Review Article

Starch as Pharmaceutical Excipient

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ABSTRACT

It is very well known that none of pharmaceutical preparations either for internal or external use can be manufactured without excipients. Excipient is defined as any substance other than active drug or pro-drug that is included in the manufacturing process or is contained in finished pharmaceutical dosage forms. Selecting best excipients, however, requiring a balance between time and cost efficiencies as well as anticipated product performance. Starch is one of the traditional excipients used in the manufacture of tablets. Chemically, starches are polysaccharides, composed of a number of monosaccharides or sugar (glucose) molecules linked together with α-d-(1-4) and/or α-d-(1-6) linkages. Starch has been investigated as an excipient in novel drug delivery systems for nasal, oral, periodontal, and other site-specific delivery systems. Depending on the application, specific starches are available for use as disintegrants, fillers or binders. As a result of its partial cold water solubility, starch functions exceptionally well in tablet manufacture by wet granulation applications and performs dual functions of both a disintegrant and a binder. In capsule filling processes, Starch and Star Cap Co-Processed Starch Excipients function as effective binders. As a result of its partial cold water solubility, starch functions exceptionally well in tablet manufacture by wet granulation applications and performs dual functions of both a disintegrant and a binder. In capsule filling processes, Starch function as effective binders. Starch is also one of the most commonly used tablet disintegrants at concentrations of 3–15% w/w. However, unmodified starch does not compress well and tends to increase tablet friability and capping if used in high concentrations. As a diluent, starch is used to facilitate subsequent mixing or blending processes in manufacturing operations.

Keywords: Starch, Binder, Disintegrants, Diluent.

INTRODUCTION

According to the international pharmaceutical excipient council, Excipient is defined as "Any substance other than active drug or pro-drug that is included in the manufacturing process or is contained in finished pharmaceutical dosage forms". The US pharmacopoeia-National formulary (USPNF) categorizes excipients according to the functions they perform in the formulations e.g. Binders, disintegrants etc[1]. Choosing the right excipients can make all the difference in the efficient production of robust tablets. Pharmaceutical formulators are seeking ways to improve the manufacturing process and product quality through the use of functional excipients. Selecting the best excipients, however, is a juggling act, requiring a balance between time and cost efficiencies as well as anticipated product performance.

Excipients are pharmaceutical additives, the inactive ingredients used to make up a medication. They include dyes, flavors, binders, emollients, fillers, lubricants, preservatives, and many more classifications. Common excipients used as fillers include corn starch, lactose and Dibasic Calcium phosphate dehydrate.[1,2]

Starch is one of the most abundant natural carbohydrates stored in plants. It is found in many different plant organs including seeds, fruits, tubers and roots, functioned as a source of energy. Although starch is widespread, abundantly available, cheap, degradable, pollution-free and renewable, it has many short falls, i.e., insoluble in cold water, easy to dehydration, low emulsifying power and unstable in acid, due to which commercial application is limited.[3] A survey of the literature shows that the usefulness of starches from various botanical sources as pharmaceutical excipients. Starches are widely available and have been very useful in tablet production due to their inertness, cheapness and utilization as fillers, binders, disintegrants and glidants. [4]

Chemically, starches are polysaccharides, composed of a number of monosaccharides or sugar (glucose) molecules linked together with α-d-(1-4) and/or α-d-(1-6) linkages. Starch consists of 2 main structural components, the amylose, which is essentially a linear polymer in which glucose residues are α-d-(1-4) linked typically constituting 15–20% of starch, and amylopectin, which is a larger branched molecule with α-d-(1-4) and α-d-(1-6) linkages and a major component of starch. Amylose is linear or slightly branched with a degree of polymerization up to 6000, and has a molecular mass of 105–106 g/mol. The chains can easily form single or double helices. Amylopectin on the other hand, has a molecular mass of 107–109 g/mol. It is highly branched and has an average degree of polymerization of 2 million, making it one of the largest molecules in nature. Chain lengths of 20–25

glucose units between branch points are typical of amylopectin. About 70% of the mass of starch granule is regarded as amorphous and about 30% as crystalline. The amorphous regions contain the main amount of amylose, and a considerable part of the amylopectin. The crystalline region consists primarily of the amylopectin.[5,6]

The corn plant (*Zea mays*) is a high-capacity, factory for efficiently converting large amounts of radiant energy from the sun into stable chemical energy. This energy is stored as cellulose, oil and starch in the corn plant and in the corn kernel. The corn plant is also one of nature's greatest multipliers. Approximately four months after planting, a single kernel of corn weighing about one one-hundredth of an ounce will yield 800 kernels weighing eight ounces. In comparison to this 800-fold seed multiplication in corn, wheat will produce a 50-fold yield per seed planted. Corn Starch is one of the traditional excipients used in the manufacture of tablets. Depending on the application, specific starches are available for use as disintegrants, fillers or binders. tablet and capsule diluent; tablet and filler. [7,8]

Starch has been investigated as an excipient in novel drug delivery systems for nasal, oral, periodontal, and other site-specific delivery systems. Starch is also used in topical preparations; for example, it is widely used in dusting powders for its absorbency, and is used as a protective covering in ointment formulations applied to the skin. Starch mucilage has also been applied to the skin as an emollient, has formed the base of some enemas, and has been used in the treatment of iodine poisoning.[9]

Isolated starch is typically a dry, soft, white powder. It is insoluble in cold water, alcohol, ether and most organic solvents. Starch, if kept dry, is stable in storage for indefinite periods. Though starch granules are physically durable, they can be disrupted quite easily. If granules in water suspension are gradually heated, they begin to absorb water. The granules hydrate, increase in size and finally lose their structural integrity. This results in loss of characteristic birefringence and opacity, an increase in viscosity, and the eventual formation of a paste or gel. This process is referred to as starch *pasting* or *gelatinization*. The temperature at the which gelatinization of a starch occurs — the *gelatinization temperature* — is dependent upon such factors as starch concentration, pH of the suspension, rate of heating, the presence of certain salts, and the specific procedure being followed. Under well-defined conditions, starches can be classified using gelatinization temperature as a means for differentiation. The properties of the starch granule are dependent upon the arrangement of the bonds which link glucose units to one-another within the starch molecule itself. [10]

Starch As Binder

Binders are used in the formulation of solid oral dosage forms to hold the active pharmaceutical ingredient and inactive ingredients together in a cohesive mix. Binder products are usually differentiated based on the manufacturing process to be used. Dry binders used for direct compaction must exhibit cohesive and adhesive forces so that when compacted the particles agglomerate.

Binders used for wet granulation are hydrophilic and soluble in water and are usually dissolved in water to form a wet mass that is then granulated. Binders function as binder for both direct compression and wet granulation. As a dry binder, it compresses well, predominately deforming plastically. It has been shown to produce cohesive dry blends due to its granular morphology and superior adhesive characteristics. As a result of its partial cold water solubility, starch functions exceptionally well in tablet manufactur by wet granulation applications and performs dual functions of both a disintegrant and a binder. In capsule filling processes, Starch and Star Cap Co-Processed Starch Excipients function as effective binders improving the uniformity of the capsule fill as well as forming a stable capsule plug.[11]

Binders are pharmaceutical excipients that are commonly used in tablet formulation to impart cohesion on the powder mix [12,13]. The resultant cohesiveness ensures that the tablet remains intact after compression [14.] Binders are used either in solutions or dry form depending on the other ingredients in the formulations and the method of preparation especially in wet granulation [13,15]. The quantity of binders used has a considerable influence on the characteristics of the compressed tablets [8,16]. Increasing the binder concentration invariably raises the disintegration times. [17]

In tablet formulations, freshly prepared corn starch paste is used at a concentration of 5–25% w/w in tablet granulations as a binder. Selection of the quantity required in a given system is determined by optimization studies, using parameters such as granule friability, tablet friability, hardness, disintegration rate, and drug dissolution rate.[9]

Classification of Binders

- Solution binders are dissolved in a solvent (for example water or alcohol can be used in wet granulation processes). Examples Corn Strach.
- Dry binders are added to the powder blend, either after a wet granulation step, or as part of a direct powder compression (DC) formula. Examples include cellulose, methyl cellulose, polyvinylpyrrolidone and polyethylene glycol. [11]

Oyi, et al (2009), conducted a research on “Comparative Binding Effects of Wheat, Rice and Maize Starches in Chloroquine Phosphate Tablet Formulations” Formula chloroquin tablets are made with various binder and with various concentrations.

Table 1: Form ular for chloroquine phosphate granules formulated using the selected starch as binder.

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Ingredients	Weight/tablet (mg)	Weight/200 tablets (g)
Chloroquine phosphate	250	50
Intragranular starch (SMS)	15.15	3.03
Binder (batch Ia, Ib, Ic, IIa, IIb, IIc, IIIa, IIIb, IIIc)	7.57	1.514
Extragranular starch (MS, BP)	23.65	4.73
Talc	6.00	1.212
Magnesium stearate	0.60	0.12
Total	303.00	60.60

Key: Ia, Ib, Ic = Official maize starch used at 2.5, 5.0, 7.5%w/v.
IIa, IIb,IIc = Rice starch used at 2.5, 5.0, 7.5%w/v.
IIIa, IIIb, IIIc = Wheat starch used at 2.5, 5.0, 7.5%w/v.
MS, BP = Maize starch BP.

Table 2: Granule properties of chloroquine phosphate formulated using the selected starches as binder

BATCH	Ia	Ib	Ic	IIa	IIb	IIc	IIIa	IIIb	IIIc
Binder concentration (%w/v)	2.5	5	7.5	2.5	5	7.5	2.5	5	7.5
Moisture content (%)	4	5	4	4	4	6	6	5	6
Flow rate (g/sec.)	6.08	6.04	5.59	5.79	5.58	5.75	5.92	6.42	4.73
Angle of repose (^{O})	26.6	26.3	25.5	25.3	25.3	23.1	25.5	26.6	25.4
Bulk density (g/ml)	0.51	0.49	0.48	0.51	0.49	0.48	0.49	0.49	0.51
Tapped density (g/ml)	0.64	0.61	0.57	0.61	0.60	0.57	0.65	0.61	0.60
Carr's index (%)	20.3	19.7	15.8	16.4	20	15.8	24.6	19.7	15
Hausner's ratio	1.25	1.24	1.19	1.2	1.22	1.19	1.33	1.24	1.18

Table 3: Tablet properties of chloroquine phosphate tablets formulated using the selected starches as binder

BATCH	Ia	Ib	Ic	IIa	IIb	IIc	IIIa	IIIb	IIIc
Binder concentration (%w/v)	2.5	5.0	7.5	2.5	5.0	7.5	2.5	5.0	7.5
Average tablet thickness (mm)	3.25	3.25	3.32	3.31	3.30	3.25	3.29	3.26	3.29
Crushing strength (kgF)	4.00	5.25	6.25	6.90	7.25	8.25	6.00	10.00	8.90
Tensile strength (MNm)	0.078	0.103	0.120	0.132	0.140	0.135	0.116	0.198	0.143
Friability (%)	4.13	1.08	0.30	1.41	1.06	0.71	1.42	0.71	0.69
Disintegration time (sec.)	141	207	129	141	185	301	261	305	297

Tablet hardness was observed to be higher with wheat starch at all the concentrations employed compared to those of rice and maize starches. This indicates that lower concentration of wheat starch could be used to achieve the same level of bond strength and probably granules made from wheat starch mucilage were more readily deformed than those produced with either rice or maize starch, but the corn starch can be used as a binder. [14]

Uhumwangho, *et al* (2006) conducted a research on "Influence of some starch binders on the brittle fracture tendency of paracetamol tablets". The study was carried out to compare the binder effects of cassava and cocoyam starch with that of maize starch BP. The parameters investigated were the brittle fracture index (BFI), the tablet packing fraction (Pf), and tensile strength (T). Mucilages of the starches of varying concentrations; 15, 20, and 25% (w/v) were formed; their viscosities were determined and used to form paracetamol granules by wet massing. The granules were compressed at different compression loads (arbitrary units on the load scale; 8, 9 and 9.5).[7]

Table 4: Effect of binder type and concentration on the tensile strength (T) and packing fraction (Pf) of the tablets.

Starch mucilage conc. (%, w/v)	Cassava			Cocoyam			Maize		
	T (MNm^{-2})	P_f	BFI	T (MNm^{-2})	P_f	BFI	T (MNm^{-2})	P_f	BFI
15	0.12	0.94	0.25	0.10	0.79	0.28	0.06	0.72	0.41
20	0.15	0.95	0.13	0.13	0.85	0.18	0.12	0.87	0.35
25	0.35	0.97	0.08	0.15	0.86	0.15	0.14	0.89	0.28

Note: Compression load, 8 arbitrary units on load scale.

The results (Table 4) showed that cassava starch binder produced harder and more compact tablets compared with the cocoyam and the maize starch binders. Cassava starch is therefore the more effective binder which is

attributable to the higher gel strength of its mucilages. Increase in binder concentration generally led to an increase in Pf and T values irrespective of the nature of the binder. It is known that binders promote plastic deformation of particles and thereby increase the area of contact for interparticulate bonding. Hence, an increase in T is invariably associated with an increase in Pf values of the tablets. The results (Table 4) thus showed that granules made with the cassava starch mucilage were more readily deformable than those produced with either cocoyam or maize starch, but the corn starch can be used as a binder.[7]

Table 5: Effect of compression load on the brittle fracture tendency of the tablets.

Arbitrary unit on the load scale	BFI values of tablets with binders		
	Cassava starch	Cocoyam starch	Maize starch BP
8	0.13	0.18	0.35
9	0.20	0.22	0.38
9.5	0.32	0.33	0.41

Note: mucilage concentration used in forming the granules is 20% (w/v).

The study has shown that cassava starch mucilage is a more effective binder than the mucilage of maize starch BP, producing harder tablets with lower brittle fracture tendency. Also, the study underscores the need to moderate the applied loads if the incidence of brittle fracture is to be minimized during tableting.[7]

Starch as Disintegran

Starch is one of the most commonly used tablet disintegrants at concentrations of 3–15% w/w.[3,11] However, unmodified starch does not compress well and tends to increase tablet friability and capping if used in high concentrations. In granulated formulations, about half the total starch content is included in the granulation mixture and the balance as part of the final blend with the dried granulation. Also, when used as a disintegrant, starch exhibits type II isotherms and has a high specific surface for water sorption.[9]

Disintegrants bring about tablet matrix break-up in an aqueous medium and are commonly classified further in literature as disintegrants and superdisintegrants. “Normal” disintegrants include starch- and cellulose-based excipients such as corn starch, partially pregelatinized starch, microcrystalline cellulose, and lowsubstituted hydroxypropyl cellulose. Some clays (e.g., Veegum HV),gums (e.g., agar, guar, tragacanth, alginate), resins (e.g., polacrilin potassium), and finely divided solids (e.g., colloidal silicon dioxide, magnesium aluminum silicate) have also been employed as disintegrants.[19]

The most accepted mechanism for tablet disintegration is by disintegrant swelling. Swelling is associated with dimensional amplification where particles enlarge omni-directionally to push apart the adjoining components, thereby initiating the break-up of the tablet matrix.[19]

Disintegration leads to the breakup of the tablet into the component granules, thereby presenting a greater surface area of the tablet to the dissolution medium before the active drug substance is finally released from the tablet. An immediate release tablet formulation of a drug is usually not useful until it‘s active component is made available for absorption hence the disintegrant arguably become the most important excipient in a tablet to facilitate immediate drug release. Although modified release dosage forms is the focus of most research due to their benefits such as reduced dosing frequency and attendant improved patient adherence, reduced side effects and increased duration of therapeutic action; immediate release dosage forms still occupy a crucial space in drug delivery especially in disease conditions that require rapid onset of action.[20]

Musiliu *et al* (2009), conducted a research “Disintegrant activities of natural and pregelatinized trifoliate yams, rice and corn starches in paracetamol tablet” Results is shown by Fig. 1.

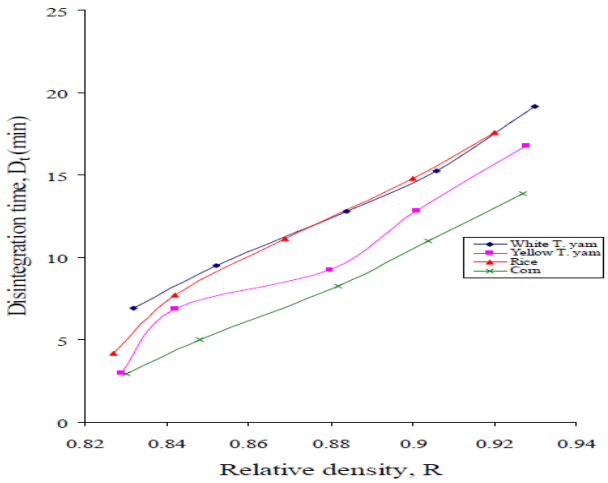

Figure. 1: Plots of disintegration time (Dt) versus relative density (R) for paracetamol tablets formulated with 6% w/w natural starch exo-disintegrants (Musiliu *et al*., 2009)

The disintegrant activity of starches is determined by their nature, form, mode of incorporation and their concentration. Physicochemical parameters as water solubility, swelling capacity as well as water absorption capacity exhibit some direct effect on disintegrant activity of the starches. Pregelatinized starches produced better combined disintegrant properties of (Cs/Fr)/Dt than natural starches. White T. yam starch gave the best (Cs/Fr)/Dt ratio of all the starches. Tablets formulated with official corn starch disintegrant exhibited the lowest disintegration time values, but generally all the tablets containing the experimental starches also passed the official disintegration time test.[21]

Starch As A Diluent

As a diluent, starch is used for the preparation of standardized triturates of colorants or potent drugs to facilitate subsequent mixing or blending processes in manufacturing operations. Starch is also used in dry-filled capsule formulations for volume adjustment of the fill matrix.[22]

Diluents are fillers used to increase the bulk volume of a tablet or capsule. By combining a diluent with the active pharmaceutical ingredients, the final product is given adequate weight and size to assist in production and handling.

To provide satisfactory performance in a tablet dosage form, a diluent should be:

- Inert so as not to cause pharmacological activity of its own.
- Compatible with the drug substance and other excipients used in the formulation.
- Non-hygroscopic so the formulation does not absorb significant amounts of moisture from its surroundings.
- Compactable and of similar particle size to the active ingredient.

Diluents may serve multiple functions in addition to being filler. Multifunctional starch excipients, such as Starch 1500® partially pregelatinized maize starch and Star Cap 1500® co-processed starch excipient can serve as binders, disintegrants, flow aids, lubricants and/or taste masking. They also promote formulation flexibility by complementing and enhancing the functionality of other excipients.[11]

Study on the physicochemical properties of Saudi starch as a tablet excipient was carried out by Alanazi et al[23]. The Saudi corn starch was compared to an imported corn starch that is used by a leading pharmaceutical company. The comparison included the following examinations: quality control data, physical characterization, binding properties, granulation effect and disintegrant properties. Theophylline was used as a model drug to evaluate its release behavior from tablet prepared from both the Saudi and the imported starch. Different dissolution parameters were evaluated such as percent dissolution and relative dissolution rate. The two compared starches were also subjected to freeze or spray drying process to enhance their pharmaceutical properties.

CONCLUSIONS

Therefore, the correct selection of excipient will hugely affecting the preparation result. Starch is a very good excipient and has a lot of advantages wheather as a binder, disintegrant and diluent.

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