ladder, regular administration and use of adjuvant drugs d) explain how counselling patients helps to improve quality of life e) describe the various routes and action of local anaesthetics to improve treatment outcomes f) gives examples of drugs for each route	D1 a) discuss how pathology of the central nervous system (CNS) may lead to disorders, both short and long term b) explain factors involved in the choice of therapeutic agents c) explain, in detail, the action of drugs used to treat these disorders d) discuss the major problems that occur in treating these diseases and make suggestions of possible solutions e) explain how understanding the psychological/emotional component of pain can maximise analgesia in the treatment of chronic pain

Grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
i) provide examples of situations in which general anaesthetics are used in combination	g) explain why the combinations of medicines are used in anaesthesia h) explain the process of induction and maintenance of anaesthesia i) give examples of drugs used for each, giving their advantages and limitations	f) explain how muscle relaxants work and how their action can be blocked or reversed g) explain the advantages and limitations of the various routes of local anaesthetics h) discuss how adrenaline works and explain how it is used and what are the limitations i) explain the process of general anaesthesia is achieved and how it can be reversed
P2 a) describe the symptoms of disorders of the eye b) give examples of drugs used to treat these disorders c) list problems and side effects the patient may encounter d) describe information given to patients on the use of eye preparations including common non-prescription medicines e) identify common simple eye disorders that can occur including problems with contact lenses	M2 a) describe the action of drugs used to treat these conditions b) discuss the reasons why side effects may occur c) explain the compliance problems when administering eye preparations d) describe how these problems can be overcome	D2 a) explain how the pathology of eye conditions may lead to eye disorders b) discuss the factors involved in the choice of therapeutic agents c) recommend ways the patient can manage their condition effectively

Grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P3 a) identify the symptoms and causes of common disorders of the ear, nose, mouth and throat b) give examples of drugs used to treat these disorders c) list the problems and common side effects of these drugs d) identify the products that can be sold as non-prescription medicines for these conditions	M3 a) describe the action of drugs used to treat ENT conditions b) discuss the reasons why side effects may occur c) identify a range of common ENT conditions and suggest appropriate non-prescription medicines products to treat these conditions d) show how good questioning techniques improve identification of these conditions e) discuss conditions that must be referred f) counsel patient for safe and effective use of treatment and dosage forms	D3 a) explain how the pathology of ENT conditions can lead to ENT disorders b) discuss what factors are involved in the choice of therapeutic agents c) provide detailed information to the patient so they can manage their condition effectively d) discuss how good questioning and problem-solving skills can provide a suitable resolution of the patient's problem

Grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P4 a) identify the symptoms of common skin disorders b) list examples of drugs used to treat these disorders c) list the common side effects of these preparations d) describe information given to patients on how to correctly use moisturisers, steroid creams and other non-prescription medicines products	M4 a) describe the action of drugs used in common skin disorders b) discuss the reasons why side effects may occur c) discuss how formulation of topical products can influence drug delivery d) explain what information patients will need to use their preparations correctly to achieve maximum benefit and minimises problems e) show how good questioning techniques are important in determining whether a non-prescription medicines sale is appropriate	D4 a) explain how the pathology of skin disease can lead to various skin disorders b) discuss what factors are involved in the choice of therapeutic agent c) discuss how good questioning and problem-solving skills are essential in diagnosing various conditions

Grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P5 a) identify the main methods of contraception b) describe how each contraceptive method works c) list the side effects and limitations of contraceptives.	M5 a) explain what factors can reduce contraceptive efficacy b) demonstrate how anticipating problems and providing effective advice could reduce these.	D5 a) explain in detail the pharmacological action of various contraceptives b) show how this may lead to side effects c) discuss the limitations of hormonal contraceptives d) provide information for a patient in order to make the correct choice of contraceptive method.

Essential guidance for tutors

Delivery

The delivery of this unit requires a large degree of formal direction. Opportunities exist for learners to take an active role in developing and demonstrating analytical and problem-solving skills. These opportunities can be found in the use of case studies, role play, patient counselling, the production of patient information leaflets and posters and links, where possible, to activities in the workplace. It is important that learners are aware of their own limitations and when they need to refer to a pharmacist or prescriber.

This is a subject that changes rapidly and the programme should be updated regularly so that new developments are included and obsolete material removed.

Although these units cover specific areas of therapeutics there needs to be an overarching theme for learners in terms of their role in the future of helping to manage a patient and their medicines and this needs emphasising in the method of delivery of this unit. Resources used to help learners glean information, particularly the BNF which will become their standby as they study these units and should feature throughout the delivery of Units 3, 4, 5 and 6.

Assessment

In the grading grids we use the word discuss to mean: *to put forward both sides of an argument, identifying salient points and exploring solutions.*

This unit is broad in content and provides opportunities for learners to produce a number of assignments as evidence of achievement.

Assignments should be designed to be relevant to current and future workplace practices and to encourage learners to demonstrate a clear understanding of drug usage rather than copying information directly from textbooks or the web.

Assignments that could meet these criteria are case studies, design of patient information booklets, role play in the sale of non-prescription medicines and patient counselling, information posters, demonstrations, talks and patient surveys followed by analysis and discussion groups with critical reporting.

There may be opportunities, particularly within the work on non-prescription medicines, for learners to use assessment materials from their Level 3 NVQ Pharmacy Services in providing evidence for the grading criteria within this unit.

Pass

To achieve a pass, learners will be able to link drugs with the treatment of specific diseases. Learners may require support in identifying diseases from symptoms/ photographs. They will be able to briefly describe the drug action and list the most common side effects. Learners will be able to provide patient information but they may have to refer should the patient require detailed information or have a problem that needs solving.

Merit

To achieve a merit, learners will be able to identify diseases from case studies, photographs and descriptions in role play and prescriptions. Learners should be able to explain the pharmacological action of the drug and link this to the side effects. They should be able to apply their knowledge in identifying problems and solving them. Learners should be able to counsel patients and respond to requests for further/more detailed information.

Distinction

To achieve a distinction, learners should be able to understand how pathological changes produce the symptoms of the disease encountered in role play, case studies, photographs, prescriptions etc. Learners will have an understanding of complex issues and, by bringing together several areas of knowledge, be able to present valid conclusions in explaining the choice of drugs used. They should be aware that in treatment of patients, compromises often have to be made between clinical factors and patients' abilities. They can give a detailed explanation of the pharmacological action of the drug and link it to side effects or required monitoring.

Learners should be able to analyse the information patients will require for optimum treatment and demonstrate that they can tailor this information to the patient's ability. If learners can establish that other professionals should be involved, they should demonstrate they have sufficient knowledge and communicative skills to approach them with suitable suggestions. They should be able to predict any problem or difficulty likely to occur with the treatment and make suitable suggestions as to how these should be solved.

Links to National Occupational Standards, other BTEC units, other BTEC qualifications and other relevant units and qualifications

This unit is one of four units on the action and use of medicines and it is necessary to study all four units to develop a comprehensive knowledge of drug use. The knowledge covered is linked closely with *Unit 8*: *Human Physiology for Pharmacy* and these units should be delivered in an integrated way. The units also build on learners' knowledge gained in *Unit 1: Scientific Principles for Pharmacy* and *Unit 9: Microbiology for Pharmacy*. Knowledge of factors affecting disease states can be linked in with health promotion, counselling with effective supply and use of medicines found in *Unit 10*: *Pharmacy Practice*.

This unit has links with the non-prescription medicines unit in the Level 3 NVQ in Pharmacy Services and possibly with the unit relating to the supply of community specialist services.

This unit provides opportunities to gather evidence towards key skills in communication and information and communication technology.

Essential resources

Staff delivering this unit should be experienced registered pharmacists or pharmacy technicians. This will ensure that the relevant knowledge and understanding needed in this unit is given. Centres will not be expected to supply the full range of resources but should provide an appropriate selection which learners should have easy access to. The British National Formulary (BNF) and a medical dictionary are regarded as essential. Access to the *Pharmaceutical Journal* would be an advantage.

Indicative reading for learners

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Henry J A — *The British Medical Association's Concise Guide to Medicines and Drugs, Second Edition* (Dorling Kindersley, 2005) ISBN 1405306947

McGavock H — *How Drugs Work, Second Edition* (Radcliffe Medical Press, 2005) ISBN 1857756916

Nathan A — *Non-Prescription Medicines, Second Edition* (Pharmaceutical Press, 2002) ISBN 0853695067

Other useful publications

A medical dictionary — nursing level is suitable

MIMS (Monthly Index of Medical Specialities)

Websites

Electronic data sheet compendium	www.emc.vhn.net
Medicines Guides	www.medicines.org.uk

Key skills

Achievement of key skills is not a requirement of this qualification but it is encouraged. Suggestions of opportunities for the generation of Level 3 key skill evidence are given here. Tutors should check that learners have produced all the evidence required by part B of the key skills specifications when assessing this evidence. Learners may need to develop additional evidence elsewhere to fully meet the requirements of the key skills specifications.

Communication Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• taking part in a group discussion on, eg the action and uses of medicines for any of the five learning outcomes, etc	C3.1a Take part in a group discussion.
• making a formal presentation of at least eight minutes using an image or other support material on, eg the action and use of medicines for any of the five learning outcomes	C3.1b Make a formal presentation of at least eight minutes using an image or other support material.
• reading and synthesising information from at least two documents about the same subject, each document being a minimum of 1000 words long on, eg the action and uses of medicines for any of the five learning outcomes	C3.2 Read and synthesise information from **two** documents about the same subject. Each document must be a minimum of 1000 words long.
• writing two different types of documents, each one giving different information about complex subjects, eg the action and uses of medicines for any of the five learning outcomes.	C3.3 Write **two** different types of documents, each one giving different information about complex subjects. One document must be at least 1000 words long.

Information and communication technology Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• planning and carrying out a search for information on, eg the action and use of drugs for any of the five learning outcomes, etc.	ICT3.1 Search for information, using different sources, and multiple search criteria in at least one case.

Unit 6: Cardio-respiratory and Genito-urinary Medicines, and Medicines Management

NQF Level 3: **BTEC National**

Guided learning hours: 60

Unit abstract

Much of a pharmacy technician's role is concerned with dispensing medicines and advising patients on their correct use. This unit, along with *Unit 3: An Introduction to Action and Uses of Medicines, Unit 4: Cytotoxic, Endocrine and Nutritional Medicines* and *Unit 5: Central Nervous System, Eyes, ENT, Skin and Gynaecological Medicines*, covers all the sections found in the British National Formulary (BNF). This means that in studying all these units pharmacy technicians will cover all the categories of medicines they are likely to encounter in their professional lives.

The aim of this unit is for the learner to develop an understanding of the underlying principles behind the way medicines work on the human body. The unit extends the learner's knowledge from physiology in health to disease processes. It explains the appropriate use and limitations of therapeutic agents. The role of the pharmacy technician is expanding so learners will require a good knowledge of therapeutics and must be able to demonstrate good communication skills.

The unit develops general concepts around knowledge of disease states and the principles of drug action in these conditions. The fundamental principles are expanded so that the learner can apply the concepts of drug action in their workplace to provide appropriate dispensing, counselling and over-the-counter sales. This unit also forms the basis for other medicine management training. The pharmacy technician should also demonstrate that they are aware of their own limitations and when they need to refer to a pharmacist, senior pharmacy technician or prescriber.

This unit examines the main medicine categories and their actions in the treatment of cardiovascular, respiratory and genito-urinary disorders and the skills involved in medicines management.

Learning outcomes

On completion of this unit a learner should:

1 Understand the use and limitations of medicines used in the treatment of respiratory disorders

2 Understand the use and limitations of medicines used in the treatment of cardiovascular disorders

3 Understand the use and limitations of medicines used in the treatment of genito-urinary disorders

4 Be able to understand the principles and procedures involved in medicines management.

Unit content

1 **Understand the use and limitations of medicines used in the treatment of respiratory disorders**

Airway function: use of devices in airway disease; counselling of patients in the use of inhalation devices (metered dose inhalers, breath-actuated inhalers, dry powder inhalers, spacers, nebulisers, other devices); peak flow meters; assessment of lung function

Asthma: nature of the asthmatic condition; drug treatment (beta 2 agonists, antimuscarinic bronchodilors, theophylline, corticosteroids, cromoglicate and nedocromil, leukotriene receptor antagonists, and newer therapies); British Thoracic Society guidelines for the management of acute and chronic asthma

Medication for coughs and colds: the common cold and influenza; coughs and nasal congestion; drug treatment of the conditions (mode of action, side effects, contra-indications); non-prescription medicines treatment of coughs and colds (patient counselling, uses and limitations of non-prescription medicines preparations)

Chronic obstructive pulmonary disease (COPD): bronchitis, emphysema and their treatment (use of short-acting and regular beta 2 agonist and antimuscarinic bronchodilor, corticosteroids); oxygen at home

Allergy, hyposensitisation and hay fever: allergy; allergic emergencies and hyposensitisation (anaphylaxis, angioedema); hay fever; drug treatment, antihistamines (oral and topical), non-prescription medicines treatment of hay fever (patient counselling, uses and limitations of non-prescription medicines preparations)

2 **Understand the use and limitations of medicines used in the treatment of cardiovascular disorders**

Congestive heart failure: cardiac glycosides and other positive inotropics; diuretics (thiazides and related diuretics, loop and potassium-sparing diuretics)

Blood pressure regulation: hypertension, symptoms, thresholds and targets for treatments (British Hypertension Society recommendations); beta blockers; vasodilators (thiazides, calcium blockers, ACE inhibitors and blockers, potassium channel activators, alpha blockers and central acting); hypotension, symptoms, treatments (inotropic sympathomimetics, vasoconstrictor sympathomimetics)

Cardiac arrythmias: symptoms and treatments; membrane stabilising drugs (lidocaine, flecainide and derivatives); beta blockers; amiodarone; calcium channel blockers and digoxin

Angina: symptoms and treatments, nitrates, beta blockers, calcium channel blocker, antiplatelet drugs

Lipid regulation: cholesterol testing; low-density lipoprotein (LDL), high-density lipoprotein (HDL); hypercholesterolaemia; hyperlipidaemia; anion-exchange resins; fibrates; statins; nicotinic acid group

Myocardial infarction: symptoms and treatments anticoagulants (including warfarin and heparin); antiplatelet drugs (including aspirin and clopidogrel); fibrinolytics

Cardiac arrest: symptoms; risk factors; cardiac stimulants (including sympathomimetics, atropine and calcium); cardioversion

3 **Understand the use and limitations of medicines used in the treatment of genito-urinary disorders**

Genital system: infections of genitals; symptoms and treatments of gonorrhoea, syphilis, vaginal and vulval candidiasis and other sexually transmitted diseases

Genito-urinary system: medicines used in the treatment of urinary retention, urinary incontinence and nocturnal enuresis; uses and limitation of medicines used in the treatment of erectile disorders

4 **Be able to understand the principles and procedures involved in medicines management**

Medicine history taking: principles of medicine history taking; identification of patient medication; medication administration record sheets (MARS); previous hospital records/charts; GP printouts; patient summaries; repeat prescriptions; patient's own medication (PODs); referral letters; community pharmacy; patient's relatives/carers

Medication use reviews (MURs): principles of MURs, common groups for MURs; patients on long-term medication (epileptics, diabetics etc); patients with mental health problems; patients on multiple drug regimens; patients with compliance issues (elderly, stroke patients etc)

Communication: patient confidentiality; talking to patients (use of open questions, checking patient alertness, body language), talking to other healthcare professionals (limitations of your job role, when to refer); dealing with patients with special requirements (deaf and hard of hearing, visually impaired, English as a second language, mental illness and learning disabilities)

Problems with medication: allergies, adverse drug reactions; compliance problems; ensuring safe storage and use of medicines

Documentation: procedures and policies; endorsing prescriptions; prescription intervention forms

Grading grid

In order to pass this unit, the evidence that the learner presents for assessment needs to demonstrate that they can meet all of the learning outcomes for the unit. The criteria for a pass grade describes the level of achievement required to pass this unit.

Grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P1 a) list the common disorders affecting the respiratory system b) name common medicines used in each of the disorders c) list the common side effects of these medicines d) give examples of the different devices used in the treatment of airways disease	M1 a) describe how each medicine listed works b) compare the different devices used in the treatment of airways disease	D1 a) recommend ways in which patients can manage their conditions effectively b) evaluate the advantages and disadvantages of each different device used in the treatment of airways disease
P2 a) list the common disorders affecting the cardiovascular system b) name some common medicines used in each of the disorders c) list the common side effects of these medicines	M2 a) describe how each medicine listed works b) discuss the risk factors that are associated with cardiovascular disorders	D2 a) recommend ways in which patients can manage their conditions effectively b) discuss the use of anticoagulants and the potential problems associated with taking them

Grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P3 a) list the common disorders affecting the genito-urinary system b) list the common infections of the genitals c) name some common medicines used in each of the disorders and infections d) list the common side effects of these medicines	M3 a) describe how each medicine listed works b) discuss how patients can achieve maximum benefit from these medicines with minimal side effects	D3 a) recommend ways in which patients can manage their conditions effectively b) discuss the factors that influence the choice of drug treatment for these conditions
P4 a) list the main principles of medicines management b) give examples of the communication skills required to undertake medicines management c) list the ways in which a patient's drug history can be identified.	M4 a) describe the main principles of medicines management b) describe the communication skills required to undertake medicines management c) describe the problems patients can have with their medication d) compare the different ways in which patient drug history can be identified.	D4 a) evaluate the main principles of medicines management b) recommend ways to improve communication skills when dealing with patients with special requirements c) recommend ways in which patients can maximise their compliance in terms of their treatment.

Essential guidance for tutors

Delivery

The delivery of this unit requires a large degree of formal direction. The unit offers opportunities for learners to take an active role in developing and demonstrating analytical and problem-solving skills. These opportunities can be found in the use of case studies, role play, patient counselling, the production of patient information leaflets and posters and links, where possible, to activities in the workplace. It is important that learners are aware of their own limitations and when they need to refer to a pharmacist, senior technician or prescriber.

This is a subject that changes rapidly and the medicines discussed should be updated regularly so that new developments are included and obsolete material removed.

Although these units cover specific areas of therapeutics there needs to be an overarching theme for learners in terms of their role in the future of helping to manage a patient and their medicines and this needs emphasising in the method of delivery of this unit. Resources used to help learners glean information, particularly the BNF which will become their standby as they study these units and should feature throughout the delivery of Units 4, 5 and 6.

Assessment

In the grading grids we use the word discuss to mean: *to put forward both sides of an argument, identifying salient points.*

This unit is broad in content and provides opportunities for learners to produce a number of assignments as evidence of achievement.

Assignments should be designed to be relevant to current and future workplace practices and encourage learners to demonstrate a clear understanding of drug usage rather than copying information directly from textbooks or the web.

Assignments that could meet these criteria are case studies, design of patient information booklets, role play in the sale of non-prescription medicines and patient counselling, information posters, demonstrations, talks and patient surveys followed by analysis and discussion groups with critical reporting.

Pass

To achieve a pass, learners will be able to link drugs with the treatment of specific diseases. They may require support in identifying diseases from symptoms/ photographs. Learners will be able to briefly describe common drugs used and list the most common side effects. Learners will be aware of the concept of medicines management. They will be able to provide patient information but they may have to refer should the patient require detailed information or have a problem that needs solving.

Merit

To achieve a merit, learners will be able to identify diseases from case studies, photographs and descriptions in role play and prescriptions. Learners should be able to explain the pharmacological action of the drug and link this to the side effects. They should be able to apply their knowledge in identifying problems and solving them and have some idea of the meaning of medicines management. Learners should be able to counsel patients and respond to requests for further/more detailed information.

Distinction

To achieve a distinction, learners should be able to understand how pathological changes produce the symptoms of the disease encountered in role play, case studies, photographs, prescriptions etc. Learners will have an understanding of complex issues and, by bringing together several areas of knowledge, be able to present valid conclusions in explaining the choice of drugs used.

Learners should be able to analyse the information patients will require for optimum treatment and demonstrate that they can tailor this information to the patient's ability. Learners should be able to predict any problem or difficulty likely to occur with the treatment and make suitable suggestions as to how these should be solved.

Learners at this level will have a good understanding of their potential role in terms of medicines management.

Links to National Occupational Standards, other BTEC units, other BTEC qualifications and other relevant units and qualifications

This unit is one of four units on the action and use of medicines and it is necessary to study all four units to develop a comprehensive knowledge of drug use. The knowledge covered is linked closely with *Unit 8*: *Human Physiology for Pharmacy* and these units could be delivered in an integrated way. The units also build on the learner's knowledge gained in *Unit 1*: *Scientific Principles for Pharmacy* and *Unit 9*: *Microbiology for Pharmacy*. Knowledge of factors affecting disease states can be linked in with health promotion, counselling with effective supply and use of medicines, found in *Unit 10*: *Pharmacy Practice*.

This unit presents opportunities to gather evidence towards key skills in communication and information and communication technology.

Essential resources

Staff delivering this unit should be experienced registered pharmacists or pharmacy technicians. This will ensure that the relevant knowledge and understanding needed in this unit is given. Centres will not be expected to supply the full range of resources but should provide an appropriate selection which learners should have easy access to. The British National Formulary (BNF) and a medical dictionary are regarded as essential. Access to the *Pharmaceutical Journal* would be an advantage.

Indicative reading for learners

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Websites

Electronic data sheet compendium	www.emc.vhn.net
Medicines Guides	www.medicines.org.uk

Key skills

Achievement of key skills is not a requirement of this qualification but it is encouraged. Suggestions of opportunities for the generation of Level 3 key skill evidence are given here. Tutors should check that learners have produced all the evidence required by part B of the key skills specifications when assessing this evidence. Learners may need to develop additional evidence elsewhere to fully meet the requirements of the key skills specifications.

Communication Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• taking part in a group discussion on, eg the action and uses of medicines for any of the four learning outcomes, etc	C3.1a Take part in a group discussion.
• making a formal presentation of at least eight minutes using an image or other support material on, eg the action and use of medicines for any of the four learning outcomes	C3.1b Make a formal presentation of at least eight minutes using an image or other support material.
• reading and synthesising information from at least two documents about the same subject, each document being a minimum of 1000 words long on, eg the action and uses of medicines for any of the four learning outcomes	C3.2 Read and synthesise information from **two** documents about the same subject. Each document must be a minimum of 1000 words long.
• writing two different types of documents, each one giving different information about complex subjects, eg the action and uses of medicines for any of the four learning outcomes.	C3.3 Write **two** different types of documents, each one giving different information about complex subjects. One document must be at least 1000 words long.

Information and communication technology Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• planning and carrying out a search for information on, eg the action and use of medicines for any of the four learning outcomes, etc.	ICT3.1 Search for information, using different sources, and multiple search criteria in at least one case.

Unit 7: Pharmaceutics

NQF Level 3: BTEC National

Guided learning hours: 60

Unit abstract

Pharmaceutics is concerned with the preparation and dispensing of pharmaceutical products (medicines) from the initial formulation stage to the final issuing to a patient. It is important that those employed as technicians in the pharmaceutical workplace have the knowledge and skills to undertake all these activities safely and accurately in order to ensure the safety of both themselves and the patient. It is important, therefore, that learners appreciate the pharmaceutical factors that can result in inaccuracy and poor quality and the subsequent effects that these can have on the health of patients.

The unit provides the learner with an understanding of the pharmaceutical aspects of pharmaceutical products and the dispensing process. It aims to develop learners' practical skills in fundamental dispensing procedures, measurements and calculations. The learners will study the theoretical aspects and apply practical skills in the safe and accurate preparation of effective, acceptable dispensed pharmaceutical products.

Learning outcome 1 looks at the dispensing process covering good procedures and practices and highlighting areas where errors can occur. Learning outcome 2 is concerned with the accurate use of calculations and measurements in the dispensing process. Learning outcome 3 covers the practical aspects of extemporaneous dispensing (compounding) including preparation, labelling and packaging of non-sterile pharmaceutical products. Learning outcome 4 is concerned with the theoretical aspects of formulation including physical, chemical and microbiological components.

Learning outcomes

On completion of this unit a learner should:

1 Understand and follow good dispensing procedures and practices

2 Be able to perform accurate measurements and calculations for pharmaceutical formulae

3 Be able to safely and accurately prepare pharmaceutical products for dispensing

4 Understand the formulation of pharmaceutical products including packaging materials.

Unit content

1 **Understand and follow good dispensing procedures and practices**

Procedures and practices: principles of good dispensing practice for the whole dispensing process (standard operating procedures, application of organisational policies, dosage checks using the BNF); standards for pharmacies (including hygiene standards); the extent of the technician's authority in the dispensing process (when to refer to a pharmacist); checking procedures for self and others

Prescriptions: types of prescriptions, NHS prescriptions (including repeat, controlled drug), private prescription forms; hospital in- and outpatient forms; legal requirements; endorsement; interpretation of the prescriber's intentions including directions for use; Latin abbreviations, drug interactions; compatibility; dosage calculations relating to age, weight and surface area; calculation for amounts to be supplied based on the dosage and time period

Recording and regulatory systems: patient medication record (PMR) systems; clinical trials; private prescriptions; emergency supply; controlled drugs; patient group directions (PGD)

2 **Be able to perform accurate measurements and calculations for pharmaceutical formulae**

System and equipment for weights and measures: metric system (SI units); balances, measuring cylinders, conical (dispensing) measures, pipettes, syringes; care of equipment including cleanliness, accuracy, potential errors and limits of tolerance

Calculations for pharmaceutical formulations to include: weights, volumes, percentage, ratios, dilutions (including serial dilutions and triturations), displacement values, small quantity calculations, concentrations; use of formulae for extemporaneous dispensing

Reference sources: standard pharmaceutical reference texts, eg *British Pharmacopoeia*; Pharmaceutical Codex, Drug Tariff, British National Formulary; use and content with regard to information about pharmaceutical products

3 **Be able to safely and accurately prepare pharmaceutical products for dispensing**

Preparation: extemporaneous preparation of a selected number of pharmaceutical products for dispensing which illustrate the range of products available to be prescribed by a practitioner and dispensed in the pharmacy

Special procedures: for weighing semi-solids, hygroscopic substances; for measuring opaque and viscous liquids; procedures for weighing and measuring hazardous substances; Control of Substances Hazardous to Health (COSHH) regulations including the practical application of safety data sheets

Labelling: purpose of label; labels on medicines (cautionary and additional labels); generating computerised labels

Packaging materials: types, advantages and disadvantages; effect on shelf life; advising patients on correct storage of medicines

4 **Understand the formulation of pharmaceutical products including packaging materials**

Routes of administration: different dosage forms; advantages and disadvantages

Product preparation: methods of preparation including safety precautions for handling raw materials; purity; quality standards and sampling; cross-contamination

Clarification and filtration: methods; filter types and properties

Mixing and comminution: techniques for mixing (solid with solid, solid with semi-solid, solid with liquid, liquid and liquid); levigation; size reduction (including sieving); doubling up

Types of water: potable, distilled, deionised, purified, preparations, water for injections, sterile water, pyrogen-free water, carbon dioxide-free water; preparation of water, eg distillation, ion exchange

Formulation of pharmaceutical products: eg solutions, suspensions, mixtures, linctuses, elixirs, emulsions, ointments, pastes, creams, capsules, suppositories, pessaries, lotions, liniments, mouth washes, gargles, powders and other pharmaceutical products

Physical properties of solutions: solubility, solute, solvent, saturated, supersaturated, isotonicity; factors affecting rate of solution

Microbiological aspects: sources of microbial contamination; cross contamination; preservatives; storage; shelf life

Physical and chemical properties of pharmaceutical products: shelf life; storage; British Pharmacopoeia (BP) standards for medicines

Stock control: basic principles (including ordering and receipt); stock rotation and how to deal with expired stock; storage conditions; special precautions; controlled storage; electronic control systems; stock delivery systems and services

Grading grid

In order to pass this unit, the evidence that the learner presents for assessment needs to demonstrate that they can meet all of the learning outcomes for the unit. The criteria for a pass grade describes the level of achievement required to pass this unit.

Grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P1 state the procedure for dispensing a prescription	M1 describe where errors can occur in the prescription-dispensing procedure	D1 explain how errors can be minimised in the prescription-dispensing procedure
P2 identify a range of prescription forms	M2 validate a range of prescription forms	D2 detect errors on prescriptions and explain remedial procedures required before dispensing
P3 choose the correct formulae and accurately carry out a range of pharmaceutical calculations and measurements (by weight or volume)	M3 identify any possible sources of errors in the measurements carried out	D3 calculate the limits of tolerance for the measurements carried out
P4 demonstrate basic manipulative skills in the preparation of a range of extemporaneous pharmaceutical products	M4 competently and safely prepare a range of extemporaneous pharmaceutical products	D4 work independently in the full range of manipulations required for extemporaneous preparation
P5 state the basic dispensing method used in the preparation of a range of extemporaneous pharmaceutical products	M5 describe in detail the dispensing methods used, including safety aspects, in the preparation of a range of extemporaneously prepared pharmaceutical products	D5 explain the dispensing methods used, including interpretation of safety data sheets, in the preparation of a range of extemporaneously prepared pharmaceutical products

Grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P6 produce a label using ICT skills for a range of extemporaneous pharmaceutical products	M6 generate appropriate additional labels using ICT skills for a range of extemporaneous pharmaceutical products	D6 state and explain any additional advice required for a range of extemporaneous pharmaceutical products
P7 identify the formulation type of a range of extemporaneous pharmaceutical products.	M7 describe the formulation requirements of a range of extemporaneous pharmaceutical products.	D7 explain the formulation requirements of a range of extemporaneous pharmaceutical products.

Essential guidance for tutors

Delivery

This unit should preferably be taught in conjunction with or after *Unit 2: Pharmacy Law, Ethics and Practice* so that the learner has the opportunity to apply the knowledge acquired in Unit 2.

A range of delivery methods can be used, including lectures, tutorials, demonstrations, practicals and use of personal experience in discussions.

Whichever delivery methods are used it is vital that tutors stress the importance of safe and accurate dispensing procedures so that a quality pharmaceutical product is achieved for a patient. Risk assessments, using safety data sheets, should be integrated where relevant in practical work linked with the theory in Unit 2.

The development of good practical skills is essential for this unit. A minimum of five different types of pharmaceutical preparations should be extemporaneously prepared, three of them under controlled conditions for assessment purposes. Examples of different products include solutions, suspensions, mixtures, linctuses, elixirs, emulsions, ointments, pastes, creams, capsules, suppositories, pessaries, lotions, liniments, mouth washes, gargles, powders and other pharmaceutical products. This list is not restrictive and the particular formulations chosen are dependent on ingredient availability and relevance to local pharmacy needs.

Learning outcome 1 may be delivered and assessed in a non-work-based setting, eg lectures, tutorials, discussions and practical classes in a centre, depending on the local pharmacy and learners.

Learning outcomes 2, 3 and 4 are directly linked. They are likely to be delivered through formal lectures and practical work.

Learning outcome 2 covers the selection and use of formulae reference sources and any calculations and subsequent measurements required to produce the preparation.

Learning outcome 3 requires the practical skills and procedures to prepare and issue a pharmaceutical product.

Learning outcome 4 is concerned with the formulation type (eg suspension) and the formulation requirements to extemporaneously produce the particular formulation type (eg preservative, suspending agent etc).

Assessment

Generic guidance on assessment

All learners are entitled to initial guidance in planning their work, but the level of assistance required should be taken into account when their work is assessed. The grading grid refers to learners working 'independently'. Assessors should apply the following guidelines.

- '*Independently*': The tutor supports the learner initially in the choice of topic for the investigation or task. Thereafter, the tutor occasionally assists the learner, and only when asked, but monitors progress throughout. This level of support gives access to all three grades: pass, merit and distinction.

Unit-specific guidance on assessment

A variety of assessment methods can be used to generate evidence for this unit. Practical skills will need to be assessed, particularly for learning outcomes 2 and 3, since the emphasis of the unit is on demonstrating both the practical skills and the ability to apply theory to the dispensing of pharmaceutical products.

Grading criterion one covers standard operating procedures (SOPs) and prescription forms which may be assessed as two separate written assessments. The context of SOPs should focus on their use and development in the learner's own workplace.

Grading criteria two, three and four are directly linked and may be assessed by a combination of observation records and written work. However criteria four can be assessed by written work alone (eg an assignment on formulation) or combined with grading criteria two and three practical work. A laboratory-style worksheet may be used to give the learner the opportunity to attempt to meet all criteria. Three different pharmaceutical products from different formulation groups should be prepared under controlled conditions for assessment purposes. Observation records should be used as evidence for the practical elements, which the tutor observes under controlled conditions.

Guidance on observation records is available on the Edexcel website.

Health and safety issues relating to the practical use of hazardous substances must be stressed and reinforced with Unit 2 content.

Evidence from the NVQ Pharmacy Services in the learner's workplace may prove a suitable means of assessment of parts of this unit and assessors should attempt to work in co-operation.

Pass

To achieve a pass grade, learners must achieve the four pass criteria listed on the grading grid provided.

For P1 learners are expected to have knowledge of the procedure for dispensing a prescription.

P2 requires learners to be able to recognise four different types of prescription forms. Evidence for this could involve a written assignment on SOPs and prescription forms for identification.

P3 requires learners to be able to select the formula required for the extemporaneous preparation of three pharmaceutical products and to accurately carry out any calculations required. In addition, the learner must demonstrate practical skills in accurate measurement (by weight or volume) of the ingredients required for the three extemporaneous pharmaceutical products. Evidence for this could take the form of a completed written worksheet and an observation record.

P4 is linked with the practical dispensing aspects of P3. Learners will demonstrate basic manipulative skills requiring significant support from their tutor in the preparation of the three pharmaceutical products.

P5 requires learners to give a basic description of the method used.

P6 requires learners to produce a computer generated label for each of the three products. Evidence for this could take the form of a completed written worksheet, including a sample label and an observation record.

P7 requires learners to identify the formulation type of a range of pharmaceutical products. Evidence for this could take the form of a completed written worksheet for the three extemporaneously prepared pharmaceutical products as prepared for grading criteria two and three or as a separate generic assignment.

Merit

To achieve a merit grade, the learner must achieve all of the pass grade criteria **and** the four merit grade criteria.

M1 expects learners to indicate where errors can occur during the procedure of dispensing a prescription.

M2 requires learners to determine whether there are defects on any of the four different prescription forms (ie fulfilment of legal requirements including NHS exemption completion etc). Evidence may take the same format as P1 or P2.

M3 requires learners to be able to identify at least three possible sources of errors in the measurements carried out in the extemporaneous preparation of three pharmaceutical products. Evidence for this could take the form of a completed written worksheet.

M4 is linked with the practical dispensing aspects of M3. Learners will demonstrate competency in the preparation of the three pharmaceutical products, including regard for safety with minimal tutor support.

M5 requires learners to give a detailed description of the method used, including safety aspects.

M6 requires learners to produce computer generated additional labels for each of the three products. Evidence for this could take the same format as P4, P5 or P6.

M7 requires learners to describe the formulation requirements of a range of pharmaceutical products. Evidence for this could take the same format as P7.

Distinction

To achieve a distinction grade, the learner must achieve all of the pass and merit grade criteria **and** the four distinction grade criteria.

D1 requires learners to explain how errors can be minimised during the procedure of dispensing a prescription.

D2 requires learners to determine whether there are errors on any of the four different prescription forms (eg dose related, drug interaction etc). Evidence may take the same format as P1 or P2.

D3 requires learners to be able to calculate the limits of tolerance for two measurements made for each of the three pharmaceutical products extemporaneously prepared. These should be chosen to cover both weighing and volume measurement if possible. Evidence for this could take the same format as P3.

D4 is linked with the practical dispensing aspects of D3. Learners will demonstrate high skill and complete independence in the preparation of the three pharmaceutical products.

D5 requires learners to give a detailed explanation of why the method was used, including safety aspects, with reference to relevant safety data sheets.

D6 requires learners to describe any additional advice if any for each of the three products. Evidence for this could take the same format as P4 or P5 only.

D7 requires learners to explain the formulation requirements of a range of pharmaceutical products. Evidence for this could take the same format as P7.

For a particular grade to be achieved overall, each of the criteria must be achieved in all of the three extemporaneous products dispensing.

Links to National Occupational Standards, other BTEC units, other BTEC qualifications and other relevant units and qualifications

The learning outcomes associated with this unit are closely linked with of *Unit 1: Scientific Principles for Pharmacy, Unit 2*: *Pharmacy Law, Ethics and Practice, Unit 9*: *Microbiology for Pharmacy* and *Unit 13: Scientific Method for Pharmacy Technicians* and all of the action and use of drugs units.

This unit presents opportunities to demonstrate key skills in application of number, communication and problem solving.

This unit provides underpinning knowledge for the Level 3 NVQ in Pharmacy Services (see *Annexe D* for mapping).

A strong link with the learner's workplace will be of prime importance to the unit.

Essential resources

Staff delivering this unit should be experienced registered pharmacists or pharmacy technicians. This will ensure they can provide the relevant knowledge and understanding needed in this unit. Much of this unit is practical in nature, therefore learners will require access to suitable laboratory facilities equipment with dispensing equipment such as weighing balances, water baths and large porcelain evaporating dishes, dispensing measures, ointment slabs and spatulas, mortars and pestles and formula ingredients. Adequate library facilities and pharmaceutical reference resources should be available for this unit both in the centre and in the learner workplace.

Indicative reading for learners

Pharmacy textbooks are expensive and learners should not be expected to buy them. However, these texts should be available at the centre and/or library.

Textbooks

Bonner M C, Wright D J and George B — *Practical Pharmaceutical Calculations* (Petroc Press, 1999) ISBN 1900603578

Lapham R and Agar H — *Drug Calculations for Nurses* (Arnold, 2003) ISBN 0340604794

Marriott J, Wilson K, Langley C and Belcher D — *Pharmaceutical Compounding and Dispensing, First Edition* (Pharmaceutical Press, 2005) ISBN 085369575X

Rees J and Smith I — *Pharmaceutical Calculations Workbook, First Edition* (Pharmaceutical Press, 2005) ISBN 0853696020

Rees J, Smith I and Smith B — *Introduction to Pharmaceutical Calculations, Second Edition* (Pharmaceutical Press, 2004) ISBN 0853696039

Winfield A J and Richards R M E — *Pharmaceutical Practice, Third Edition* (Churchill Livingstone, 2003) ISBN 0443071373

Key skills

Achievement of key skills is not a requirement of this qualification but it is encouraged. Suggestions of opportunities for the generation of Level 3 key skill evidence are given here. Tutors should check that learners have produced all the evidence required by part B of the key skills specifications when assessing this evidence. Learners may need to develop additional evidence elsewhere to fully meet the requirements of the key skills specifications.

Application of number Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• selecting and using appropriate methods of measurements and calculations, eg dose calculations	N3.2 Use this information to carry out multi-stage calculations to do with: a amounts or sizes b scales or proportion c handling statistics d using formulae.
• calculating the limits of tolerance for errors in measuring.	N3.3 Interpret the results of your calculations, present your findings and justify your methods.
Communication Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• taking part in group discussions about a complex subject such as formulation of medicines or physical and chemical properties of medicines	C3.1a Take part in a group discussion.
• presenting the results and conclusions of an investigation about the complex subjects above	C3.1b Make a formal presentation of at least eight minutes using an image or other support material.
• using literature sources to develop and synthesise information about complex subjects such as the above	C3.2 Read and synthesise information from **two** documents about the same subject. Each document must be a minimum of 1000 words long.

Communication Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• preparing the report of an investigation about the complex subjects above.	C3.3 Write **two** different types of documents, each one giving different information about complex subjects. One document must be at least 1000 words long.
Problem solving Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• selecting appropriate methods for extemporaneous preparation of a pharmaceutical product	PS3.1 Explore a problem and identify different ways of tackling it.
• explaining how errors can be minimised in the prescription-dispensing procedure.	PS3.2 Plan and implement at least one way of solving the problem.

Unit 8: Human Physiology for Pharmacy

NQF Level 3: BTEC National

Guided learning hours: 60

Unit abstract

Human physiology deals with the functioning of the human body. Bodily function depends upon bodily structure and so this unit also refers to the structure, or anatomy, of the various body systems.

Tissues are groups of cells that carry out a particular function. Learning outcome 1 of this unit is concerned with the ways that cells have become specialised, or differentiated, to form tissues.

The importance of physiological homeostasis and the co-ordination of the body's activities by the nervous and endocrine systems are considered in learning outcome 2.

Oxygen is essential for life. Learning outcome 3 covers the role of the cardiovascular and respiratory systems in supplying the body tissues with oxygen. The protective function of the lymphatic system is also covered.

Humans, in common with all other living organisms, rely upon suitable nutrition. The essential nutrients and the ways that they are ingested, digested and absorbed, are covered in learning outcome 4 of this unit. The functions of the urinary system, one of which is the removal of bodily waste, are also considered.

Reproduction is the means by which life continues from generation to generation. Learning outcome 5 deals with the physiology of the human reproductive system.

Learning outcomes

On completion of this unit a learner should:

1 Be able to identify different types of human tissue

2 Understand how the nervous and endocrine systems maintain homeostasis

3 Understand the functions of the cardiovascular and respiratory systems

4 Understand the functions of the digestive and urinary systems

5 Know the physiological basis of reproduction.

Unit content

1 **Be able to identify different types of human tissue**

Tissues: differentiation of cells to form tissues; structure and function of tissues; epithelial, connective, muscle and nerve tissues; organisation of tissues to form organs

2 **Understand how the nervous and endocrine systems maintain homeostasis**

Principles of homeostasis: significance of maintaining an optimum internal environment for cell function; role of negative and positive feedback mechanisms

Organisation of the nervous system: central nervous system, peripheral nervous system, structure of a neurone; structure of a nerve; sense organs; effector organs; structure and function of eye and ear

Functions of the nervous system: initiation and transmission of the nerve impulse; synapses; sensory (afferent) and motor (efferent) neurones; reflex arc; somatic and autonomic (sympathetic and parasympathetic) control; co-ordination

Organisation of the endocrine system: pituitary gland; hypothalamus; thyroid; parathyroid; pancreas; adrenal medulla; adrenal cortex; gonads

Functions of the endocrine system: significance of homeostatic regulation by hormones; characteristics of hormones; endocrine control and feedback; names and actions of principal hormones produced by each gland

3 **Understand the functions of the cardiovascular and respiratory systems**

Structure of the cardiovascular system: blood; heart; blood vessels (arteries, veins, arterioles, venules, capillaries)

Functions of the cardiovascular system: transport; defence; temperature regulation

Structure of the lymphatic system: lymphatic vessels; lymph nodes; spleen

Functions of lymphatic system: drainage of tissue fluid and formation of lymph; outline of defensive role

Structure of the respiratory system: nasal cavities; pharynx; larynx; trachea; bronchii; bronchioles; alveoli; capillary networks

Functions of the respiratory system: breathing; gaseous exchange

4 **Understand the functions of the digestive and urinary systems**

Essential dietary components: carbohydrates; lipids; proteins; vitamins; minerals; fibre; water

Structure of the digestive system: mouth; pharynx; oesophagus; stomach; pancreas; liver; gall bladder; small intestine; large intestine

Functions of the digestive system: relation of digestive system to cellular homeostasis; ingestion; mechanical digestion, chemical digestion; absorption; egestion of dietary components

Metabolism and energy: the body's energy requirements; glucose and cellular respiration; regulation of blood glucose (insulin, glucagon, adrenaline, glucocorticoids)

Regulation of body fluids: significance of maintaining fluid, electrolyte and pH balance; nephron structure; filtration, absorption and urine production by the nephron; storage and release of urine by the bladder; regulation of urine volume and composition

5 **Know the physiological basis of reproduction**

Structure of the reproductive system: in male (testis, epididymis, scrotum, sperm duct, penis, accessory glands); in female (ovary, oviduct, uterus, vagina, external genitalia, mammary glands)

Functions of the reproductive system: production of gametes (gametogenesis); hormonal regulation of sperm production in the male; hormonal regulation of the female ovarian and menstrual cycles; fertilisation, pregnancy and birth; lactation

Grading grid

In order to pass this unit, the evidence that the learner presents for assessment needs to demonstrate that they can meet all of the learning outcomes for the unit. The criteria for a pass grade describes the level of achievement required to pass this unit.

Grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P1 describe different types of tissue	M1 identify different types of tissue from tissue sections and/or photographs	D1 summarise (relate) cellular differentiation to tissue function
P2 describe the functions of the nervous and endocrine systems	M2 explain the roles of the nervous and endocrine systems in the maintenance of homeostasis	D2 identify the causes and treatment of a common homeostatic disorder by analysis of relevant physiological information
P3 describe the functions of the cardiovascular and respiratory systems	M3 relate the structure of the cardiovascular and respiratory systems to their functions	D3 interpret physiological data relating to the cardiovascular and respiratory systems
P4 describe the functions of the digestive and urinary systems	M4 relate the structure of the digestive and urinary systems to their functions	D4 interpret physiological data relating to the digestive and urinary systems
P5 describe gametogenesis in the male and female.	M5 explain the hormonal regulation of reproductive physiology.	D5 interpret data on sex hormone levels in the blood with relation to reproductive physiology.

Essential guidance for tutors

Delivery

An active and investigative approach will be needed to enable learners to achieve the outcomes. Learners should be encouraged to be autonomous and, over time, to act reflectively, critically and independently. Practical scientific investigation will help to develop these qualities. Learners who have access to a range of learning materials in a variety of media will have the opportunity to become more independent of the tutor.

Learners should be encouraged to develop skills in data analysis, which are necessary to achieve the distinction grade criteria.

The order of outcomes and content given here should not be construed as a scheme for teaching and it is assumed that tutors will tailor delivery and assessment to meet the needs of their learners.

Learning outcome 1 is likely to involve practical work, with learners gaining proficiency in using the light microscope. This section is shorter than the others, which should enable learners to achieve the respective grading criteria in a relatively short time, thus building confidence and motivation.

Learning outcomes 2–5 are likely to be delivered via formal lectures, practical work and independent research. Delivery should include the analysis of relevant physiological data.

Assessment

This unit is broad in content and learners are likely to produce a number of assignments as evidence of achievement.

Assignments should be designed to encourage learners to demonstrate a clear understanding of relevant concepts, principles and processes rather than excessive description of anatomical structures.

In such a broad unit, there are opportunities for learners to work individually or in groups to investigate different aspects of a learning outcome. Evidence can be presented in a range of formats such as posters or oral presentations as alternatives to written reports.

Pass

To achieve a pass grade, learners must achieve the five pass criteria listed in the grading grid.

To achieve P1, learners must describe the various types of tissues; to achieve P2–P5, they must describe the functions of the various body systems.

Merit

To achieve a merit grade, the learner must achieve **all** of the pass grade criteria **and** the five merit grade criteria. Learners must demonstrate understanding through analysis and applying knowledge.

For M1, learners are required to correctly identify different types of tissue by applying their knowledge of tissue structure. Ideally this should be achieved through microscopic examination of tissue sections; however, photographs of tissue sections may be used as an alternative. Learners should be expected to distinguish between different types of tissue, for example different types of epithelial tissue. It would not therefore be sufficient to simply use four illustrations of the four basic tissue types. As this is a merit criterion, at least eight photographs or sections should be used and learners would be expected to explain their answers.

To achieve M2, the learner must explain the roles of the nervous and endocrine systems in maintaining homeostasis, by reference to at least one specific homeostatic process. Learners must demonstrate understanding of the interaction between the two systems.

For M3 and M4, it is necessary to explain how the structure of the various systems is adapted to their physiological functions; it is important that learners should not simply describe structure in isolation from function.

M5 requires an explanation of the hormonal regulation of reproductive physiology; the actions of both male and female sex hormones must be explained.

Distinction

To achieve a distinction grade, the learner must achieve **all** of the pass and merit grade criteria **and** the five distinction grade criteria. Learners must evaluate a variety of information sources, bringing together several areas of knowledge to present valid conclusions. Learners must take an independent approach to analysing and applying knowledge, skill and understanding and be able to solve problems.

For D1, learners must explain how the cells of each of the main tissue types have become specialised, or differentiated, to enable the tissue to function efficiently.

To achieve D2–D5, the learner must be able to interpret relevant physiological data. Data could come from practical investigations, such as enzyme investigations, or from case studies, tables or graphs, such as the interpretation of graphical representations of blood glucose or hormone levels.

Links to National Occupational Standards, other BTEC units, other BTEC qualifications and other relevant units and qualifications

This unit will enable learners to apply their knowledge and understanding gained from *Unit 1: Scientific Principles for Pharmacy* to understand the differentiation of cells and the different types of tissues.

This unit provides links with other biology-related units such as *Unit 3: An Introduction to Action and Uses of Medicines, Unit 4: Cytotoxic, Endocrine and Nutritional Medicines, Unit 5: Central Nervous System, Eyes, ENT, Skin and Gynaecological Medicines* and *Unit 6: Action and Uses of Cardio-respiratory and Genito-urinary Medicines and Medicines Management*. *Unit 8: Human Physiology for Pharmacy* concentrates on the normal functioning of the different body systems. Abnormal function is covered in more depth in Units 3, 4, 5 and 6. Similarly, although body defences are introduced in this unit, this topic is covered in more detail in Units 3, 4, 5 and 6.

This unit also provides underpinning knowledge and understanding for a wide range of vocationally-specific units. These links offer the opportunity for an integrative approach in the delivery and assessment of the units.

The unit offers opportunities for learners to provide evidence for *Unit 13*: *Scientific Method for Pharmacy Technicians*.

There are also opportunities for learners to develop key skills in communication and information and communication technology.

This unit provides underpinning knowledge for the Level 3 NVQ in Pharmacy Services (see *Annexe D* for mapping).

Essential resources

Learners will need access to appropriate laboratory facilities where they can carry out investigations into, for example, the action of digestive secretions. The use of anatomical models, microscopic tissue sections and/or photomicrographs should enhance the learning experience. Learners will also need access to a library and to computers for the research and presentation of assignments. Relevant information is available on CD ROMs such as:

Bodyworks 6.0 (Mindscape) ASIN B00004UAAU

Essential Anatomy & Physiology (Essential Training Solutions Ltd) ASIN B0006MTTJ0

The Ultimate Human Body 2.0 (Dorling Kindersley Ltd) ASIN B00004UAAP

The British Educational Communications and Technology Agency (BECTA) provides reviews of many educational CD ROMs.

There are many good human anatomy and physiology textbooks, which cover the outcomes in this unit, see *Indicative reading for learners* for examples.

Indicative reading for learners

Eroschenko V P — *Di Fiores Atlas of Histology* (Lippincott Williams & Wilkins, 2004) ISBN 0781750210

Junqueira et al — *Basic Histology* (McGraw-Hill Publishing Co, 2005) ISBN 0071440917

Marieb E N — *Essentials of Human Anatomy and Physiology* (Pearson Higher Education, 2005) ISBN 0805373276

Rizzo D C — *Fundamentals of Anatomy & Physiology (with CD ROM)* (Delmar Thomson Learning, 2005) ISBN 1401871887

Ross J S et al — *Anatomy and Physiology in Health and Illness* (Churchill Livingstone, 2006) ISBN 0443101019

Solomon E P et al — *Human Anatomy and Physiology* (Saunders (W B) Co Ltd, 1990) ISBN 0030323894

Tortora G J — *Introduction to the Human Body* (John Wiley and Sons, 2003) ISBN 047144894X

Tortora G J — *Principles of Anatomy and Physiology* (John Wiley and Sons, 2005) ISBN 0471718718

Most advanced biology textbooks will also provide suitable reading material. For example:

Bailey M and Hirst K — *Biology Core* (Collins Educational, 1995) ISBN 0003223817

Boyle M and Indge B — *Human Biology* (Collins Educational, 2002) ISBN 0007135998

Jones M and Jones G — *Human Biology for AS Level* (Cambridge University Press, 2004) ISBN 0521548918

Jones M et al — *CIE Biology AS Level and A Level* (Cambridge University Press, 2003) ISBN 052153674X

Reiss M J et al — *Advanced Biology* (Nelson Thornes, 2000) ISBN 0174387326

Simpkins J and Williams J I — *Advanced Biology* (Collins Educational, 1987) ISBN 000322290X

Websites

BBC — Science & Nature: Human Body & Mind	www.bbc.co.uk/science/humanbody
Biology4all	www.biology4all.com
BiologyMad	www.biologymad.com
Mark Rothery's Biology website	www.mrothery.co.uk
S-Cool!	www.s-cool.co.uk

Key skills

Achievement of key skills is not a requirement of this qualification but it is encouraged. Suggestions of opportunities for the generation of Level 3 key skill evidence are given here. Tutors should check that learners have produced all the evidence required by part B of the key skills specifications when assessing this evidence. Learners may need to develop additional evidence elsewhere to fully meet the requirements of the key skills specifications.

Communication Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• taking part in group discussions about a complex subject, eg functions of the nervous system	C3.1a Take part in a group discussion.
• presenting the results and conclusions of an investigation into, eg functions of the nervous system	C3.1b Make a formal presentation of at least eight minutes using an image or other support material.
• using literature sources to develop familiarity with the technological methods to be used in, eg an investigation into metabolism and energy	C3.2 Read and synthesise information from **two** documents about the same subject. Each document must be a minimum of 1000 words long.
• preparing reports of an investigation on, eg functions of the nervous system, metabolism and energy, etc.	C3.3 Write **two** different types of documents, each one giving different information about complex subjects. One document must be at least 1000 words long.
Information and communication technology Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• planning and carrying out a search for information on, eg metabolism and energy.	ICT3.1 Search for information, using different sources, and multiple search criteria in at least one case.

Unit 9: Microbiology for Pharmacy

NQF Level 3: BTEC National

Guided learning hours: 60

Unit abstract

The need to understand the relevance of microbiology has become more important as environmental awareness and the demand for services such as aseptic dispensing and preparation have developed in pharmacy. The quality of pharmaceuticals, eg sterile and non-sterile products, requires those employed in pharmaceutical manufacture and in managing such services to have relevant microbiological knowledge and skills to undertake these activities. The relevance of disinfectants and antibiotics in the control of pathogenic micro-organisms has become important in today's society.

This unit provides the microbiological knowledge and skills required in pharmacy. The relevance of microbiology in pharmacy will be stressed during the delivery of the unit by the provision of appropriate pharmaceutical examples.

Learning outcomes 1 and 2 look at the general properties and requirements of micro-organisms. Learners will look at how the properties of micro-organisms may influence pharmaceutical procedures and techniques.

Learning outcome 3 looks at the control of micro-organisms in the environment including the use of antimicrobial agents. Learners will look at how microbial contamination is controlled in their workplace.

Learning outcome 4 will consider pathogenic micro-organisms, transmission of pathogens and the infections they cause. Learners will be expected to undertake a study of infectious diseases.

Learning outcome 5 covers the microbiological techniques commonly used in the laboratory. Sampling methods will be used to explore the environment for microbial contamination and look at methods for testing disinfectants and antibiotics.

Learning outcomes

On completion of this unit a learner should:

1 Understand the structure and classification of micro-organisms

2 Understand the growth and cultural requirements of micro-organisms

3 Understand environmental control and the use of antimicrobial agents

4 Understand the transmission of infection

5 Be able to undertake microbiological techniques.

Unit content

1 **Understand the structure and classification of micro-organisms**

Micro-organisms: bacteria; viruses; microscopic fungi; chlamydia; protozoa

Microscopy: light microscope; electron microscope; other types of microscopy (phase contrast; dark ground; fluorescent)

Structure and form: prokaryotic; eukaryotic; size; shape; cell arrangement; cellular components; bacterial spores

Classification: bacteria (Gram stain); viruses; microscopic fungi

2 **Understand the growth and cultural requirements of micro-organisms**

Growth and reproduction: binary fission; asexual reproduction; growth curves; counting (total and viable)

Cultural requirements: physical factors (pH, temperature, osmotic, atmospheric); chemical factors including general nutrients (water, carbon, nitrogen, energy, trace nutrients); nutritional classification of micro-organisms

Laboratory media: types (liquid, semi-solid, selective, differential, enriched), uses, advantages and disadvantages

Culturing micro-organisms: bacteria; viruses, microscopic fungi

3 **Understand environmental control and the use of antimicrobial agents**

Environmental control: methods used to control and monitor the microbial content of the environment; basic hygiene; use of disinfectant solutions

Antimicrobial agents: types and mode of action of disinfectants and antiseptics

4 **Understand the transmission of infection**

Pathogens: obligate and opportunistic pathogenic micro-organisms; indigenous human body flora

Causes and transmission of infection: routes and modes of transmission

5 **Be able to undertake microbiological techniques**

Basic laboratory techniques: isolation and cultivation (culture transfer techniques, isolation of pure cultures, discrete colonies); cultural characteristics of micro-organisms

Staining and microscopy: bacteria and other micro-organisms, eg fungi; preparation of films for staining; simple staining; Gram staining (bacteria); other types of staining

Nutritional and physical requirements of micro-organisms: bacteria and fungi; media used for routine cultivation; use of differential, selective and enriched media; physical factors (temperature, pH, atmospheric oxygen, osmotic effects)

Bacterial counting: serial dilution; spread and pour plate methods of counting

Disinfectants and antibiotics: the effect on microbial growth of disinfectants and antibiotics (gutter plates or similar methods, bacteriostatic tests, use of antibiotic discs)

Microbial monitoring of the environment: microbial examination of animate and inanimate objects through the use of swabbing techniques; examination of the atmosphere by using settle plates and other air-sampling devices

Grading grid

In order to pass this unit, the evidence that the learner presents for assessment needs to demonstrate that they can meet all of the learning outcomes for the unit. The criteria for a pass grade describes the level of achievement required to pass this unit.

Grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P1 describe the different types of micro-organisms and their relevance to pharmacy	M1 explain the classification of bacteria with reference to the Gram stain and the reason why bacteria react differently to this stain	D1 describe the various cellular structures of micro-organisms and their function
P2 explain the various environmental factors that may affect the growth of micro-organisms	M2 describe how to investigate the effect of environmental factors on the growth of micro-organisms in the laboratory	D2 explain how an understanding of environmental factors affecting microbial growth may influence pharmaceutical products and processes
P3 describe how the environment may be microbiologically controlled and sampled for the presence of micro-organisms and explain the relevance to pharmacy	M3 explain the different types of disinfectant and antiseptic solutions and their mode of action	D3 explain the importance of the microbial control of the environment in various pharmaceutical procedures and processes
P4 describe the transmission of pathogenic micro-organisms including examples of named pathogens, their mode of transmission and disease caused	M4 explain, with reference to a named infection or disease, the transmission of the pathogen and its control	D4 explain with reference to a number of named infections or diseases, details of the causative pathogen, transmission, disease symptoms, treatment and incidence

Grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P5 undertake the range of microbiological techniques through experiment and describe the methods used and report the results obtained.	M5 undertake the range of microbiological techniques through experiment and describe the methods used and results obtained and discuss the results.	D5 undertake the range of microbiological techniques through experiment and describe the methods used and results obtained, discuss the results and give an evaluative conclusion which has relevance to pharmacy.

Essential guidance for tutors

Delivery

This unit needs both theory and practical sessions. Tutors delivering this unit have opportunities to use a wide range of teaching techniques, lectures, discussions, seminar presentations, laboratory practicals, demonstrations, investigations using the internet and library resources. The use of personal and pharmacy experience would be suitable. Delivery should stimulate, motivate, educate and enthuse the learner, by using a variety of teaching methods to appeal to the learners' differing learning styles.

The practical work should cover basic microbiological techniques and procedures. The use of these techniques should then allow learners to investigate a series of microbiological practical exercises related to the content of the unit.

Pharmacy work experience should be utilised to ensure the quality of the learning experience. It would be beneficial if learners were made aware of the requirements of this unit prior to any work-related activities, so that naturally occurring evidence could be collected at the time. For example, learners may have the opportunity to observe aspects of microbiological work in the pharmacy environment or attend training events in microbiology. They should be encouraged to ask for observation records and/or witness statements to be provided as evidence. Guidance on the use of observation records and witness statements is provided on the Edexcel website.

Whichever delivery methods are used, it is essential that tutors stress the importance of microbiology in pharmacy.

Health and safety issues relating to working in the laboratory must be stressed and regularly reinforced. Risk assessments must be undertaken prior to practical microbiological activities.

Tutors should consider integrating the delivery, private study and assessment relating to this unit with any other relevant units and assessment instruments the learner may also be taking as part of the programme of study.

Learning outcomes 1, 2 and 3 are directly linked and also link to learning outcome 5. These are likely to be delivered through formal lectures, discussion and microbiological practical work. Independent investigations by learners will also be part of the unit. Learners will become aware of the techniques and methods used in microbiology and in particular their relevance to pharmacy. Health and safety microbiological issues must be addressed before learners undertake experimental work. Visiting expert speakers could add to the relevance of the subject for the learner, eg a microbiological quality control manager or technician could talk about their role in monitoring, the problems encountered and the methods used for pharmacy processes and procedures.

Learning outcome 4 covers the transmission of infection and pathogenic micro-organisms and can be linked to learning outcome 1. Learning outcome 4 will be delivered by lectures, seminars and discussion as well as independent investigations by the learners. Visiting expert speakers could add to the relevance of the subject for the learner, eg a hospital pharmacist specialist in microbiology could talk about their work and the problems they encounter.

Learning outcome 5 looks at the techniques and methods commonly used in the microbiology laboratory. Delivery techniques should be varied, probably comprising formal lectures, demonstrations and supervised laboratory practical exercises. Health and safety issues specific to the use of micro-organisms must be addressed before learners undertake any practical work. Suitable risk assessments should be produced before learners are allowed to work in the laboratory. Visiting expert speakers could add to the relevance of the subject, eg a hospital pathology microbiologist could talk about their work and the microbiological methods used.

Assessment

In the grading grids we use the word discuss to mean: *to put forward both sides of an argument, identifying salient points and exploring solutions.*

Pass

To achieve a pass grade learners must achieve the five pass criteria listed in the grading grid. For P1, learners will be expected to describe the different types of micro-organisms and their relevance to pharmacy. They will be expected to cover the range of micro-organisms listed in the unit content.

P2 requires learners to explain the various environmental factors that may affect the growth of micro-organisms. This criterion could be linked to and assessed in P5, directly related to practical activities in the laboratory.

For P3, learners must describe how the environment may be microbiologically controlled and sampled for the presence of micro-organisms. Learners must explain the relevance of environmental control in pharmacy. This criterion could be linked to P5 and/or evidence may be obtained from the workplace.

P4 requires learners to describe the transmission of pathogenic micro-organisms including examples of named pathogens, their mode of transmission and disease caused. Learners should ensure that the pathogens chosen include examples of each type of micro-organism listed in the unit content. This criterion allows learners to investigate independently and to share their findings with other learners. Examples of the pathogens and diseases may be obtained from the workplace.

P5 requires learners to undertake the range of microbiological techniques through experiment and describe the methods used and report the results obtained. Learners should present their descriptions in a scientific way and produce a portfolio of work relating to practical exercises.

Merit

To achieve a merit grade, the learner must achieve all of the pass grade criteria **and** the five merit grade criteria. For M1, learners are required to explain the classification of bacteria with reference to the Gram stain and the reason why bacteria react differently to this stain. This criterion can be linked to M5 if Gram stain is included in the laboratory practical work.

For M2, learners must describe how to investigate in the laboratory the effect of environmental factors on the growth of micro-organisms. This criterion could be linked to M5 and undertaken as laboratory practical work.

M3 requires learners to explain the different types of disinfectant and antiseptic solutions and their mode of action. This criterion can be linked directly to work learners are undertaking in the laboratory.

For M4, learners must explain, with reference to a named infection or disease, the transmission of the pathogen and its control.

For M5, learners must undertake the range of microbiological techniques through experiment and describe the methods used and results obtained and discuss the results. Learners should present their descriptions in a scientific way and produce a portfolio of work related to the practical exercises.

Distinction

To achieve a distinction grade the learner must achieve all of the pass and merit grade criteria **and** the five distinction grade criteria. For D1, learners are required to describe the various cellular structures of micro-organisms and their function.

D2 requires learners to explain how an understanding of environmental factors affecting microbial growth may influence pharmaceutical products and processes. This criterion could be linked and assessed in D5 if directly linked to practical work in the laboratory.

D3 requires learners to explain the importance of the microbial control of the environment in various pharmaceutical procedures and processes. This criterion could be linked and assessed in D5 if directly linked to practical work in the laboratory.

D4 requires learners to explain, with reference to a number of named infections or diseases, details of the causative pathogen, transmission, disease symptoms, treatment and incidence.

For D5, learners must undertake the range of microbiological techniques through experiment and describe the methods used, results obtained, discussion and conclusion of the results and relevance to pharmacy. Learners should present their descriptions in a scientific way and produce a portfolio of work related to the practical exercises.

Links to National Occupational Standards, other BTEC units, other BTEC qualifications and other relevant units and qualifications

The learning outcomes associated with this unit are closely linked with *Unit 3: An Introduction to Action and Uses of Medicines, Unit 7: Pharmaceutics, Unit 11: Pharmacy Production* and *Unit 13: Scientific Method for Pharmacy Technicians*.

This unit has links to Level 3 NVQ in Pharmacy Services.

This unit presents opportunities to demonstrate key skills in application of number, communication, information and communication technology, improving own learning and performance, problem solving and working with others.

Essential resources

Facilities required for this unit include a laboratory suitable for undertaking practical experiments using micro-organisms, general equipment normally used in microbiological techniques including suitable light microscopes for the observation of micro-organisms, facilities for the production of microbiological media and its decontamination after use. Staff delivering this unit should be competent and experienced in microbiology and have an understanding of the relevance of microbiology in pharmacy. Ideally, they should have experience in pharmacy and have contact with the profession. Technical updating in microbiological aspects relating to pharmacy would be beneficial for staff delivering the unit.

Indicative reading for learners

Cappuccino J G and Sherman N — *Microbiology: a laboratory manual, Seventh Edition* (Pearson, 2004) ISBN 0321270061

Clegg C J — *Microbes in Action, First Edition* (John Murray, 2002) ISBN 0719575540

Denyer S P, Hodges N A and Gorman S P — *Hugo and Russell's Pharmaceutical Microbiology, Seventh Edition* (Blackwell, 2004) ISBN 0632064676

Greenwood D, Slack R C B and Peutherer J F — *Medical Microbiology, Sixteenth Edition* (Churchill Livingstone, 2002) ISBN 0443070776

Madigan M T, Martinko J M and Parker J — *Brock Biology of Microorganisms, Tenth Edition* (Pearson, 2003) ISBN 0132017849

Mannion K and Hudson T — *Microbes and Disease, Second Edition* (HarperCollins, 2001) ISBN 0003277429

Mims C et al — *Medical Microbiology, Third Edition* (Mosby, 2005) ISBN 0323035752

Key skills

Achievement of key skills is not a requirement of this qualification but it is encouraged. Suggestions of opportunities for the generation of Level 3 key skill evidence are given here. Tutors should check that learners have produced all the evidence required by part B of the key skills specifications when assessing this evidence. Learners may need to develop additional evidence elsewhere to fully meet the requirements of the key skills specifications.

Application of number Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• determining the number of bacterial cells in a population.	N3.1 Plan an activity and get relevant information from relevant sources. N3.2 Use this information to carry out multistage calculations to do with: a amounts or sizes b scales or proportion c handling statistics d using formulae. N3.3 Interpret the results of your calculations, present your findings and justify your methods.
Communication Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• describing a number of microbial diseases and their treatment.	C3.1a Take part in a group discussion. C3.1b Make a formal presentation of at least eight minutes using an image or other support material. C3.2 Read and synthesise information from **two** documents about the same subject. Each document must be a minimum of 1000 words long. C3.3 Write **two** different types of documents, each one giving different information about complex subjects. One document must be at least 1000 words long.

Information and communication technology Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• collecting information relating to microbial diseases and investigating supporting evidence for practical microbiological work.	ICT3.1 Search for information, using different sources, and multiple search criteria in at least one case. ICT3.2 Enter and develop the information and derive new information. ICT3.3 Present combined information such as text with image, text with number, image with number.
Improving own learning and performance Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• undertaking practical microbiological investigations in the laboratory.	LP3.1 Set targets using information from appropriate people and plan how these will be met. LP3.2 Take responsibility for your learning, using your plan to help meet targets and improve your performance. LP3.3 Review progress and establish evidence of your achievements.
Problem solving Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• describing methods used in microbiological laboratory experiments.	PS3.1 Explore a problem and identify different ways of tackling it.
Working with others Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• undertaking microbiological practical work in the laboratory.	WO3.1 Plan work with others. WO3.2 Seek to develop co-operation and check progress towards your agreed objectives. WO3.3 Review work with others and agree ways of improving collaborative work in the future.

Unit 10: Pharmacy Practice

NQF Level 3: BTEC National

Guided learning hours: 60

Unit abstract

This unit offers an opportunity to consolidate and build on *Unit 2: Pharmacy Law, Ethics and Practice* and *Unit 7: Pharmaceutics*. It develops a wider and more rounded view of the profession and working environment of pharmacy. Learners' interpersonal skills when dealing with patients and customers in a variety of contexts will be refined.

The unit should also enable learners to review their role within the healthcare sector and to understand how they function within that environment. One of the learning outcomes deals with first aid in some detail. It is anticipated that in conjunction with material from *Unit 8*: *Human Physiology for Pharmacy* learners could be assessed for a recognised first-aid certificate if they and their employers wish.

The unit will also enable the learner to understand the developing role of the pharmacy technician in expanding services to the public and how this works in concordance with local and national policies.

This unit provides some of the underpinning knowledge for those learners undertaking the Level 3 NVQ in Pharmacy Services and who are currently working towards achieving National Occupational Standards.

This unit presents opportunities to demonstrate the Level 3 key skill in communication.

Learning outcomes

On completion of this unit a learner should:

1 Understand the purpose of health promotion

2 Be able to undertake first-aid procedures

3 Know how to advise on the appropriate use of non-medicinal pharmaceutical products

4 Understand and be able to advise on the safe and effective supply and use of medicines within expanding pharmacy services.

Unit content

1 **Understand the purpose of health promotion**

Health promotion: purpose and aims of health promotion, methods used for the dissemination of health messages; national/regional/local targets for the health of the community, local campaigns; government policies and priorities; healthy lifestyle advice

Roles: the role of the technician and the pharmacist in health promotion

Information relating to services: diagnostic testing/family planning/pregnancy testing; personal health monitoring services/aids, blood and cholesterol testing, blood pressure monitoring, urine testing, provision of emergency hormonal contraception, self-help organisations relating to particular chronic conditions; service providers as well as equipment should be considered

Alternative therapies: positive aspects and possible dangers inherent in these therapies

Drug misuse: impact on the practice of pharmacy; drug misuse, its extent, local and national support organisations

2 **Be able to undertake first-aid procedures**

Aims of first aid: the legal responsibilities of the first aider

Communication and delegation: in emergencies

Assessment: of a casualty and prioritising treatment

Identifying hypoxia: its signs and symptoms and the subsequent care of the airway

Cardiopulmonary resuscitation: for adults

Resuscitation: the ABC

Care: of the unconscious casualty

Control of bleeding: both external and internal

Shock and assessing blood loss: of the casualty

Assessment: of burns, scalds and chemical injury

Minor injuries: to eyes, ears, minor abrasions and stings

Poisoning: both accidental and self-inflicted

Injury to connective tissue and bones: breaks, fractures, sprains and strains

Injuries: to the head, face and chest

Recognition and management of chronic conditions: such as diabetes, epilepsy, asthma and common heart conditions

Contents: of first-aid boxes and/or rooms

Lifting and handling: casualties safely

Regulations: record keeping and RIDDOR regulations

3 **Know how to advise on the appropriate use of non-medicinal pharmaceutical products**

Wound-dressing products: availability and features of an ideal wound dressing and features of commercial wound dressings; primary and secondary dressings; basic physiological mechanisms and external factors involved in wound healing

Unconventional methods to aid wound healing: maggot therapy; leeches; herbal remedies

Elastic hosiery: therapeutic use, measurement and fitting of elastic hosiery products currently on the market

Ostomies: reasons for use of urostomy, ileostomy and colostomy; care and maintenance and supply of ostomy products

Monitored dosage systems: the management of monitored dosage systems; relationship between pharmacies and residential/nursing homes; domiciliary delivery and collection services; storage of medicines in nursing and residential homes; national and local regulations and policies relating to supply for patients in care

Non-GP prescribing: its impact on pharmacy and the concept of 'seamless care'; patient group directions and its impact on pharmacy services; how medicines management has impacted on these services; supplementary and independent prescribing in pharmacy

The Drug Tariff: the relation between the regulations governing supply and pricing of appliances; allowable products in the NHS and endorsing of prescriptions

4 **Understand and be able to advise on the safe and effective supply and use of medicines within expanding pharmacy services**

Concordance issues: the reasons (social, psychological and physical), which result in poor concordance, using effective communication in order to achieve concordance with medicine regimens; safe and effective use of medicines; how the introduction of professional pharmacy services has contributed to improved medicines management

Referral of medicine administration and therapeutic problems: when to do so, to whom (the pharmacist, general practitioner, doctor or other prescriber)

Communication skills: identifying other's needs (patients and healthcare professionals); questioning, listening, explaining; sensitivity and confidentiality

Supporting learning in patients and healthcare professionals: differing learning styles; creating a suitable learning environment; instructional techniques and how to structure a demonstration

Pharmacy protocols: general sales list items; non-prescription medicines, pharmacy-only medicines (POM); responsibilities of the pharmacist and the technician in relation to patient safety and the need to supply, in relation to the needs of the employing organisation

Development of pharmacy services: services to patients with disabilities, and older people; working in areas outside the traditional pharmacy environment, eg lithium clinics, anticoagulant clinics, A and E departments, medical admissions; developing role of the pharmacy technician, eg ward-based technicians, accredited checking technicians, management of services; essential, enhanced and advanced services of the new pharmacy contract encompassing new services in line with new legislation and policies

Grading grid

In order to pass this unit, the evidence that the learner presents for assessment needs to demonstrate that they can meet all of the learning outcomes for the unit. The criteria for a pass grade describes the level of achievement required to pass this unit.

Grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P1 identify and describe a local, regional and national health promotion campaign aimed at the public, giving information discussing one of the following: health promotion, complementary therapies, drug misuse or the use of diagnostic aids	M1 explain the basis for the local, regional and national campaign	D1 explain the importance of providing information to the public and evaluate the media used to disseminate health messages locally, regionally and nationally
P2 carry out activities that cover first aid in the areas of cardiopulmonary resuscitation, managing an unconscious patient, care of the patient's airway and the ability to control bleeding using a variety of techniques, and describe first aiders' responsibilities		

Grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P3 describe the different wound-management products available, and undertake one of the following tasks: a) measure and correctly fit a patient for elastic hosiery b) gather information and develop an information pack suitable for a new ostomy patient to be used in a stoma clinic — choose either urostomy, ileostomy or colostomy, including information about care and maintenance of the appliance c) describe the different types of care homes that pharmacies undertake domiciliary visits to, identify the monitored dosage systems available	M3 a) categorise the different wound-management products according to their particular function and state how they are fit for purpose b) describe how to explain the use of your chosen appliance to a patient, highlighting the maintenance and possible dangers the patient may encounter c) discuss the underlying conditions that may result in an ostomy being required, giving examples d) explain how to establish whether the appliance is available through the NHS e) discuss how to set up a new home with a monitored dosage system. The plan must include information for staff about supply and storage of medicines	D3 explain the physiological mechanisms and external factors involved in wound healing and describe how wound-management products promote wound healing

Grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P4 a) advise patients on how to take their medicines in such a way to ensure compliance/concordance and safe use b) identify when to refer a problem with supply or sale and to whom c) choose one specialist topic from those studied, or one particular to your pharmacy. Make a presentation or demonstration to a group or individual on that aspect of practice.	M4 a) advise patients on how to take their medicines by using effective questioning, listening skills and a degree of empathy b) explain the need to refer a problem with supply or sale and to whom c) choose one specialist topic from those studied, or one particular to your pharmacy. Make a presentation or demonstration to a group or individual on that aspect of practice. Show that the recipients of the session are able to demonstrate knowledge or a skill they have acquired.	D4 a) confidently advise patients on how to take their medicines by using effective questioning, listening skills and a degree of empathy, and confirm the patient has understood b) choose one specialist topic from those studied, or one particular to your pharmacy. Make a presentation or demonstration to a group or individual on that aspect of practice. Show that the recipients of the session are able to demonstrate knowledge or a skill they have acquired. Evaluate the session.

Essential guidance for tutors

Delivery

It is vital that learning takes place in the context of pharmacy and the learner's working environment.

The material within this unit can be delivered through a variety of means including formal lectures, industrial visits, lectures from outside speakers, practical laboratory work and individual and group project work, as well as tutorials and small group seminars.

Learners should be encouraged to be independent and make full use of resources provided within their formal learning environment and their workplace. Since learners taking this unit will be working in some form of pharmacy for a registered pharmacist they will have access to many sources of information and advice when researching topics for projects.

Learning outcome 1 focuses the learner on the importance of health promotion in the role of the pharmacy technician. Health promotion lends itself to learner-centred learning where delivery is likely to be discussions, group work, presentations and research. Consideration should be given to allowing the learners opportunities to experience and handle a range of diagnostics aids.

Learning outcome 2 covers all aspects of first aid and centres are strongly advised to arrange for learners to study for a recognised first-aid certificate. Learning outcome 3 covers wound management and part of the first-aid certificate could cover the range of dressings and appliances used in first aid.

Learning outcome 3 also covers a range of appliances and services provided predominantly within the community sector. Learners should, if possible, be given the opportunity to see and handle these appliances. Knowledge of domiciliary services and services to residential and nursing homes could be gained by visiting local community pharmacies or pharmacists from the community could talk about their work. If it is not possible for learners within the hospital or industry sector to have 'hands-on' experience within the workplace, tutors could provide examples of different nursing or residential homes and using materials from visiting lecturers, learners could show they understand the principles of providing these services through pharmacies. It is also possible for learners within the hospital sector who have access to 'home care' services to observe or experience time in these departments to help them achieve this learning outcome.

Learning outcome 4 looks at safe and effective supply of medicines to patients. Delivery techniques would be a range of communication tasks such as group work, presentations, role plays and discussion seminars. This learning outcome links directly with the action and uses of medicines units (Units 3, 4, 5 and 6), *Unit 2: Pharmacy Law, Ethics and Practice*, *Unit 7: Pharmaceutics* and learning outcomes 1, 2 and 3 of this unit. Much of the communication of safe use of medicines can be assessed through these units. Learning outcome 4 also covers the skills pharmacy technicians need to demonstrate and pass on skills to peers, other healthcare professionals and their patients.

Assessment

In the grading grids we use the word discuss to mean: *to put forward both sides of an argument, identifying salient points and exploring solutions.*

A number of assessment activities may be used to demonstrate the learning outcomes. Much of the assessment activity will need to be of a practical nature using role plays, discussion groups and preparing visual/IT display materials. The emphasis within this unit is on learners being able to demonstrate their ability in a pharmacy practice setting where good communication skills are essential. Assessments may be undertaken on a group or individual basis, depending on activity. Some of the activities in the assessment guidance grid relating to skills are carried across the pass, merit and distinction criteria as these are the required levels at which a pharmacy technician should be operating.

Pass

To achieve a pass, learners will require significant support throughout from the tutor and their workplace. They must achieve the four pass criteria listed in the graded grid. For P1, they will be expected to understand and produce a health promotion leaflet that could relate to any of the other areas in learning outcome 1, ie health promotion or drug misuse, complementary medicines or diagnostic aids, and this enables the learner to combine two or more aspects of health promotion.

For P2, learners are required to demonstrate basic knowledge of first aid, assessed preferably through a recognised first-aid certificate.

For P3, learners must demonstrate knowledge of wound-management (wound-care) products available, and both knowledge and practice of either ostomy products, fitting elastic hosiery or mds use in care homes. This allows the tutor and learner some flexibility with how this part is assessed. It isn't always possible for learners to have experience in these areas. Learners could produce witness statements from their supervising pharmacist or technician to demonstrate their ability in the workplace.

For the ostomy products information learners could work in a group or individually to present an information pack for patients. This would also allow them to generate evidence for the NVQ and key skills linked with this learning outcome.

For the final part of P3, learners can produce evidence of experience of residential or nursing homes within the workplace. It is also possible for learners within the hospital sector who have access to 'home care' services to observe or experience time in these departments to help them achieve P3.

Learners need not undertake P4 as a discrete assessment although section c would lend itself to a 'training session' of some kind, which could tie in with the requirements for the Level 3 NVQ. Evidence for this could be generated through assessments set for other units, ie in the action and uses of medicines units (Units 3, 4, 5 and 6) the assessment may include advising patients about the side effects of certain medicines and learners could discuss how they would do this. This would generate good evidence for P4 and enable learners to meet criteria for part of two

Merit

For a merit, learners must achieve all the pass grade criteria and the four merit grade criteria. For M1, learners are required to evaluate the health promotion leaflet produced in comparison to genuine health promotion leaflets.

M3 requires learners to undertake a number of tasks. They will have to perform a comparison of wound-healing products and highlight the advantages and disadvantages of these. Learners have to discuss the use of either hosiery or stoma products and their maintenance and possible dangers to the patient. Evidence for P4, M4 and D4 can also be generated through this task. For the next part of M3 learners need to discuss the conditions where ostomy products are needed. The assessment could combine parts of other medicines use units and underlying bowel conditions or incontinence problems. The learner also needs to understand part of the Drug Tariff relating to restricted items, through either a list of questions or setting a number of case studies where they could ascertain whether a product is allowable on prescription. The final part of M3 requires the learner to write a plan in setting up a monitored dosage system (MDS) for a nursing or residential home and to provide information to staff within the home on the safe storage of medicines. There is plenty of opportunity for learners to base their work on the P3 work and demonstrate independent research and planning. Learners in a community pharmacy environment may have NVQ assessments which will fulfil some assessment criteria for this unit.

For M4, learners must be able to advise patients and effectively teach them and other healthcare professionals about the use of their medicines, both POM and non-prescription medicines products and appliances. They could undertake a number of role plays in a group and analyse each other's performance. Case studies could be set for learners to prepare and be assessed in an Objective Structured Clinical Examination (OSCE) situation. The case studies and tasks could be set to allow learners to identify situations where referral is necessary. Merit learners should be able to show some evidence of critical faculty and of being able to evaluate and select material uncovered during research. These learners should be able to plan and prioritise their work with minimal help and show good attention to detail.

Distinction

For a distinction grade, learners must achieve all of the pass and merit grade criteria and the four distinction grade criteria. For D1, learners must discuss in detail how giving information to the public is an essential part of pharmacy working within a healthcare team. It is also important for the learner to be able to discuss how policies and strategies devised by bodies, institutions and governments can disseminate information about public health and how this is a crucial element in health promotion in the UK.

For D3, learners are expected to discuss the mechanisms of wound healing and how the different products can promote or hinder wound healing. This could be linked with *Unit 8: Human Physiology for Pharmacy* covering the mechanisms of clotting and could be achieved by combining the assessments to meet both criteria.

To achieve D4 learners have to be able to confidently advise patients on the safe use of medicines. This works well with P4 and M4 in the context of allowing the learners to undertake role plays in advising on safe and effective use of medicines, including POM and non-prescription medicines, and to critically appraise each other's performance. Assessment of learners' performance will occur both within the workplace and through observing the role plays over a number of occasions. Learners will require minimal supervision from the tutor. They will show significant evidence

of independent working and a good level of skill when it comes to review and evaluation, both of research materials and of their own performance, particularly

when instructing patients or teaching other healthcare professionals. Learners should be able to monitor their own performance throughout a task, have good planning and organisational skills and show a significant level of attention to detail.

Links to National Occupational Standards, other BTEC units, other BTEC qualifications and other relevant units and qualifications

This unit links with *Unit 2: Pharmacy Law, Ethics and Practice, Unit 3: An Introduction to Action and Uses of Medicines, Unit 4: Cytotoxic, Endocrine and Nutritional Medicines, Unit 5: Central Nervous System, Eyes, ENT, Skin and Gynaecological Medicines, Unit 6: Cardio-respiratory and Genito-urinary Medicines, and Medicines Management, Unit 7: Pharmaceutics* and *Unit 9: Microbiology for Pharmacy* as well as the theoretical knowledge gained in *Unit 8: Human Physiology for Pharmacy*.

It provides the essential underpinning knowledge for Level 3 NVQ in Pharmacy Services.

This unit also provides opportunities to gather evidence towards the communication key skill.

If learners are interested in other first-aid qualifications Edexcel offers the following qualifications:

- Edexcel Level 2 BTEC Award in Paediatric First Aid
- IHCD First Person on Scene Awards.

Please see the Edexcel website for more details (www.edexcel.org.uk).

Essential resources

Staff delivering this unit should be experienced registered pharmacists or pharmacy technicians. This will ensure that they can provide the relevant knowledge and understanding needed in this unit. Sufficient library and workshop resources, including IT facilities with internet access, should be available for it is imperative that learners be working in a pharmacy for a registered pharmacist and have access to standard pharmacy text, eg BNF, Martindale, Drug Tariff, and appropriate pharmaceutical and trade journals, eg *Pharmaceutical Journal* or *Chemist and Druggist*.

Indicative reading for learners

Textbooks

Pharmacy textbooks are expensive. Books are usually written for degree or postgraduate-level learners. The following recommendations are materials from which tutors/lecturers can derive information rather than texts learners would use themselves.

Bond C — *Concordance — A Partnership in Medicine-Taking, First Edition* (Pharmaceutical Press, 2004) ISBN 0853695725

Edwards C and Stillman P — *Minor Illness or Major Disease? — Responding to symptoms in the pharmacy* (Pharmaceutical Press, 2000) ISBN 0853694478

Harman R — *Development and Control of Medicines and Medical Devices, First Edition* (Pharmaceutical Press, 2004) ISBN 0853695679

Harman R — *Handbook of Pharmacy Health Education, Second Edition* (Pharmaceutical Press, 2001) ISBN 0853694710

Harman R — *Patient Care in Community Practice — A handbook of non-medicinal healthcare, Second Edition* (Pharmaceutical Press, 1989) ISBN 0853692092

Kayne S — *Complementary Therapies for Pharmacists, First Edition* (Pharmaceutical Press, 2002) ISBN 0853694303

Mason P — *The Handbook of Pharmacy Healthcare* (Pharmaceutical Press, 2002) ISBN 0853695075

Stone P and Curtis S — *Pharmacy Practice, Third Edition* (Taylor & Francis, 2001) ISBN 0415271592

The British National Formulary (BMA and Pharmaceutical Press, current edition) ISBN 0853696683

Wills S — *Drugs of Abuse* (Pharmaceutical Press, 1997) ISBN 0853693528

Winfield A J and Richards R M E — *Pharmaceutical Practice, Second Edition* (Churchill Livingstone, 1998) ISBN 044305729X

Other useful publications

The Drug Tariff (HMSO) — available from www.tsoshop.co.uk

Key skills

Achievement of key skills is not a requirement of this qualification but it is encouraged. Suggestions of opportunities for the generation of Level 3 key skill evidence are given here. Tutors should check that learners have produced all the evidence required by part B of the key skills specifications when assessing this evidence. Learners may need to develop additional evidence elsewhere to fully meet the requirements of the key skills specifications.

Communication Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• taking part in group discussions about a complex subject, eg issues surrounding concordance and why patients don't take their medicines	C3.1a Take part in a group discussion.
• presenting the results and conclusions of an investigation into, eg the purpose of health promotion, planning an MDS system for a nursing home or stoma care	C3.1b Make a formal presentation of at least eight minutes using an image or other support material.
• using literature sources to develop familiarity with the technological methods to be used in an investigation into, eg the different MDS systems available on the market and their advantages and disadvantages	C3.2 Read and synthesise information from **two** documents about the same subject. Each document must be a minimum of 1000 words long.
• preparing the report of an investigation into, eg the different types of wound-healing products on the market and their relative merits.	C3.3 Write **two** different types of documents, each one giving different information about complex subjects. One document must be at least 1000 words long.

Unit 11: Pharmacy Production

NQF Level 3: BTEC National

Guided learning hours: 60

Unit abstract

Knowing how medicines are made is important for pharmacy technicians. This unit is designed to give learners an insight into the complex and varied aspects of the work involved in medicines manufacture. Technicians will study the manufacture of medicines to enable them to understand the concept of formulation, stability, shelf life, drug recall and the need to work in a systematic and auditable way according to devised procedures.

The purpose of this unit is to provide pharmacy technicians with the knowledge and skills they need to work in sterile/non-sterile pharmacy-manufacturing units, either in the hospital sector, in specialised pharmacy manufacturing units (PMU), or in the pharmaceutical industry. The knowledge and practical aspects will be of use to hospital technicians working in aseptic or centralised intravenous additive services (CIVAS). The underlying knowledge will be invaluable for community pharmacy technicians and will enable them to understand these areas of pharmacy work.

Pharmacy technicians need to understand the basic principles underlying batch production of pharmaceuticals and to perform aseptic manipulations. They need to have a grasp of the rules, regulations and legislation that govern the manufacture of medicines in the UK. They will also develop the skills necessary to work within a 'process' environment with due regard for health and safety, the environment and total quality management.

Learning outcomes

On completion of this unit a learner should:

1 Know about the rules and guidance for pharmaceutical manufacturers and how they apply in the workplace

2 Understand the application of legislation and documentation to the pharmaceutical manufacture of medicines, including the differences between preparation for named patients (dispensing) and licensed production for stock

3 Understand the role of quality control, quality assurance and Total Quality Management in the manufacture of all types of medicines and associated processes

4 Be able to perform some simple aseptic manipulations and explain the reasons behind precautions taken when preparing such medicines.

Unit content

1 **Know about the rules and guidance for pharmaceutical manufacturers and how they apply in the workplace**

Rules and guidance for pharmaceutical manufacturers — objectives and related legislation: understand and apply the EEC Directive on Good Manufacturing Practice for Human Medication, the Rules and Guidance for Pharmaceutical Manufacturers and Distributors and current appendices thereof (orange guide); Health and Safety at Work Act (HASAWA); Chemicals Hazard Information and Packaging Regulations (CHIP2); Control of Substances Hazardous to Health Regulations (COSHH); Aseptic Dispensing for NHS Patients Report; Quality Assurance of Aseptic Preparation Services EL(97)52

Practical application of the above rules and legislation: training of personnel, hygiene requirements; manufacturing equipment; its use and maintenance including planned preventative maintenance (PPM); manufacturing environment, essential requirements for sterile and non-sterile products (fabric and fittings of buildings, layout of sterile and non-sterile unit, general considerations as found in COSHH and HASAWA); Total Quality Management (TQM) and use of standard operating procedures (SOPs)

2 **Understand the application of legislation and documentation to the pharmaceutical manufacture of medicines, including the differences between preparation for named patients (dispensing) and licensed production for stock**

Pharmacy manufacturing: the application of legislation to documentation, working procedure manuals and SOPs; batch worksheets and associated documents; storage, distribution and transport of pharmaceutical products; packaging and labelling requirements for manufactured products; work practices in manufacturing units

Dispensing versus production for stock: the difference between named patient dispensing of extemporaneous; aseptic items and licensed manufacturing; how this is implemented in the workplace

Non-sterile, sterile and aseptic: methods employed in these areas (preparation of areas prior to work, changing requirements, SOPs, training records, sterilisation methods, cleaning, packaging, labelling, storage and delivery); maintenance of optimum storage conditions

Equipment: autoclaves; stills; mixing equipment; filling and sealing equipment; pumps; unidirectional air flow and isolator cabinets; filters and planned preventative maintenance systems for equipment

3 **Understand the role of quality control, quality assurance and Total Quality Management in the manufacture of all types of medicines and associated processes**

Quality control: contamination/impurities in pharmaceutical materials and formulated products; their sources and control; in-process testing; degradation of pharmaceutical products; chemical analysis of raw materials and final products; product sampling and reliability; sterility and pyrogen testing (why and how to perform them)

Quality assurance: standards in the dispensing/manufacturing process; master formulae and worksheets; official standards relating to containers; raw materials and finished products (quality and freedom from toxicity), product contamination by personnel; environment and personnel monitoring; labelling requirements for manufactured products; shelf life and accelerated stability testing; statutory requirements on quality of pharmaceutical raw materials and formulated products; packaging, labelling and quarantine of completed products; release procedures; batch reconciliation and product recall procedures

Total Quality Management (TQM): implementation of TQM; philosophy/operations management; process control; product definition (specifications for chemicals and packaging materials); sterilisation control, steriliser validation; record keeping; health and safety and COSHH reporting procedures; staff training; records, SOPs and work/procedure files; validation, competence validation, eg broth and process validation

The audit process: the basis of audit; EEC Directives; official guidance notes; ISO9000; Investors in People; internal and external audit; self-inspection; the role of the Medicines and Healthcare Products Regulatory Agency (MHRA)

4 **Be able to perform some simple aseptic manipulations and explain the reasons behind precautions taken when preparing such medicines**

Basic aseptic dispensing manipulations of a range of sterile products: different formulations, eg eye drops, injections; antibiotic reconstitutions; cytotoxic products; total parenteral nutrition (TPN); radiopharmaceutical products; CIVAS (Centralised Intravenous Additive Service) batches; materials for syringe drivers

Asepsis: the maintenance of sterility during the preparation of dispensed items; potential contaminants of aseptically dispensed items in terms of the environment, equipment, materials and personnel

Health and safety: COSHH and RIDDOR regulations and standard operating procedures; aseptic dispensing for NHS patients, the quality assurance of aseptic services; waste disposal, contamination risk and how to prevent it occurring; calculations, eg body surface area calculations and parenteral nutrition and radiopharmacy calculations

Precautions taken: waste-disposal regulations and procedures in relation to aseptic dispensing; the environment and equipment, eg unidirectional flow cabinets and isolators, raw materials and personnel; preparation prior to dispensing; pharmaceutical packaging and labelling regulations

Quality assurance: its role in the process of aseptic dispensing in terms of microbiological monitoring and process/personnel validation; documentation sterility testing; Section 10 exemptions under the Medicines Act; the differences between aseptic manufacturing and aseptic dispensing

Transport and secure storage arrangements: maintenance of cold chain, documentation associated with transport; special arrangements for cytotoxic materials; labelling and packaging requirements

Grading grid

In order to pass this unit, the evidence that the learner presents for assessment needs to demonstrate that they can meet all of the learning outcomes for the unit. The criteria for a pass grade describes the level of achievement required to pass this unit.

Grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P1 state the main rules and guidance governing the manufacture of pharmaceuticals	M1 illustrate with examples how the rules and guidance, and their component parts, governing the manufacture of pharmaceuticals are applied to an actual workplace situation	
P2 show how the legislation and its implications, eg documentations, training, environmental control, apply in the manufacture of a range of medicinal products	M2 differentiate between the differing areas of manufacture, sterile, non-sterile and aseptic, in terms of how the legislation and rules of manufacture apply	D2 formulate reasons for the differences that legislation and the rules, applied to pharmacy manufacturing, have on the conditions required for each type, eg sterile, non-sterile and aseptic, and consider the differences which arise between manufacturing and named patient dispensing and why these distinctions are important
P3 state why quality assurance is so important in pharmacy manufacturing	M3 examine a quality assurance system — either in your workplace or in a simulated one — and analyse the reasons for the way it has been implemented.	D3 construct an argument for why the concept of total quality management is vital for the manufacture of pharmaceuticals.

Grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P4 competently perform a range of aseptic manipulations either in the real working environment or as a simulation, taking all the necessary precautions.		

Essential guidance for tutors

Delivery

This unit should be delivered to ensure that learners have a comprehensive knowledge of all areas of pharmacy production and quality systems and a thorough understanding of the rules that govern pharmacy production.

The underpinning knowledge should allow interlinking between outcomes and enable learners to develop confidence and understanding of the concepts behind production and legislation.

The use of external specialist speakers from various areas of this branch of pharmacy would enhance the delivery of this unit — individuals may be contacted through local hospitals, universities and any nearby pharmaceutical manufacturers.

Learners should be able to use the underpinning knowledge to design environments and paperwork and should be able to understand why procedures are in place for the manufacture of high-quality medicines.

The tutor must ensure that learners know the differences between licensed and unlicensed units and production for stock and preparation for named patients.

Examples of medicines made in licensed units could be proprietary medicines, or in hospitals specialist items like syringes for epidural anaesthesia. Medicines made in unlicensed units could be total parenteral nutrition solutions, antibiotic reconstitutions, radiopharmaceutical injections. Tutors will find that lists of the medicines made will depend greatly on the kind of unit in which learners are working — they need to work with what falls within the learner's experience.

Ideally, it would be good for all learners at least to have seen a working production unit. This can either be a commercial facility or a hospital pharmacy manufacturing unit, whichever is in the locality for the student technician. Where this proves to be impossible due to geographical location or an access problem, a video/DVD presentation would be an acceptable alternative. Learners should be able to see a range of relevant paperwork of all types associated with manufacturing processes, either in college or in the workplace. On their visit it is expected that learners will see a range of pharmaceutical equipment used in the manufacture of medicines. Manufacturing facilities are very diverse and uncommon in certain parts of the UK so deliverers are going to need to help learners meet any deficits through a classroom theory basis. The best experience a learner can have is working in a pharmacy manufacturing unit or, failing that, in a CIVAS or aseptic dispensing unit of some description.

Most learners will be taking the Level 3 NVQ in Pharmacy Services alongside this programme of study. This unit has been designed to provide underpinning knowledge for two optional units of the NVQ, notably those associated with the *Manufacture and assembly of sterile and non-sterile batch medicinal products* and *Preparation of pharmaceutical products aseptically*.

Some learners undertaking these NVQ units in their workplace are likely to be able to fulfil any practical requirements for this unit at work. Deliverers may have to provide simulations for those learners for whom a real workplace experience is not possible.

There will also be opportunities to meet certain key skill requirements within this unit.

Assessment

A variety of assessments can be used for this unit. Ideally, practical components could be tied in with NVQ assessments within the learner's workplace, but simulations in a classroom are also acceptable, particularly where the development of practical skills will take time. Learners undertaking work by simulation are unlikely to achieve levels of competence one would expect in the workplace and consequently the P4 assessment criterion requires safe rather than competent performance.

An example of an assessment covering the entire range of grading criteria except P4 would be to require learners to design a production suite and/or a worksheet using their comprehensive knowledge and understanding of the relevant legislation and guidance.

Learners should understand the need for 'quality' and the processes involved in making a product that is fit for its intended use. They should also be able to explain the differences between dispensing for named patients and production of medicines for stock.

Learners should be able to deliver comprehensive evidence of understanding and be able to perform basic aseptic manipulations. Most evidence will be written or diagrammatic and may be computer generated, although multiple choice questions (MCQs) and short-answer questions will be necessary to cover areas not included in the assignments.

Classroom discussion and demonstration of equipment by a specialist may be useful.

All work needs to be organised and tidy to evidence the learner's understanding of the type of environments and the level of care required when medicines are made.

Pass

To achieve a pass, learners should be able to describe the essential features of the Rules and Guidance for Pharmaceutical Manufacturers and Distributors, and show that they understand how the legislative framework applies in the pharmacy workplace. Learners should also show a clear understanding of the importance of quality assurance in terms of medicines manufacture. Student technicians will also, at this level, be able to perform safely some basic aseptic manipulations and an understanding of why work is performed according to SOPs and guidelines. P1 could be achieved with a piece of written work, as could P2, although both could be demonstrated in more practical ways such as making a presentation, running a training session, designing a worksheet or a production unit. P3 could be built into all these activities.

P4 can most easily be demonstrated by real work produced in the learner's own workplace and tied up with NVQ Level 3 assessments and witness testimonies.

For learners who do not have access to such facilities at work, provision to allow them to do this simulated practice in a training environment could be just as useful, although it would be important for working conditions and quality assurance activities to mimic reality as far as possible. The range of manipulations and facilities pertaining to this kind of activity is likely, in colleges, to be much more limited than the expensive installations in the learner's workplace.

Merit

To achieve a merit, learners should be able to describe the essential features of the Rules and Guidance for Pharmaceutical Manufacturers and Distributors and explain why they are needed and important. They should be able to show that they understand how the legislative framework applies in the pharmacy workplace and give real examples of how this occurs. They should also show a clear understanding of the importance of quality assurance in terms of medicines manufacture and be able to explain how to carry out quality assurance activities. Student technicians will also, at this level, be able to perform some basic aseptic manipulations and an understanding of why work is performed according to SOPs and guidelines. To achieve the merit criteria one would expect learners to complete the same tasks as for the pass criteria, but one would look for evidence of deeper understanding of how this would apply in the workplace, either their own or one they have visited.

Distinction

To achieve a distinction, learners should have a good detailed knowledge of production design and processes, and be able to understand, explain and evaluate legislation and guidance.

Learners should be able to describe the essential features of the Rules and Guidance for Pharmaceutical Manufacturers and Distributors and explain why they are needed and important. Learners should be able to show that they understand how the legislative framework applies in the pharmacy workplace and give real examples of how this occurs. They should also show a clear understanding of the importance of quality assurance in terms of medicines manufacture and be able to explain how to carry out quality assurance activities. At distinction level learners should be able to appreciate some of the subtleties and distinctions that occur between licensed and non-licensed operations and be able to critically evaluate items like worksheets, SOPs and production processes.

Student technicians will also, at this level, show an understanding of why work is performed according to SOPs and guidelines.

Assessments at this level would be derived from the same tasks as for pass and merit, but one would be looking for the learner's ability to evaluate systems and processes and make judgements and be able to justify why procedures in manufacturing are conducted in the way they are. Evidence of analysis and creative thought should be evident at this level.

Links to National Occupational Standards, other BTEC units, other BTEC qualifications and other relevant units and qualifications

This unit links well with *Unit 9: Microbiology for Pharmacy*. Much of the learning in Unit 9 will have a direct impact on this unit and the two units could be delivered simultaneously or sequentially with benefit for both learners and deliverers. It would be possible to combine some assessment activities in these two units to good effect.

This unit is linked to *Unit 7: Pharmaceutics*, which covers the practical side of manufacturing, calculations, weights and measures, formulation and preparation.

It links in with the Level 3 NVQ in Pharmacy Services units as follows:

- Health and safety, Manage work and develop self, Manufacture and assemble sterile and non-sterile batch medicinal products and Prepare pharmaceutical products aseptically.

This unit also provides opportunities to gather evidence towards the key skill in communication.

Opportunities for practical assessment should be sought in the learner's work environment for the practical components of this unit.

Essential resources

Facilities required for this unit include a laboratory suitable for undertaking practical experiments using aseptic materials — in terms of colleges this would equate with a laboratory in which practical microbiology lessons can be carried out.

Some deliverers of this unit may have links with universities running pharmacy degree courses where better aseptic facilities are to be had; others may have links with employers who may be prepared to donate redundant equipment to the centre. Such initiatives which enhance the learner's experience while not essential are to be encouraged.

Staff delivering this unit should be competent and experienced in pharmaceutical production and aseptic dispensing. Ideally, they should have contact with the profession, in particular with the pharmaceutical industry or with a manufacturing unit in a hospital. Where this is not the case, the use of outside speakers and guest lecturers in the specialist area is important. Technical updating in legal and practical aspects relating to pharmacy would be beneficial for staff delivering the unit.

A visit to a working production unit and/or aseptic dispensing unit, either commercial or within the hospital service, will be useful where possible.

Demonstrations of equipment by specialists would be useful.

Presentations by speakers such as quality control analysts, production managers and specialists in cytotoxic dispensing, total parenteral nutrition or radiopharmacy would be an asset to delivery.

Indicative reading for learners

Textbooks

Pharmacy textbooks are expensive. It is expected that tutors would provide the bulk of reading material for their learners in the form of notes. Class copies of the following texts should be available for learners to consult as they work.

Barnett H L and Hunter B B — *Illustrated Genera of Imperfect Fungi* (Prentice Hall, 1987) ISBN 0023063955

Beaney A M — *Quality Assurance of Aseptic Preparation Services* (Pharmaceutical Press, 2005) ISBN 0853694877

Collett D M and Aulton M E — *Pharmaceutical Practice* (Churchill Livingstone, 1990) ISBN 0443036446

Denyer S P, Hodges N A and Gorman S P — *Hugo and Russell's Pharmaceutical Microbiology, Seventh Edition* (Blackwell, 2004) ISBN 0632064676

Lund W — *The Pharmaceutical Codex, Twelfth Edition* (The Pharmaceutical Press, 1994) ISBN 0853692904

Medicines Control Agency — *Rules and Guidance for Pharmaceutical Manufacturers and Distributors* (The Stationery Office, 2002) ISBN 0113225598

Winfield A J and Richards R M E — *Pharmaceutical Practice, Third Edition* (Churchill Livingstone, 2003) ISBN 044307206X

Key skills

Achievement of key skills is not a requirement of this qualification but it is encouraged. Suggestions of opportunities for the generation of Level 3 key skill evidence are given here. Tutors should check that learners have produced all the evidence required by part B of the key skills specifications when assessing this evidence. Learners may need to develop additional evidence elsewhere to fully meet the requirements of the key skills specifications.

Communication Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• taking part in group discussions about a complex subject such as TQM in pharmacy production	C3.1a Take part in a group discussion.
• presenting the results and conclusions of an investigation about a complex subject, eg microbiological monitoring of a clean room	C3.1b Make a formal presentation of at least eight minutes using an image or other support material.
• using literature sources to develop familiarity with the technological methods to be used in an investigation — using *The Orange Guide* as a tool in an assignment.	C3.2 Read and synthesise information from **two** documents about the same subject. Each document must be a minimum of 1000 words long.

Unit 12: Chemistry for Pharmacy

NQF Level 3: BTEC National

Guided learning hours: 60

Unit abstract

The aim of this unit is for learners to develop knowledge of the important concepts of chemistry applicable to pharmacy. Chemistry is the main science from which the profession of pharmacy developed. An underlying knowledge of chemistry is essential for the everyday understanding of many pharmaceutical principles. Concepts such as stability of medicines, pharmacological actions of medicines, quality control of raw materials and preservation of pharmaceuticals all have a fundamental chemical basis.

On completing the unit, learners will have acquired both the practical skills and the theoretical knowledge that will provide a sound basis for understanding the chemistry they need for pharmacy.

The fundamental concepts studied in this unit are most usefully developed when studied in conjunction with *Unit 1*: *Scientific Principles for Pharmacy* and will provide an excellent foundation for those learners wishing to develop an understanding of chemistry as a fundamental of pharmaceutical science.

This unit presents opportunities to demonstrate key skills at Level 3 in application of number, communication, information and communication technology, improving own learning and performance and problem solving.

Learning outcomes

On completion of this unit a learner should:

1 Understand the importance of chemistry and its relationship to pharmacy

2 Know the basic principles of physical chemistry

3 Understand the properties of organic biochemicals and xenochemicals

4 Understand the nature and use of natural products in medicine.

Unit content

1 **Understand the importance of chemistry and its relationship to pharmacy**

The chemical nature of drugs: basic chemical concepts such as the states of matter, chemistry and its role in society, the importance of chemistry to drugs and medicine development

Drugs and medicines: an introduction to the concept of the distinction between drugs and medicines; drugs being chemical materials unprepared for medicinal use, eg aspirin powder, medicines being the final complete form, eg an aspirin tablet

Sources of drugs: where; concept of natural and synthetic drug agents; serendipitous discovery of active drugs, eg Fleming's discovery of penicillin

'Non-drug' chemicals: many chemicals are used in formulating medicines that are not active drugs agents, eg solvents (extraction and purification, glidants and lubricants (tablet manufacture) and fillers; examples of useful chemicals, eg lactose, alcohols, magnesium stearate

2 **Know the basic principles of physical chemistry**

Further study of units: common units used in pharmaceutical science; SI units, eg in the expression of mass, volume, concentration, density, pressure; use of Greek symbols in expression of small quantities of substances, eg mg (milligram), μg (microgram), ηg (nanogram)

Solutions: the concept of solutions and dissolution; pharmaceutical vehicles and solvents; various expressions of concentration referring to pharmaceutical products; use of co-solvents; calculations involving solubility of pharmaceuticals

pH: description of acids and bases; common laboratory acids and bases; pharmaceutical examples of acids and bases; pH scale; indicators, pH meter and measurement of pH; pH of body fluids and pharmaceutical preparations

Salts and salt solutions: preparation of simple salts; neutralisation reactions; isotonicity and body fluids; recognition of importance of drugs as salts; sodium chloride and its pharmaceutical use (fluid replacement therapy); chemical aspects of intravenous fluids, eg chemical incompatibilities

3 **Understand the properties of organic biochemicals and xenochemicals**

Hydrocarbons: bonding in organic compounds; simple covalent bonding; molecular formulae; structural formulae; displayed formulae; structural isomers; homologous series; electro-negativity and polar bonding

Functional groups and their properties: alkanes; alkenes; benzene and other aromatic compounds; halogenoalkanes; alcohols; aldehydes; ketones; carboxylic acids and their derivations; amines; ubiquity of carbon compounds; carbon's unique properties as an element

Organic biochemicals: food groups, eg carbohydrate, fats, proteins and vitamins; chemical properties of carbohydrate; fats and proteins; enzymes and co-enzymes

Xenochemicals: drugs as organic substances foreign to the body; examples of drugs or families of drugs that are organic chemicals; further functional groups; relationship between chemical features of drug agents of a given family and pharmacological activity, eg beta blockers, opiates, ACE inhibitors

4 **Understand the nature and use of natural products in medicine**

Natural products: introduction to natural products; plant families that are traditionally associated with herbal medicines, eg foxglove (*Digitalis sp.*), willow (*Salix sp.*), liquorice, garlic and the drug agents that are derived from them

Chemical properties of natural products: many natural products with pharmacological properties may be grouped into chemical families, eg the essential oils (terpenes) and the alkaloids (strychnine)

Chemistry of specific products: an investigation into the chemistry, actions and uses of particular herbal product or plant family; theoretical and/or practical investigation of a specific plant and plant group

Natural is best?: are herbal products safe or safer than conventional medicines? do non-active plant chemicals play a role in improving the activity of an active drug (synergy), eg is digoxin or a complete extract from the foxglove more effective?; methods of separation, eg chromatography; introduction to the concept of British Pharmacopoeia standards for natural and synthetic drug agents; safety and quality of products and markers for chemical purity, eg melting point and instrumental analysis such as IR, UV spectroscopy and NMR

Grading grid

In order to pass this unit, the evidence that the learner presents for assessment needs to demonstrate that they can meet all of the learning outcomes for the unit. The criteria for a pass grade describes the level of achievement required to pass this unit.

Grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P1 list some commonly used medicines in pharmacy, indicate which are the active drug ingredients/chemicals and which are the non-active ingredients/ chemicals; include information about the use of the medicine in pharmacy and provide information about the sources of the active ingredients/chemicals	M1 provide information on the chemical nature and the sources of the active drug ingredients and show what the role of the non-active ingredients is within each medicine	D1 investigate the chemical nature and the sources of the active drug ingredients and describe the role of the active and non-active ingredients within each medicine
P2 recall common scientific units used in pharmacy	M2 use correctly specified units when carrying out calculations involving solubility of pharmaceuticals	
P3 describe different solutions used in pharmacy	M3 describe the use of different solutions used in pharmacy	D3 compare the use of different solutions used in pharmacy
P4 list common pharmaceutical examples of acids and bases	M4 list the useful applications of the pH scale to pharmacy and medicine	D4 describe the useful applications of the pH scale to pharmacy and medicine
P5 describe the importance of drugs as salts	M5 describe the preparation of simple salts and the use of salts in medicine	D5 explain the concept of isotonicity

Grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P6 list relevant examples of organic biochemicals and xenochemicals	M6 explain the functions/uses of relevant examples of biochemicals and xenochemicals	D6 explain that the nature of a chemical's pharmacological activity is governed by its chemical properties
P7 choose a medicine, either a licensed pharmaceutical or a herbal product, with the active ingredient being a plant or animal-based 'natural' product, and describe the medicinal function and source of the 'natural' ingredient.	M7 show which product group the natural product is derived from, eg alkaloid, and deduce what the chemical properties of the 'natural' substance are likely to be.	D7 explain the nature of the chemical's pharmacological activity from its chemical properties and predict what the likely advantages and disadvantages of the 'natural' product are likely to be.

Essential guidance for tutors

Delivery

In this unit emphasis should be placed on the relevance of chemistry to pharmacy. The use of pharmaceutically relevant examples is important as chemistry is often difficult to relate to everyday practice.

Teaching will often be tutor led, and the key to learner-centred learning success will be through the practical opportunities that chemistry presents. Learners should be encouraged to make and dilute solutions, measure pH and relate any knowledge of diffusion and osmosis gained elsewhere in understanding the concept of isotonicity. The 'natural product' concept is introduced and this can be taught using a variety of strategies including learner-led discussions, mini–dissertations and practicals involving microscopy and extraction of actives from raw materials.

Calculations are an important part of this unit. Dilution, molar calculations etc form a basis of pharmaceutics (formulation studies) and basic skills should be developed within this unit so that each learner grasps basic concepts.

Molecular modelling, computer modelling and viewing of organic structures are essential for understanding organic and biochemistry and should be incorporated wherever possible.

Assessment

Assessment should probably take place by formal means. Learners need to demonstrate an acquisition of the fundamental basis of chemistry as well as a very good grounding in the mathematics involved in chemistry calculations. Group work or more formal didactic means may be used for delivery but individual understanding of calculations, properties of chemicals and the basis of chemical science needs to be clearly demonstrated.

Integrated practical and written assignments, internet-based searches and formal assessment of calculations will form the cornerstone of assessment and each learner's strengths and weaknesses will be monitored.

More-able learners will show degrees of lateral thinking and be able to relate chemistry to aspects of their everyday work and other parts of the course. Merit and distinction learners will also be able to explain and compare the properties of the chemicals. Studies and assignment should be set allowing them the opportunity to do so.

'Natural products' were the source of the bulk of medicines used historically. Today most are synthesised in the laboratory. However, there has been a resurgence of interest in the use of herbal and other 'natural' products for medicinal purposes. This is an area of some controversy in pharmaceutical circles and learners should be encouraged to air their views on the matter (provided they have performed the appropriate research groundwork).

Pass

The learner should be able to understand the basic principles of physical chemistry, organic biochemistry and the nature and use of natural products in medicine and be able to explain the importance of chemistry and its relationship to pharmacy.

Merit

The learner should be able to report fully, with some guidance, the nature of a medicine, using correct pharmaceutical terminology and conventions, including solubility in terms of calculations and solutions used. The learner should be familiar with the pH scale and describe the use and preparation of simple salts and the functions of biochemicals, xenochemicals and one plant product group.

Distinction

The learner should be able to independently investigate the chemical nature and function of a medicine and a natural product, including solubility calculations and the concept of isotonicity, and be able to relate the pharmacological action to the chemical properties of the substances.

Links to National Occupational Standards, other BTEC units, other BTEC qualifications and other relevant units and qualifications

Chemistry has a fundamental link with most of the scientific-based units. Connection and relation to other units and the learners' everyday working environments should be made wherever possible.

Essential resources

Learners should have access to laboratory facilities suitable for teaching chemistry, access to the internet, molecular modelling equipment, eg ball and stick modelling, and a library containing a range of chemistry texts.

Indicative reading for learners

Textbooks

Cann P and Hughes P — *Chemistry for Advanced Level* (John Murray, 2002) ISBN 071958602X

Clugston M and Flemming R — *Advanced Chemistry* (Oxford University Press, 2000) ISBN 0199146330

Evans W C — *Trease and Evans Pharmacognosy, Fifteenth Edition* (Saunders, 2001) ISBN 0702026174

Rho J P and Lovie S G (Editors) — *Handbook of Pharmaceutical Biotechnology* (Pharmaceutical Products, 2002) ISBN 0789001527

Key skills

Achievement of key skills is not a requirement of this qualification but it is encouraged. Suggestions of opportunities for the generation of Level 3 key skill evidence are given here. Tutors should check that learners have produced all the evidence required by part B of the key skills specifications when assessing this evidence. Learners may need to develop additional evidence elsewhere to fully meet the requirements of the key skills specifications.

Application of number Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• selecting and using appropriate methods to process experimental and secondary data obtained during an investigation • carrying out molar and dilution calculations.	N3.2 Use this information to carry out multistage calculations to do with: a amounts or sizes b scales or proportion c handling statistics d using formulae.
Communication Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• taking part in group discussions (a complex subject can be included such as 'nature is best')	C3.1a Take part in a group discussion.
• presenting the results and conclusions of an investigation into a complex subject	C3.1b Make a formal presentation of at least eight minutes using an image or other support material.
• using literature sources to develop familiarity with the technological methods to be used in an investigation	C3.2 Read and synthesise information from **two** documents about the same subject. Each document must be a minimum of 1000 words long.
• preparing the report of an investigation.	C3.3 Write **two** different types of documents, each one giving different information about complex subjects. One document must be at least 1000 words long.

Information and communication technology Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• planning and carrying out a search for experimental methods appropriate to an investigation to be undertaken	ICT3.1 Search for information, using different sources, and multiple search criteria in at least one case.
• preparing the report of an investigation.	ICT3.2 Enter and develop the information and derive new information.
Improving own learning and performance Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• developing the plan for an investigation and consulting and gaining the agreement of their tutor or workplace supervisor	LP3.1 Set targets using information from appropriate people and plan how these will be met.
• implementing the plan and modifying it in accordance with results obtained and constraints and problems encountered	LP3.2 Take responsibility for your learning, using your plan to help meet targets and improve your performance.
• evaluating the plan at frequent intervals and refining it in accordance with the conclusions reached.	LP3.3 Review progress and establish evidence of achievements.
Problem solving Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• formulating the plan for a chemistry investigation and identifying and evaluating alternative methods of approach to an investigation, and deciding on the approach to be adopted	PS3.1 Explore a problem and identify different ways of tackling it.
• developing the plan for an investigation, using the preferred option	PS3.2 Plan and implement at least one way of solving the problem.

Problem solving Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• evaluating the plan continuously during an investigation, on the basis of the results and conclusions produced.	PS3.3 Check if the problem has been solved and review your approach to problem solving.

Unit 13: Scientific Method for Pharmacy Technicians

NQF Level 3: BTEC National

Guided learning hours: 60

Unit abstract

Pharmacy technicians, once they are qualified and registered, will find themselves getting involved in myriad scientific investigations. These might be experiments at work in a production unit, quality assurance work of a microbiological nature in a QC (quality control) laboratory, clinical audit carried out in wards or clinics, or an audit about some aspect of pharmacy practice within their workplace. This unit promotes the skills required to develop and write standard operating procedures and to carry out wider scientific investigations in the workplace. The format of this unit is generic so that the skills involved can be developed in the context of any area of pharmacy practice. This unit may be particularly useful for those learners wishing to demonstrate that they can manage their time and achieve set objectives or deadlines.

The investigations required for this unit should be designed to be applied to a pharmacy technician's workplace. They should involve practical experimental work as well as making literature searches and presenting the results of investigations.

To meet the learning outcomes of this unit, learners are required to plan their work, to carry out practical work safely and accurately, to identify and use sources of information effectively, to process data precisely and to present their work in a coherent, concise and rigorous form. The specialist skills required by learners will vary widely across different areas of pharmacy. The investigations contributing to the assessment of this unit may also contribute to achieving learning outcomes in other units in the programme.

Learners will benefit from studying this unit towards the end of their first year of study or in their second year of study after they have gained an appreciation of the pharmacy sector and developed relevant pharmacy technician skills.

Learning outcomes

On completion of this unit a learner should:

1 Be able to plan scientific investigations of a pharmaceutical nature

2 Be able to undertake a scientific investigation of a pharmaceutical nature

3 Know how to analyse information and data resulting from the investigation

4 Be able to report the results or findings of scientific/pharmaceutical investigations.

Unit content

1 **Be able to plan scientific investigations of a pharmaceutical nature**

Nature of the investigation: experimental research, eg practical, laboratory, clinical, supply, workshop, audit etc; literature-based research

Information gathering: how to decide what information will be relevant and where it is found, eg texts, journals, magazines, newspapers, CD ROMs, the internet

Principles of design of investigations: experimental design and controls; literature-based investigation; stating the objectives; formulating a hypothesis

Setting objectives: SMART (specific, measurable, achievable, relevant, time bound)

Hazards in practical work: assessment and elimination of risk

Sources of error: in experimental work; in secondary sources

Assessment of error: accuracy and precision in experimental work; validity of literature sources

2 **Be able to undertake a scientific investigation of a pharmaceutical nature**

Information from primary and/or secondary sources: how to use information sources; how to extract information relevant to the investigation; recording of sources used (referencing systems); assessment of reliability and validity of information

Health and safety: safety regulations; risk analysis; safe working practice; SOP (standard operating procedures); COSHH (Control of Substances Hazardous to Health)

Experimental techniques: assembly of equipment and materials; health and safety procedures; manipulative skills; techniques for making measurements; data gathering in audit; observational skills; recording results; accuracy; precision and integrity of results

3 **Know how to analyse information and data resulting from the investigation**

Retrieved information: assessment of relevance to the investigation; summarising of information; use of information to support experimental work

Practical data: organisation of data; class intervals and tallying; methods of data processing and analysis, eg mean, median, mode, standard deviation, correlation/relationship between two variables; significant figures in numerical data; units of experimental quantities; methods of assessment of experimental accuracy and precision; collection of biological data and clinical information; quantitative and qualitative data used in audit situations

Validation of method and results: fitness for purpose of methods used; repeatability; sources and magnitudes of error in readings

4 **Be able to report the results or findings of scientific/pharmaceutical investigations**

Scientific reports: structure and format; use of correct and precise scientific language; reference to and compilation of bibliography

Scientific evaluation: evaluation of results; drawing conclusions from scientific principles; experimental, practical and literature investigations; evaluation of the achievement of objectives

Standard operating procedures: writing and formatting of textual instructions so that others can replicate methods; work instructions (HASAWA and COSHH); governance considerations

Data presentation: methods of data presentation (textual, numerical, graphical)

Grading grid

In order to pass this unit, the evidence that the learner presents for assessment needs to demonstrate that they can meet all of the learning outcomes for the unit. The criteria for a pass grade describes the level of achievement required to pass this unit.

Grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P1 use given information and methods to determine objectives for the investigation and devise an outline plan	M1 with limited guidance investigate the problem, research possible methods and present a detailed plan of the investigation based on clear objectives	D1 independently carry out an analysis of the problem to be addressed and present a detailed plan of the investigation based on SMART objectives
P2 use given methods to carry out the planned investigation and collect information/data correctly, safely and honestly	M2 with limited guidance carry out selected methods, recording relevant information/data at appropriate intervals with the required precision and honesty in accordance with the plan	D2 carry out the plan independently, review progress at each stage and repeating measurements or revising the method as appropriate to provide the required accurate and precise and honest information and/or data
P3 use given methods and process correctly the information and data obtained from the experimental work and from other sources	M3 draw valid conclusions from the evaluation and analysis of the information and data obtained	D3 validate the methods used and the results obtained, showing clearly the extent to which the objectives were met

Grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P4 present the results of the investigation with conclusions as a professional-looking report, using correct scientific language.	M4 explain how the investigation is based on the application of scientific principles.	D4 explain how their investigation addressed the underlying scientific principles.

Essential guidance for tutors

Delivery

This unit requires learners to engage in meaningful investigative work, for which they have been adequately prepared. Learners will benefit from this unit towards the end of their first year of study or in the second year of study after they have gained an appreciation of the pharmacy sector and developed relevant technical skills. The context could be the development of standard operating procedures for use by technicians in the workplace. An alternative might be to use a workplace clinical audit as the subject of an investigation. The achievement of the outcomes requires the development of a variety of process skills, and of the practical skills appropriate to the applied science route. Within a college setting a specific investigation can be designed for this unit or this unit can be integrated with other core or specialist units: *Unit 1: Scientific Principles for Pharmacy*, *Unit 9: Microbiology for Pharmacy* and *Unit 12: Chemistry for Pharmacy* would lend themselves well to this linked approach.

The work done in this unit can be covered in the context of other core or specialist units on this course.

Skills in identifying and using information sources are essential for this unit. These skills should be developed through structured exercises in which the learner becomes familiar with relevant and useful sources. Also, the learner will be able to extract, summarise and present relevant information to specific investigations. Some effort needs to be put into developing critical skills in pharmacy technicians so they can evaluate the mass of information available to them and decide what is useful and what is not.

It is essential that learners carry out investigative work using a logical framework, which is transferable to a wide range of investigations.

This unit will provide much evidence for use with learners undertaking the Level 3 NVQ in Pharmacy Services, particularly in terms of managing their time and meeting deadlines.

Assessment

Generic guidance on assessment

All learners are entitled to initial guidance in planning their work, but the level of assistance required should be taken into account when their work is assessed. In the grading grid, reference is made to learners working with 'limited guidance' and 'independently'. When marking the learners' work, assessors should apply the following guidelines:

- '*Limited guidance*': the tutor supports the learner initially in the choice of topic for investigation. Thereafter, the tutor reacts to questions from the learner and suggests a range of ideas that the learner acts upon. The learner frequently checks matters of detail. The tutor needs to assist in some aspects of the work.

This level of support restricts the learner's mark to a pass or a merit grade, irrespective of the quality of the evidence.

- '*Independently*': the tutor supports the learner initially in the choice of topic for the investigation or task. Thereafter, the tutor occasionally assists the learner, and only when asked, but monitors progress throughout. This level of support gives access to all three mark bands: pass, merit and distinction.

Unit-specific guidance on assessment

This unit requires learners to plan, carry out and report on an investigation appropriate to their scientific interests or employment in pharmacy. A wide range of topics will be appropriate to developing and delivering their evidence. However, the outcomes require the topics selected to involve meaningful scientific enquiry requiring some planning by the learner. **A series of standard exercises set and controlled by the tutor will not meet the outcomes of this unit.** Tutors may need to negotiate with the learner's workplace since there may be projects available there for the learner to use.

The topics for investigation can be set by the tutor or selected by the learner, but must involve the application of scientific principles appropriate to the learner's programme of study and work environment. Topics for investigation will ideally have a clear vocational relevance and significance. The learning outcomes may be met by individual or group investigations. In the latter case, assessors must document each learner's contribution to the investigation and provide appropriate authentication of the evidence presented.

Much of the evidence for this unit will be generated by practical work. The quality of each learner's work will be only partially reflected in the final report. It is important that the assessor observes all phases of the work and records each learner's performance. Witness testimonies and observed assessments in the workplace as part of the Level 3 NVQ in Pharmacy Services will be of value too. These records should be included in the learner's evidence as authentication of performance and to support the grade recommended for the work. The assessor's judgement must reflect the overall quality of the work and should not be overly influenced by the media through which it is reported.

All grades require the learner to undertake some initial planning before the commencement of practical work. This requires the learner to consider carefully what is involved in the work and how they are to approach the constituent tasks. The initial plan must be submitted and agreed before any practical work is started. However, an action plan should not be a static document. It may need to be revised in reaction to progress made or results obtained. Learners should be given the opportunity to review their plans at frequent intervals and to revise them as appropriate. Each revision should be clearly dated and recorded by the assessor. It is likely that learners who aspire to merit or distinction grades will review their action plans more frequently and in more detail than the pass learner. Distinction learners will work more independently from the assessor and their changes to plans will be more a matter of report than asking for help.

Pass

To achieve a pass, learners will require significant support from the tutor or workplace mentor throughout. Learners will work mainly from supplied methods, but must provide evidence of an initial appreciation of the basis of the investigation through the initial action plan, in which they identify clearly why the work is to be carried out and which outcomes should be achieved.

The work must be reported in accordance with scientific conventions. The written report will be the normal method of reporting. There is an expectation that this being a pharmaceutical environment the report will be presented in a professional and neat and tidy manner as far as the learner is able within the resources available to them. However, scientific work may also be reported orally or through electronic media. Whatever medium is chosen, the learner must communicate the conduct of the work and the results achieved, the extent to which their objectives were met and how the work addressed the appropriate scientific principles. The work must be documented sufficiently well to enable the assessment and grading to be verified. Where reporting is carried out orally, evidence must include the learner's preparatory materials and an assessor commentary. The pass learner does not need to access secondary sources of information, other than those provided or recommended by the tutor.

Merit

The merit learner must show a more independent and analytical approach to their work. They must research and analyse the topic to be investigated before devising the action plan, which should include a clear formulation of the objectives of the work. They may use the tutor as a resource during the preparation of the plan; such consultation should not disqualify the learner from the merit grade, providing that they have clearly appreciated the background to the topic and the dimensions of the investigation to be carried out. The plan should consider the nature of the information and data to be obtained, and set realistic and achievable targets for the accuracy of the work.

To achieve a merit, learners must show, during the practical work, an appreciation of errors in measurements and, where possible, take the appropriate steps to minimise them. The information and data obtained should be processed in appropriate ways to produce valid conclusions to the work. They must show, throughout the work and in the final report, a clear appreciation of the principles underlying the investigation. Some use of appropriate secondary sources of information will be required in the initial research on the topic; the assessor should monitor this closely to ensure that the learner does not waste time by pursuing information at a level too high for the expectations of a National-level qualification.

Distinction

To achieve a distinction, learners must show the ability to work with the minimum of supervision at all stages. This could involve selection of the topic to be investigated, but study of tutor-generated topics should not disqualify them from this grade. The plan should be based on a detailed analysis of the background to the topic, including the use of secondary sources of information. The plan must be clearly structured, have identified monitoring points and set clear criteria for the success of the work. The assessor should scrutinise the plan before commencement of the work, to ensure that the overall objectives are achievable. Advice given to improve the plan in areas where the learner could not reasonably be expected to be proficient should not disqualify them from this grade. The progress of the work should be monitored as planned and any required revisions made. At this grade objectives should be specific meaningful achievable realistic and timely (SMART).

The distinction learner must carry out a detailed and independent evaluation of the work undertaken. This evaluation must include the conduct of each phase of the work, the achievement or otherwise of the objectives formulated in the plan and the application of scientific principles throughout the work. It is not necessary for all the objectives to be met to achieve the distinction grade, providing that the learner can show an appreciation of the reasons for any failures and what changes would be required to achieve success. The distinction learner must demonstrate appropriate uses of secondary sources of information and show clearly how each recorded source helped in the conduct of the work.

Links to National Occupational Standards, other BTEC units, other BTEC qualifications and other relevant units and qualifications

This unit may be linked with many other units in the programme including *Unit 1*: *Scientific Principles for Pharmacy* and *Unit 9*: *Microbiology for Pharmacy*. Centres may devise an investigation purely to meet the requirements of this unit. This unit is designed for integration into learners' workplace activities.

Achievement of the learning outcomes requires the development and use of skills in identifying, accessing and using information from a variety of sources. It also requires the development of practical skills appropriate to the programme area. These practical skills will be essential to succeed in other units in the programme. The unit also requires generic numerical and data-handling skills, including the use of information and communication technology, and planning, reporting and communicating skills. These generic skills will also be required in other parts of the programme and may form an appropriate vehicle to demonstrate key skills.

This unit presents opportunities to demonstrate key skills at Level 3 in application of number, communication, information and communication technology, improving own learning and performance and problem solving. This unit provides underpinning knowledge for the Level 3 NVQ in Pharmacy Services.

Essential resources

Learners will need access to appropriate laboratory facilities (chemical and/or biological), and to library and information and communication technology resources.

Indicative reading for learners

It is unlikely that any one text will cover the content of this unit in a manner appropriate to all learners. Learners should be referred to texts that are devoted to the practical aspects of their chosen applied route.

Key skills

Achievement of key skills is not a requirement of this qualification but it is encouraged. Suggestions of opportunities for the generation of Level 3 key skill evidence are given here. Tutors should check that learners have produced all the evidence required by part B of the key skills specifications when assessing this evidence. Learners may need to develop additional evidence elsewhere to fully meet the requirements of the key skills specifications.

Application of number Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• acquiring and interpreting data from methods appropriate to an investigation, and planning and undertaking a programme of work to provide the data required in the investigation	N3.1 Plan an activity and get relevant information from relevant sources.
• selecting and using appropriate methods to process experimental and secondary data obtained during an investigation	N3.2 Use this information to carry out multistage calculations to do with: a amounts or sizes b scales or proportion c handling statistics d using formulae.
• drawing and presenting conclusions drawn from processed experimental and secondary data.	N3.3 Interpret the results of your calculations, present your findings and justify your methods.

Communication Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• engaging in group discussions which do not necessarily arise during the investigation – they can, however, be included if required, to discuss strategies and methods to be used during the investigation	C3.1a Take part in a group discussion.
• presenting the results and conclusions of an investigation to a workplace manager	C3.1b Make a formal presentation of at least eight minutes using an image or other support material.
• using literature sources to develop familiarity with the experimental methods to be used in an investigation	C3.2 Read and synthesise information from **two** documents about the same subject. Each document must be a minimum of 1000 words long.
• preparing the report of an investigation.	C3.3 Write **two** different types of documents, each one giving different information about complex subjects. One document must be at least 1000 words long.
Information and communication technology Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• planning and carrying out a search for experimental methods appropriate to an investigation to be undertaken	ICT3.1 Search for information, using different sources, and multiple search criteria in at least one case.
• exploring, developing, exchanging and deriving new information that has been researched about the practical investigation	ICT3.2 Enter and develop the information and derive new information.
• preparing the report of an investigation.	IT3.3 Present combined information such as text with image, text with number, image with number.

Improving own learning and performance Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• developing the plan for an investigation and consulting and gaining the agreement of their tutor or workplace supervisor	LP3.1 Set targets using information from appropriate people and plan how these will be met.
• implementing the plan and modifying it in accordance with results obtained and constraints and problems encountered	LP3.2 Take responsibility for your learning, using your plan to help meet targets and improve your performance.
• evaluating the plan at frequent intervals and refining it in accordance with the conclusions reached.	LP3.3 Review progress and establish evidence of achievements.
Problem solving Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• formulating the plan for an investigation	PS3.1 Explore a problem and identify different ways of tackling it.
• identification and evaluation of alternative methods of approach to an investigation, and deciding on the approach to be adopted	PS3.2 Plan and implement at least one way of solving the problem.
• developing the plan for an investigation, using the preferred option	PS3.3 Check if the problem has been solved and review your approach to problem solving.
• evaluating the plan continuously during an investigation, on the basis of the results and conclusions produced.	

Unit 14: Information and Automation Technology for Pharmacy

NQF Level 3: **BTEC National**

Guided learning hours: 60

Unit abstract

The ability to use the computer as a tool to handle information is essential for the modern practice of pharmacy. This unit is designed to help learners develop skills in handling the types of information most commonly encountered in pharmacy practice.

The emphasis is on selecting and using appropriate techniques for pharmaceutical applications and on using commercial software packages. The unit does not depend on the use of any particular brand of package — any of the commercially available suites of software will enable the required outcomes to be met.

The principal types of information relevant to pharmacy will be introduced, and skills in storing, retrieving, processing and presenting information will be developed. The emphasis of the unit is on being able to choose applications for which the use of electronic media offers significant advantages over traditional techniques.

The newest technology in the field of pharmacy is automation in the form of robotisation (automated dispensing machines) — many pharmacies are now installing robots. Learners will be expected to consider how and where the robots will function in a pharmacy and especially the effective use of robots.

The learning outcomes will best be achieved by applying them to learners' coursework and work-based activities. The unit is sufficiently flexible to enable centres to tailor the development and assessment to a wide range of course-based and work-based activities.

This unit presents opportunities to demonstrate the Level 3 key skill in information and communication technology.

Learning outcomes

On completion of this unit a learner should:

1 Understand and use computer equipment

2 Be able to enter, store, retrieve and supply data and information electronically

3 Be able to use electronic media to present information

4 Understand the function and use of electronic/automated prescribing and dispensing systems.

Unit content

1 **Understand and use computer equipment**

Understand the basic principles: how a computer and ancillary equipment work, eg keyboard, mouse, printer, scanner, monitor

Carry out simple operations using a computer: eg use of keyboard, mouse, printer and scanner

Understand how a computer can be used as a source of information: eg CD ROM, the internet, email

Understand and use software packages: eg for word processing (to include letters, reports, posters), databases, spreadsheets, programs for slide presentations (eg PowerPoint)

Understand pharmacy applications and pharmacy MIS software: pharmacy practice software; pharmacy websites

Understand legal and ethical considerations: data protection; confidentiality; security; information governance

2 **Be able to enter, store, retrieve and supply data and information electronically**

Enter and store

Types of information: text; numerical data; graphical data

Software packages: data-processing packages

Processing operations: file structure operations; file selection; file management; inputting data; storing data; display numerical and text data; sorting and restructuring data; exchange data between packages

Retrieve and supply

Types of information: text; numerical data; graphical data

Types of presentation: text, eg patient information records, labels, stock reports; numerical data, eg use in stock control, graphical data

Format for presentation: combining text; numerical data and graphics showing fitness for purpose

Retrieving information: using the internet, search engines and appropriate software

3 **Be able to use electronic media to present information**

Types of information: text; numerical data; graphical data

Types of presentation: text, eg reports, assignments, numerical data

Format for presentation: electronically, including PowerPoint; paper-based, eg hard copy

4 **Understand the function and use of electronic/automated prescribing and dispensing systems**

Examples of electronic/automated systems: electronic prescribing; electronic tablet counters; ward-based automated dispensers; automated dispensing in aseptic units; automated stock control; pneumatic tube; baker cells; barcode readers; robotic, automatic/semi-automatic loading systems

Setting up and maintaining data files: validated interface systems software; network links; computer terminals; entering data; calibrating aseptic regimens; entering dose units; stock-control database

Retrieval process: using conveyers, gravity feed chutes, 'drop-off arms' storage modules, picking heads, pack-picker, barcode readers, single-item/multi-item picking heads, gravity-fed channels, independent picking of stock

Grading grid

In order to pass this unit, the evidence that the learner presents for assessment needs to demonstrate that they can meet all of the learning outcomes for the unit. The criteria for a pass grade describes the level of achievement required to pass this unit.

Grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P1 identify the basic components of a computer and describe specialist pharmacy practice software	M1 combine stored and acquired textual material into coherent formats, exchange data between software packages	D1 obtain relevant information from the internet, eg pharmaceutical and medicines information relating to disease states
P2 configure word-processing, spreadsheet and database packages to meet specific pharmacy information storage requirements, enter information into configured software, check entered information and correct errors	M2 sort and restructure stored information to meet specific requirements	D2 assess such information obtained from the internet, retrieve stored information under normal situations and following corruption of data
P3 select and use appropriate software to store pharmaceutical information, search available information sources to acquire pharmaceutical information for specified purposes, use appropriate techniques to process numerical data, convert numerical data for graphical display	M3 present information in forms showing fitness for purpose, present reports of practical pharmaceutical activities containing information presented in appropriate forms, demonstrate the uses of word processing, spreadsheets and databases in the report presented	D3 prepare and deliver in an appropriate format a report using ICT equipment, present the report combining text and graphical data in an appropriate format, use a catalogue system to search for source material relevant to pharmacy

Grading criteria		
To achieve a pass grade the evidence must show that the learner is able to:	**To achieve a merit grade the evidence must show that, in addition to the pass criteria, the learner is able to:**	**To achieve a distinction grade the evidence must show that, in addition to the pass and merit criteria, the learner is able to:**
P4 describe the use of electronic and automated systems used to aid the prescribing and dispensing of medicines.	M4 compare the potential costs and benefits of using electronic and automated systems in the pharmacy.	D4 explain the ways in which an integrated electronic prescribing and automated pharmacy supply system can improve patient safety and care, and enhance pharmacy efficiency.

Essential guidance for tutors

Delivery

In delivering this unit, the learners should undertake a programme to develop their expertise in the use of software packages. This should be followed by practice in working with real information and data in course- and work-related applications. Part-time learners should take any opportunity to gather information from the workplace to relate applications of information technology in pharmacy practice. Such opportunities will provide the knowledge and understanding of the use of information technology in pharmacy practice.

The unit programme should be structured to teach learners to choose the applications for which the use of information technology offers real and significant advantages over traditional methods. Current pharmacy practice is becoming increasingly dependent on information technology in order to provide quality services with regard to medicines management.

Assessment

A variety of assessment methods can be used for this unit. The emphasis should be on using information technology as a tool for pharmacy practice. Evidence should, therefore, be generated from learners' other coursework activities and, where possible, from learners' work-based activities.

Pass

The learner should be able to understand and use computer, electronic and automated systems equipment and software, and be able to enter, store, retrieve and present data and information and relate this to uses in pharmacy.

Merit

The learner should be able to manipulate data, including sorting, restructuring and exchanging between software packages, and present reports of pharmaceutical activities appropriately using word processing, spreadsheets and databases. The learner should also understand the potential costs and benefits of the practical use of electronic and automated systems in pharmacy.

Distinction

The learner should be able to access and use data from the internet, including retrieval of information following corruption of data, and present reports using text and graphics in an electronic format. Learners should be able to demonstrate understanding of the benefits to patient care and pharmacy efficiency of using electronic and automated systems.

Links to National Occupational Standards, other BTEC units, other BTEC qualifications and other relevant units and qualifications

This unit can be linked to all others in the Certificate programme. Learners should be given the opportunity to select appropriate activities to demonstrate the learning outcomes from any other unit(s) and include outcomes from work-based activities. Learners should be encouraged to consider how the use of information technology can be integrated into other units in the programme and its use in the workplace.

The unit gives learners provide opportunities to develop the information and communication technology key skill.

This unit has links with *Unit 13: Scientific Method for Pharmacy Technicians*.

This unit links to Unit 3.07 of the Level 3 NVQ in Pharmacy Services.

Essential resources

Facilities required for this unit include access to a desktop or laptop computer and appropriate generic and pharmaceutical software.

Staff delivering this unit should possess the relevant up-to-date skills and competence, be experienced in IT skills and show regular technical updating.

Indicative reading for learners

Finkelstein E — *How to Do Everything with Microsoft Office Power Point 2003* (Osborne McGraw-Hill, 2003) ISBN 0072229721

Millhollon M and Murray K — *Word 2003 Inside Out* (Microsoft Press, 2003) ISBN 0735615152

Websites

European Computer Driving Licence	www.ecdl.com
Microsoft	www.microsoft.com

Key skills

Achievement of key skills is not a requirement of this qualification but it is encouraged. Suggestions of opportunities for the generation of Level 3 key skill evidence are given here. Tutors should check that learners have produced all the evidence required by part B of the key skills specifications when assessing this evidence. Learners may need to develop additional evidence elsewhere to fully meet the requirements of the key skills specifications.

Information and communication technology Level 3	
When learners are:	**They should be able to develop the following key skills evidence:**
• planning and carrying out a search (eg an internet search) for experimental methods appropriate to an investigation to be undertaken, in another pharmacy	IT3.1 Search for information, using different sources, and multiple search criteria in at least one case.
• exploring, developing, exchanging and deriving new information that has been researched about the investigation	IT3.2 Enter and develop the information and derive new information.
• preparing the report of an investigation.	IT3.3 Present combined information such as text with image, text with number, image with number.

Assessment and grading

The purpose of assessment is to ensure that effective learning has taken place.

Assignments constructed by centres should be reliable and fit for purpose, and should build on the application of the grading criteria. Centres should use a variety of assessment methods, including case studies, assignments and work-based assessments, along with projects, performance observation and time-constrained assessments. Centres are encouraged to emphasise the practical application of the grading criteria, providing a realistic scenario for learners to adopt, and making maximum use of practical activities and work experience. The creation of assignments that are fit for purpose is vital to learners' achievement and their importance cannot be over-emphasised.

All of the criteria listed in the grading grid for each unit must be covered by one assignment, or by a series of assignments. It is advisable that criteria are clearly indicated on each assignment to provide a clear focus for learners and to assist with internal verification and standardisation processes. This will also help to ensure that feedback is specific to the criteria. Tasks and activities should enable learners to produce evidence that relates directly to the specified criteria.

When reading the grading grids and designing assignments, centres should note that for learners to achieve a merit/distinction grade they will be required to provide evidence that is qualitative, not quantitative, in its nature. Centres are encouraged to look across the units' grading grids to identify common topics.

Grading domains

The grading criteria are developed in relation to grading domains which provide for the assessment of the learning outcomes of the unit. There are four BTEC National grading domains which underpin the grading criteria:

- application of knowledge and understanding
- development of practical and technical skills
- personal development for occupational roles
- application of generic and key skills.

The qualitative nature of the merit and distinction grading criteria is based on indicative characteristics of the evidence to fulfil the higher grades. Please refer to *Annexe B*.

A grading scale of pass, merit and distinction is applied to all units.

In Edexcel BTEC Nationals all units are internally assessed.

All assessment for BTEC Nationals is criterion referenced, based on the achievement of specified learning outcomes. Each unit has specified criteria which are to be used for grading. A summative unit grade can be awarded at pass, merit or distinction:

- to achieve a 'pass' a learner must have satisfied **all** the pass criteria
- to achieve a 'merit' a learner must additionally have satisfied **all** the merit criteria

- to achieve a 'distinction' a learner must additionally have satisfied **all** the distinction criteria.

Learners who complete the unit but who do not meet all the pass criteria are graded 'unclassified'.

Quality assurance

Edexcel's qualification specifications set out the standard to be achieved by each learner in order to be awarded the qualification. This is covered in the statement of learning outcomes and grading criteria in each unit. Further guidance on delivery and assessment is given in the *Essential guidance for tutors* section in each unit. This section is designed to provide additional guidance and amplification related to the unit to support tutors, deliverers and assessors and to provide for a coherence of understanding and a consistency of delivery and assessment.

Edexcel operates an independent, external quality assurance process which is designed to ensure that these standards are maintained by all internal verifiers and external verifiers. It achieves this through the following activities.

Approval

Centres that have not previously offered BTEC qualifications will first need to apply for, and be granted, centre approval before they can apply for approval to offer the programme.

Centres wishing to offer a vocational area for the first time will need to apply for approval to offer the programme.

When a centre applies for approval to offer a BTEC qualification they will be required to enter into an approvals agreement.

The approvals agreement is a formal commitment by the head or principal of a centre to meet all the requirements of the specification and any linked codes or regulations. Sanctions and tariffs may be applied if centres do not comply with the agreement. Ultimately, this could result in the suspension of certification or withdrawal of approval.

Centres will be allowed 'accelerated approval' for a new programme where the centre already has approval for a programme that is being replaced by the new programme.

Risk assessment

Edexcel has an approval process which creates a quality profile of each qualification programme in each centre and for the centre as a whole. This profile helps to determine how the programme will be externally verified and will also be used to initiate other quality control measures by Edexcel.

Internal verification

Centres are required to have processes in place that review each assessor's decisions. This ensures that they are correctly interpreting and applying the standards set out in the specifications. The system used to do this is a matter for individual centres and Edexcel fully supports the use of the centre's own quality assurance systems where they ensure robust internal standardisation.

Centres should refer to the BTEC NQF Level 2/3 (including Short Courses at Levels 1–3) Handbook (updated annually). This information can also be found on our website www.edexcel.org.uk then click on 'Services for Centres' and then 'FE Colleges and Schools'.

External verification

Edexcel will sample assessors' decisions using sector-specialist external verifiers. For BTEC Nationals this process will follow the National Standards Sampling (NSS) protocol.

Learners' work **must** be internally assessed. Additionally, at least 50 per cent of submitted work **must** be internally verified.

Centres should refer to the BTEC NQF Level 2/3 (including Short Courses at Levels 1–3) Handbook (updated annually). This updated information can also be found on our website, go to www.edexcel.org.uk then click on 'Services for Centres' and then 'FE Colleges and Schools'.

Calculation of the qualification grade

Awarding a qualification grade

The qualification grade will be calculated through the aggregation of points achieved through the successful achievement of individual units. The number of points available will be dependent on the unit grade achieved and the size of the unit as determined by the stipulated guided learning hours.

For the calculation of a qualification grade for a BTEC National a learner must:

- complete all designated units
- achieve a minimum points score of
  - 36 points for a National Award
  - 72 points for a National Certificate
  - 108 points for a National Diploma
- achieve a pass (or above) grade for units with a combined total of
  - 300 guided learning hours for a National Award
  - 600 guided learning hours for a National Certificate
  - 900 guided learning hours for a National Diploma.

Unit points

Size of unit (GLH)	Pass grade	Merit grade	Distinction grade
10	1	2	3
30	3	6	9
60	6	12	18
90	9	18	27
120	12	24	36

Grade boundaries and UCAS points (as of 1st January 2007)

Grade boundaries BTEC National Award	Overall grade BTEC National Award		UCAS points
36–59	Pass	P	40
60–83	Merit	M	80
84–108	Distinction	D	120

Grade boundaries BTEC National Certificate	Overall grade BTEC National Certificate	UCAS points
72–95	PP	80
96–119	MP	120
120–143	MM	160
144–167	DM	200
168–216	DD	240

Grade boundaries BTEC National Diploma	Overall grade BTEC National Diploma	UCAS points
108–131	PPP	120
132–155	MPP	160
156–179	MMP	200
180–203	MMM	240
204–227	DMM	280
228–251	DDM	320
252–324	DDD	360

For the requirements of the Royal Pharmaceutical Society of Great Britain for the Technical Certificate in Pharmacy Services please see page six of this document.

Programme design and delivery

BTEC National qualifications consist of core units (which are mandatory) and specialist units. Specialist units are designed to provide a specific focus to the qualification. Required combinations of specialist units are set out clearly in relation to each qualification in the defined qualification structures in this document.

In BTEC Nationals each unit is 30, 60, 90 or 120 guided learning hours (GLH). The GLH includes an estimate of time that might be allocated to direct teaching, instruction and assessment, together with other structured learning time such as directed assignments or supported individual study. It excludes learner-initiated private study. Centres are advised to consider this definition when planning the programme of study associated with this specification.

Mode of delivery

Edexcel does not define the mode of study for BTEC Nationals. Centres are free to offer the qualifications using any mode of delivery that meets their learner's needs. This may be through traditional classroom teaching, open learning, distance learning or a combination of the three. Whichever mode of delivery used, centres must ensure that learners have appropriate access to the resources identified in the specification and to the subject specialists delivering the units. This is particularly important for learners studying for the qualification through open or distance learning.

Learners studying for the qualification on a part-time basis bring with them a wealth of experience that should be utilised to maximum effect by tutors and assessors. Assessment evidence drawn from learners' work environments should be encouraged. Those planning the programme should aim to enhance the vocational nature of the qualification by:

- liaising with employers to ensure a course relevant to learners' specific needs
- accessing and using non-confidential data and documents from learners' workplaces
- including sponsoring employers in the delivery of the programme and, where appropriate, in the assessment
- linking with company-based/workplace training programmes
- making full use of the variety of experience of work and life that learners bring to the programme.

Resources

BTEC Nationals are designed to prepare learners for employment in specific occupational sectors. Physical resources need to support the delivery of the programme and the proper assessment of the learning outcomes, and should therefore normally be of industry standard. Staff delivering programmes and conducting the assessments should be fully familiar with current practice and standards in the sector concerned. Centres will need to meet any specialist resource requirements when they seek approval from Edexcel.

Where specific resources are required these have been indicated in individual units under the *Essential resources* section.

Delivery approach

It is important that centres develop an approach to teaching and learning that supports the specialist vocational nature of BTEC National qualifications. Specifications give a balance of practical skill development and knowledge requirements, some of which can be theoretical in nature. Tutors and assessors need to ensure that appropriate links are made between theory and practical application and that the knowledge base is applied to the sector. This requires the development of relevant and up-to-date teaching materials that allow learners to apply their learning to actual events and activity within the sector. Maximum use should be made of the learner's experience.

Accreditation of Prior Learning (APL)

Edexcel encourages centres to recognise learners' previous achievements and experiences through APL. Learners may have evidence that has been generated during previous study or in their previous or current employment or whilst undertaking voluntary work that relates to one or more of the units in the qualification. Assessors should map this evidence against the grading criteria in the specification and make this evidence available to the external verifier. As with all evidence, assessors should be satisfied about the authenticity and currency of the material when considering whether or not the learning outcomes of the unit have been met.

Full guidance on Edexcel's policy on APL is provided on our website, go to www.edexcel.org.uk then click on 'About Us' and then 'Policies for Centres'.

Meeting local needs

This BTEC National Certificate in Pharmacy Services is a sector specific qualification. As it contains very specialised units to meet the requirements for registration for pharmacy technicians, meeting local needs does not apply for this qualification. Centres should note the qualification set out in this specification has been developed in consultation with centres and employers, particularly the Sector Skills Council, Skills for Health, and the Standards Setting Body of the pharmacy sector.

Limitations on variations from standard specifications

The flexibility to import standard units from other BTEC Nationals and/or develop unique units is limited to a total of:

- $^{2}/_{9}$ (for example four 60 GLH units) in a BTEC National Diploma qualification
- $^{1}/_{6}$ (for example two 60 GLH units) in a BTEC National Certificate qualification
- $^{1}/_{6}$ (for example one 60 GLH unit) in a BTEC National Award qualification.

The use of these units cannot be at the expense of the core units in any qualification.

Access and recruitment

Edexcel's policy regarding access to its qualifications is that:

- they should be available to everyone who is capable of reaching the required standards
- they should be free from any barriers that restrict access and progression
- there should be equal opportunities for all wishing to access the qualifications.

Centres are required to recruit learners to BTEC qualifications with integrity. This will include ensuring that applicants have appropriate information and advice about the qualifications and that the qualification will meet their needs. Centres should take appropriate steps to assess each applicant's potential and make a professional judgement about their ability to successfully complete the programme of study and achieve the qualification. This assessment will need to take account of the support available to the learner within the centre during their programme of study and any specific support that might be necessary to allow the learner to access the assessment for the qualification. Centres should also show regard for Edexcel's policy on learners with particular requirements.

Centres will need to review the profile of qualifications and/or experience held by applicants, considering whether this profile shows an ability to progress to a Level 3 qualification. For learners who have recently been in education, the profile is likely to include one of the following:

- a BTEC First qualification in Applied Science or a related vocational area
- an Intermediate GNVQ in an appropriate vocational area
- a GCSE equivalent to four passes at grade C
- related work experience
- other related Level 2 qualifications.

More mature learners may present a more varied profile of achievement that is likely to include experience of paid and/or unpaid employment.

Restrictions on learner entry

Most BTEC National qualifications are accredited on the NQF for learners aged 16 years and over. Learners aged 15 and under cannot be registered for a BTEC National qualification.

In particular sectors the restrictions on learner entry might also relate to any physical or legal barriers, for example people working in health, care or education are likely to be subject to police checks.

Edexcel Level 3 BTEC Nationals are listed on the DfES funding lists Section 96 and Section 97.

Access arrangements and special considerations

Edexcel's policy on access arrangements and special considerations for BTEC and Edexcel NVQ qualifications aims to enhance access to the qualifications for learners with disabilities and other difficulties (as defined by the 1995 Disability Discrimination Act and the amendments to the Act) without compromising the assessment of skills, knowledge, understanding or competence.

Further details are given in the policy 'Access Arrangements and Special Considerations for BTEC and Edexcel NVQ Qualifications', which is on the Edexcel website (www.edexcel.org.uk). This policy replaces the previous Edexcel policy (Assessment of Vocationally Related Qualification: Regulations and Guidance Relating to Learners with Special Requirements, 2002) concerning learners with particular requirements.

The Edexcel BTEC Qualification Framework for the Pharmacy Services sector

Progression opportunities within the framework are available vertically, diagonally and horizontally.

NQF Level	General Qualifications	BTEC full VRQ courses	BTEC Short Courses	NVQ/occupational
5		BTEC Higher National Certificate and Diploma in Biomedical Science		
4				
3		**National Certificate in Pharmacy Services**		Level 3 NVQ in Pharmacy Services
2	GCSE Science, GCSE Additional Science, GCSE Biology	First Certificate and Diploma in Applied Science	BTEC Award in Paediatric First Aid	Level 2 NVQ in Pharmacy Services
1		Introductory Certificate and Diploma in Applied Science		
Entry				

This is a restricted framework, showing only entry levels up to Level 5. The Edexcel Level 3 BTEC National Certificate in Pharmacy Services can help learners progress into employment within the pharmacy sector, or onto higher education.

Further information

For further information please call Customer Services on 0870 240 9800 (calls may be recorded for training purposes) or visit our website at www.edexcel.org.uk.

Useful publications

Further copies of this document and related publications can be obtained from:

Edexcel Publications
Adamsway
Mansfield
Nottinghamshire NG18 4FN

Telephone: 01623 467 467
Fax: 01623 450 481
Email: publications@linneydirect.com

Related information and publications include:

- *Accreditation of Prior Learning* available on our website: www.edexcel.org.uk
- *Guidance for Centres Offering Edexcel/BTEC NQF Accredited Programmes* — (Edexcel, distributed to centres annually)
- key skills publications — specifications, tutor support materials and question papers
- *The Statutory Regulation of External Qualifications in England, Wales and Northern Ireland* — (QCA, 2004)
- the current Edexcel publications catalogue and update catalogue.

Edexcel publications concerning the Quality Assurance System and the internal and external verification of vocationally related programmes can be found on the Edexcel website and in the Edexcel publications catalogue.

NB: Most of our publications are priced. There is also a charge for postage and packing. Please check the cost when you order.

How to obtain National Occupational Standards

Skills for Health
2nd Floor
Goldsmiths House
Broad Plain
Bristol BS2 0JP

Telephone: 0117 922 1155
Fax: 0117 925 1800
Email: office@skillsforhealth.org.uk

Professional development and training

Edexcel supports UK and international customers with training related to BTEC qualifications. This support is available through a choice of training options offered in our published training directory or through customised training at your centre.

The support we offer focuses on a range of issues including:

- planning for the delivery of a new programme
- planning for assessment and grading
- developing effective assignments
- building your team and teamwork skills
- developing student-centred learning and teaching approaches
- building key skills into your programme
- building in effective and efficient quality assurance systems.

The national programme of training we offer can be viewed on the Edexcel website (www.edexcel.org.uk). You can request customised training through the website or by contacting one of our advisers in the Professional Development and Training team via Customer Services on telephone 0870 240 9800 (calls may be recorded for training purposes) to discuss your training needs.

The training we provide:

- is active — ideas are developed and applied
- is designed to be supportive and thought provoking
- builds on best practice.

Annexe A

QCA codes

The QCA National Qualifications Framework (NQF) code is known as a Qualification Accreditation Number (QAN). This is the code that features in the DfES Funding Schedules, Section 96 and 97 and is to be used for all qualification funding purposes. Each unit within a qualification will also have a QCA NQF unit code.

The QCA qualification and unit codes will appear on the learner's final certification documentation.

The QAN for the qualification in this publication is:

Edexcel Level 3 BTEC National Certificate in Pharmacy Services 500/1138/8

These qualification titles will appear on the learners' certificates. Learners need to be made aware of this when they are recruited by the centre and registered with Edexcel. Providing this happens, centres are able to describe the programme of study leading to the award of the qualification in different ways to suit the medium and the target audience.

Annexe B

Grading domains: Level 3 BTEC generic grading domains

Grading domain 1	Indicative characteristics — Merit	Indicative characteristics — Distinction
Application of knowledge and understanding (Learning outcome stem *understand* or *know*)	• Shows depth of knowledge and development of understanding in familiar and unfamiliar situations (eg explain why, makes judgements based on analysis). • Applies and/or selects concepts showing comprehension of often complex theories. • Applies knowledge in often familiar and unfamiliar contexts. • Applies knowledge to non-routine contexts (eg assessor selection). • Makes reasoned analytical judgements. • Shows relationships between p criteria.	• Synthesises knowledge and understanding across p/m criteria. • Evaluates complex concepts/ideas/actions and makes reasoned and confident judgements. • Uses analysis, research and evaluation to make recommendations and influence proposals. • Analyses implications of application of knowledge/understanding. • Accesses and evaluates knowledge and understanding to advance complex activities/contexts. • Shows relationships with p/m criteria. • Responds positively to evaluation.

Grading domain 2	Indicative characteristics — Merit	Indicative characteristics — Distinction
Development of practical and technical skills (Learning outcome stem *be able to*)	• Deploys appropriate advanced techniques/processes/ skills. • Applies technical skill to advance non-routine activities. • Advances practical activities within resource constraints. • Produces varied solutions (including non-routine). • Modifies techniques/processes to situations. • Shows relationship between p criteria.	• Demonstrates creativity/originality/own ideas. • Applies skill(s) to achieve higher order outcome. • Selects and uses successfully from a range of advanced techniques/processes/skills. • Reflects on skill acquisition and application. • Justifies application of skills/methods. • Makes judgements about risks and limitations of techniques/processes. • Innovates or generates new techniques/processes for new situations. • Shows relationship with p and m criteria.

Grading domain 3	Indicative characteristics — Merit	Indicative characteristics — Distinction
Personal development for occupational roles (Any learning outcome stem)	• Takes responsibility in planning and undertaking activities. • Reviews own development needs. • Finds and uses relevant information sources. • Acts within a given work-related context showing understanding of responsibilities. • Identifies responsibilities of employers to the community and the environment. • Applies qualities related to the vocational sector. • Internalises skills/attributes (creating confidence).	• Manages self to achieve outcomes successfully. • Plans for own learning and development through the activities. • Analyses and manipulates information to draw conclusions. • Applies initiative appropriately. • Assesses how different work-related contexts or constraints would change performance. • Reacts positively to changing work-related contexts • Operates ethically in work-related environments. • Takes decisions related to work contexts. • Applies divergent and lateral thinking in work-related contexts. • Understands interdependence.

Grading domain 4	Indicative characteristics — Merit	Indicative characteristics — Distinction
Application of generic skills (Any learning outcome stem)	• Communicates effectively using appropriate behavioural and language registers. • Communicates with clarity and influence. • Makes judgements in contexts with explanations. • Explains how to contribute within a team. • Demonstrates positive contribution to team(s). • Makes adjustments to meet the needs/expectations of others (negotiation skills). • Selects and justifies solutions for specified problems.	• Presents self and communicates information to meet the needs of a variety of audience. • Identifies strategies for communication. • Shows innovative approaches to dealing with individuals and groups. • Takes decisions in contexts with justifications. • Produces outputs subject to time/resource constraints. • Reflects on own contribution to working within a team. • Generates new or alternative solutions to specified problems. • Explores entrepreneurial attributes.

Annexe C

Key skills

All BTEC National qualifications include mapping and/or signposting of key skills. These are transferable skills, which play an essential role in developing personal effectiveness for adult and working life and in the application of specific vocational skills.

In each unit the opportunities for the generation of evidence for key skills are signposted. These are indicative links only. Tutors will need to become familiar with key skills specifications and their evidence requirements and they are advised not to rely on the signposting in the units when presenting key skills evidence for moderation. Centres should refer to the QCA website (www.qca.org.uk) for the latest key skills standards.

Key skills provide a foundation for continual learning. They enable and empower individuals who inevitably face a series of choices in work, education and training throughout their lives. Current and future initiatives such as learndirect, lifelong learning and widening participation all require a more flexible population in the workplace and key skills play a role in setting the framework.

Learners need the chance to show current and future employers that they can:

- communicate effectively, in a variety of situations, using a wide range of techniques
- work well with others — individuals or teams — so that work can be properly planned and targets met
- manage their own development, so that they are always ready to take on the challenges of change and diversification
- use number, not just within routine tasks and functions but to help them be more effective and efficient in all they do
- use ICT in a range of applications to support all aspects of their role
- solve problems in a variety of circumstances.

Key skills mapping — summary of opportunities suggested in each unit

Key skills	Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 6	Unit 7	Unit 8	Unit 9	Unit 10
N3.1									✓	
N3.2	✓						✓		✓	
N3.3	✓						✓		✓	
C3.1a	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
C3.1b	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
C3.2	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
C3.3	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
ICT3.1	✓	✓	✓	✓	✓	✓		✓	✓	
ICT3.2	✓	✓							✓	
ICT3.3									✓	
LP3.1	✓								✓	
LP3.2	✓								✓	
LP3.3	✓								✓	
PS3.1	✓						✓		✓	
PS3.2	✓						✓			
PS3.3	✓									
WO3.1									✓	
WO3.2									✓	
WO3.3									✓	

Key skills	Unit 11	Unit 12	Unit 13	Unit 14
N3.1			✓	
N3.2		✓	✓	
N3.3			✓	
C3.1a	✓	✓	✓	
C3.1b	✓	✓	✓	
C3.2	✓	✓	✓	
C3.3		✓	✓	
ICT3.1		✓	✓	✓
ICT3.2		✓	✓	✓
ICT3.3			✓	✓
LP3.1		✓	✓	
LP3.2		✓	✓	
LP3.3		✓	✓	
PS3.1		✓	✓	
PS3.2		✓	✓	
PS3.3		✓	✓	
WO3.1				
WO3.2				
WO3.3				

Annexe D

National Occupational Standards/mapping with NVQs

The following grid maps the knowledge covered in the BTEC National Certificate in Pharmacy Services against the underpinning knowledge of the Level 3 NVQ in Pharmacy Services, SSC National Occupational Standards.

KEY

✓ indicates that the Edexcel Level 3 BTEC National Certificate in Pharmacy Services covers all of the underpinning knowledge of the NVQ unit

\# indicates partial coverage of the NVQ unit

a blank space indicates no coverage of the underpinning knowledge

Units	1	2	3	4	5	6	7	8	9	10
Level 3 NVQ in Pharmacy Services units										
3.01	#	#	#	#	#	#	#	#	#	#
3.02		#					#		#	#
3.03		#	#	#	#	#	#			#
3.04		#					#			#
3.05			#				#			
3.06		#								#
3.07										
3.08	#	#					#		#	
3.09	#	#					#		#	

Units	1	2	3	4	5	6	7	8	9	10
Level 3 NVQ in Pharmacy Services units										
3.10		#	#	#	#	#	#	#	#	#
3.11		#	#	#	#	#	#			#
3.12										

Units	11	12	13	14
Level 3 NVQ in Pharmacy Services units				
3.01	#	#		#
3.02	#			#
3.03	#		#	#
3.04	#		#	
3.05			#	
3.06				
3.07				#
3.08	#	#		
3.09	#	#		#
3.10				
3.11				#
3.12				

Annexe E

BTEC National Certificate in Pharmacy Services old (specification end date 31 August 2007)/BTEC National Certificate in Pharmacy Services new (specification start date 01 September 2007) – unit mapping overview

Old units / New units	Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 6	Unit 7	Unit 8	Unit 9	Unit 10	Unit 11	Unit 12	Unit 13	Unit 14
Unit 1	X													
Unit 2		X												
Unit 3				X										
Unit 4			P											
Unit 5			P		P	P								
Unit 6			P	P		P								
Unit 7							F							
Unit 8								P						
Unit 9									X					
Unit 10										P				
Unit 11											X			
Unit 12												F		

Old units / New units	Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 6	Unit 7	Unit 8	Unit 9	Unit 10	Unit 11	Unit 12	Unit 13	Unit 14
Unit 13													X	
Unit 14														X

KEY

P – Partial mapping (some topics from the old unit appear in the new unit)

F – Full mapping (topics in old unit match new unit exactly or almost exactly)

X – Full mapping + New (all the topics from the old unit appear in the new unit, but new unit also contains new topic(s))

BTEC National in Certificate in Pharmacy Services old (specification end date 31 August 2007)/BTEC National Certificate in Pharmacy Services new (specification start date 01 September 2007) — unit mapping in depth

New units		Old units		Mapping/Comments (new topics in italics)	
Number	Name	Number	Name		
Unit 1	Scientific Principles for Pharmacy	Unit 1	Scientific Principles for Pharmacy Technicians	X	As old Unit 1 except tissues has been removed, and *SI units* has been added.
Unit 2	Pharmacy Law, Ethics and Practice	Unit 2	Pharmacy Law and Practice	X	As old Unit 2 except *homeopathic medicines* and *veterinary drugs* have been added.
Unit 3	An Introduction to Action and Uses of Medicines	Unit 4	Action and Uses of Drugs B	X	As old Unit 4 except respiratory disorders is now in Unit 6. *Smoking cessation* and *patient counselling* have been added.
Unit 4	Cytotoxic, Endocrine and Nutritional Medicines	Unit 3	Action and Uses of Drugs A	P	Areas covered from old Unit 3 are: drugs in the treatment of infections, drugs affecting the endocrine system, immunological products. *Monoclonal antibodies* has been added.
Unit 5	Central Nervous System, Eyes, ENT, Skin and Gynaecological Medicines	Unit 3	Action and Uses of Drugs A	P	Areas covered from old Unit 3: hormones and drugs in gynaecological disorders and obstetrics.
		Unit 5	Action and Uses of Drugs C	P	Areas covered from old Unit 5: palliative care, drugs in central nervous system disorders, drugs used in aesthetics.
		Unit 6	Action and Uses of Drugs D	P	Areas covered from old Unit 6: drugs in disorders of eye, drugs in disorders of ear, nose, mouth and throat, drugs in common disorders of skin, hair and nails.
Unit 6	Cardio-respiratory and Genito-urinary Medicines, and Medicines Management	Unit 3	Action and Uses of Drugs A	P	Area covered from old Unit 3: genito-urinary system.
		Unit 4	Action and Uses of Drugs B	P	Respiratory disorders is now covered in this new unit.
		Unit 6	Action and Uses of Drugs D	P	Area covered from old Unit 6: drugs in cardiovascular disorders. *Medicines management* have been added.

New units		Old units		Mapping/Comments (new topics in italics)	
Number	**Name**	**Number**	**Name**		
Unit 7	Pharmaceutics	Unit 7	Pharmaceutics	F	As old Unit 7.
Unit 8	Human Physiology for Pharmacy	Unit 8	Human Physiology for Pharmacy	P	As old Unit 8, except organs and organ systems has been removed from the new unit.
Unit 9	Microbiology for Pharmacy	Unit 9	Microbiology for Pharmacy	X	As old Unit 9, except *bacterial counting* and *microbial monitoring of the environment* have been added.
Unit 10	Pharmacy Practice	Unit 10	Pharmacy Practice	P	As old Unit 10, except aseptic manipulations and precautions taken has been removed.
Unit 11	Pharmacy Production	Unit 11	Pharmacy Production	X	As old Unit 11, except *the audit process* has been added.
Unit 12	Chemistry for Pharmacy	Unit 12	Chemistry for Pharmacy	F	As old Unit 12.
Unit 13	Scientific Method for Pharmacy Technicians	Unit 13	Scientific Method	X	As old Unit 13, except *setting objectives* has been added.
Unit 14	Information and Automation Technology for Pharmacy	Unit 14	IT for Pharmacy Technicians	X	As old Unit 14, except *understand legal and ethical considerations, retrieving information, understand the function and use of electronic/automated prescribing and dispensing systems* have been added.

Annexe F

Wider curriculum mapping

Study of the Edexcel Level 3 BTEC National Certificate in Pharmacy Services provides opportunities for the learner to develop an understanding of spiritual, moral, ethical, social and cultural issues as well as an awareness of environmental issues, European developments, health and safety considerations and equal opportunities issues.

The Edexcel Level 3 BTEC National Certificate in Pharmacy Services make a positive contribution to wider curricular areas as appropriate.

Spiritual, moral, ethical, social and cultural issues

The specification contributes to an understanding of:

- moral and ethical issues — in Units 2, 3, 4, 5, 6, 7, 10 and 11.
- social and cultural issues — in Units 2, 3, 4, 5, 6, 7, 10 and 11.

Environmental issues

Learners are led to appreciate the importance of environmental issues through the experience of the pharmacy sector, in Units 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12 and 13.

European developments

Much of the content of the Edexcel Level 3 BTEC National Certificate in Pharmacy Services applies throughout Europe even though the delivery is in a UK context. The European dimensions of pharmacy services are specifically addressed in Units 2, 3, 4, 5, 6, 7, 11 and 13.

Health and safety considerations

The Edexcel Level 3 BTEC National Certificate in Pharmacy Services is practically based and so health and safety issues are encountered throughout the units. Learners will develop awareness of the safety of others as well as themselves in all practical activities. Learners will also explore health and safety issues across the pharmacy sector, in all units.

Equal opportunities issues

Equal opportunities issues are implicit throughout the Edexcel Level 3 BTEC National Certificate in Pharmacy Services.

Wider curriculum mapping

	Unit 1	Unit 2	Unit 3	Unit 4	Unit 5	Unit 6	Unit 7	Unit 8	Unit 9	Unit 10	Unit 11	Unit 12	Unit 13	Unit 14
Spiritual issues														
Moral and ethical issues		✓	✓	✓	✓	✓	✓			✓	✓			
Social and cultural issues		✓	✓	✓	✓	✓	✓			✓	✓			
Environmental issues	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
European developments		✓	✓	✓	✓	✓	✓			✓	✓		✓	
Health and safety considerations	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Equal opportunities issues	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

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