NSF/ANSI 455-4 GOOD MANUFACTURING PRACTICES FOR OVER-THE-COUNTER DRUGS INFORMATION GUIDE

INFORMATION GUIDE

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On behalf of the NSF Health Sciences Certification Program, we thank you for choosing NSF as your GMP certification service provider. By working with NSF, you are demonstrating your pledge to produce quality products. NSF is a public health and safety organization, committed to protecting public health and mitigating risk for our clients and consumers. This commitment means that we must continuously improve our program and incorporate the latest regulations, guidance and industry best practices.

Below are reading materials that will help you prepare for the new standard NSF/ANSI 455-4 Good Manufacturing Practices for Over-the-Counter Drugs (OTCs).

21 CFR Part 210 Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, Or Holding Of Drugs; General

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=210

21 CFR Part 211 Current Good Manufacturing Practice for Finished Pharmaceuticals

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=211

21 CFR Part 11 Electronic Records; Electronic Signatures

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11

21 CFR Part 7 Subpart C, Recalls (Including Product Corrections) – Guidance on Policy, Procedures, and Industry Responsibilities

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=7

US FDA, Guidance for Industry: Process Validation: General Principles and Practices, January 2011

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/process-validation-general-principles-and-practices

ICH, Harmonised Tripartite Guideline, Q7: Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients, November 2000

https://www.ich.org/products/guidelines/quality/quality-single/article/good-manufacturing-practice-guide-for-active-pharmaceutical-ingredients.html

ICH, Harmonised Tripartite Guideline, Q10: Pharmaceutical Quality System, June 2008

https://www.ich.org/products/guidelines/quality/quality-single/article/pharmaceutical-quality-system.html

British Retail Consortium (BRC) – 2015, Global Standard for Food Safety, Issue 7

https://www.brcgs.com/brcgs/food-safety

NSF/ANSI 455-4 Good Manufacturing Practices for Over-the-Counter Drugs*

NSF/ANSI 455-4 Good Manufacturing Practices for Over-the-Counter Drugs Audit Requirements Guideline*

NSF International Certification Policies – NSF/ANSI 455*

*Note: Available in NSF Connect

2. Certification Overview and Benefits

Overview

Good Manufacturing Practices (GMPs) are guidelines that provide a system of processes, procedures and documentation. These GMP requirements are listed in NSF/ANSI 455-4 GMP standard which is developed by the OTCs industry in accordance with 21 CFR Part 210 and 21 CFR Part 211.

NSF International independently certifies manufacturers as meeting GMP requirements. The program is open not just to manufacturers of OTCs, but also to manufacturers of ingredients, raw materials, components, and packaging and labeling companies who want to demonstrate their commitment to public safety.

Benefits

- Provides risk-based audits to 21 CFR Part 210 and 21 CFR Part 211
- Prepares a facility for FDA inspections
- Allows a facility to benchmark its quality systems
- Helps facilities to build a strong quality and GMP program
- Serves as a communication tool between manufacturers of OTCs, regulators, retailers, and consumers
- ANSI logo on certificates for global acceptance

3. Certification Documents

1. NSF/ANSI 455-4 Good Manufacturing Practices for Over-the-Counter Drugs

This standard was developed by the NSF Joint Committee on GMP for OTC drugs using the consensus process described by the American National Standards Institute. Participation from OTC drugs manufacturers, public health regulators, and consumers and retailers of OTC drugs.

This standard is intended to define a standardized approach for auditing to determine the level of compliance of OTC drug products to 21 CFR Part 210 Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General and 21 CFR Part 211 Current Good Manufacturing Practice for Finished Pharmaceuticals, as well as incorporating additional retailer requirements. It refers to the requirements for good manufacturing practices (GMPs) applicable to all OTC drugs. It will assist in the determination of adequate facilities and controls for OTC drugs manufacturers with sufficient quality to ensure suitability for intended use.

The standard has the following format and organization.

- "Shall" is used to state mandatory requirements.
- Document is written as follows:

Section (#) – Area of focus

Sub-Section (#. #), (#. #. #) – ISO quality management principle

Requirement (#. #. #), (#. #. #. #) – Standard requirement

Example 1:

4 Audit requirements

4.1 Context of the organization

4.1.2 Manufacturers of OTC drug products shall have a current drug establishment registration with the US FDA [US FDA Registration].

Example 2:

4 Audit requirements

4.5 Support

4.5.1 Resources

4.5.1.1 Adequate resources (human, financial, materials, facilities, and equipment) are provided to implement, maintain, and improve the quality system. [ICH Q10]

*Note: 4.5.1 to 4.5.4 are sub-sections.

3. Certification Documents (cont'd)

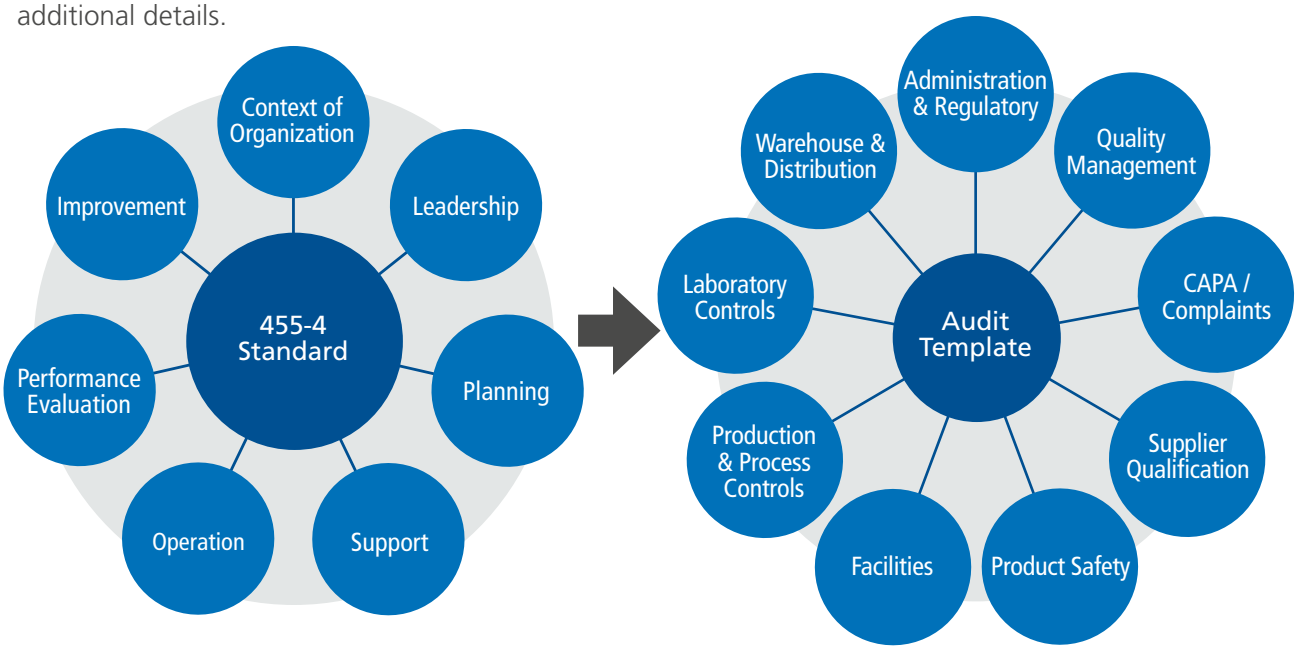
> The criteria in this standard was structured to be in the ISO 9001:2015 format, following a 7 systems approach.

- Content of Organization
- Leadership
- Planning
- Support
- Operation
- Performance Evaluation
- Improvement

2. NSF/ANSI 455-4 Good Manufacturing Practices for Over-the-Counter Drugs Audit Template

The audit template is a tool used by auditors to assist in their on-site verification activity for compliance to the standard.

To facilitate audit flow, the format of the audit template is rearranged in different sections compared to the sections in the NSF/ANSI 455-4 GMP standard. See graphical representation below comparing the two. Refer to section Comparison of NSF/ANSI 455-4 GMP Standard and Audit Template for additional details.



NSF/ANSI 455-4 GMP Standard | **Audit Template**

3. Certification Documents (cont'd)

3. NSF/ANSI 455-4 Good Manufacturing Practices for Over-the-Counter Drugs Audit Requirements Guideline (ARG)

The document was developed to assist auditors and manufacturers to understand and interpret the requirements of the NSF/ANSI 455-4 GMP. The information in the guideline reflects the most current approach to achieving compliance with the standard requirements.

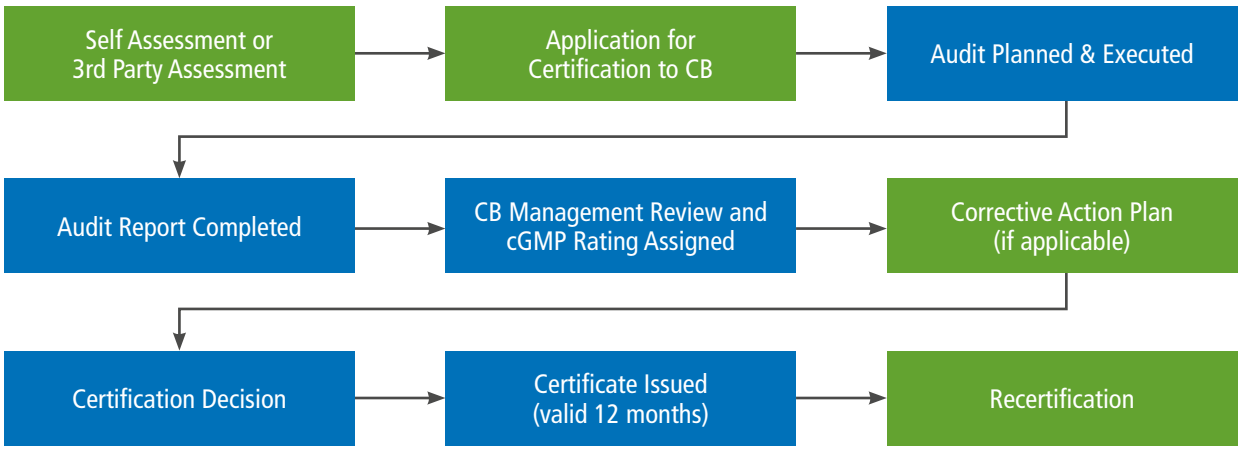
4. NSF International Certification Policies – NSF/ANSI 455

The document describes the framework for the administration of the program. The policies include, but are not limited to:

- Audit scope and process
- Requirements for acquiring and maintaining GMP certification
- Certification and monitoring audits
- Criteria for audit grade determination and audit frequency
- Requirements and timelines for corrective action responses
- Requirements for the correct use of NSF GMP certification marks

4. Certification Process

All clients shall go through a standardized audit process to gain certification. Below is an overview of the process.

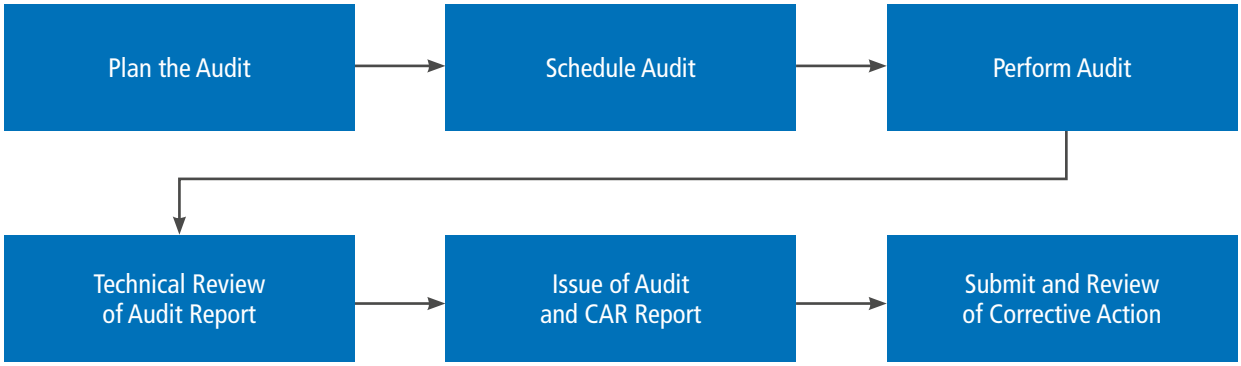


Legend:

- NSF Responsibility
- Client Responsibility

5. Audit Process

This is the general flow of the audit process.



1. Classification of Nonconformances

The auditor will cite a nonconformance when observations are made and evidence is collected during the audit that shows non-compliance with the standard requirement. Based on the auditor's judgement, nonconformances are classified according to severity and risk to product safety. The severity of nonconformances are then confirmed through a technical review prior to release of the audit report.

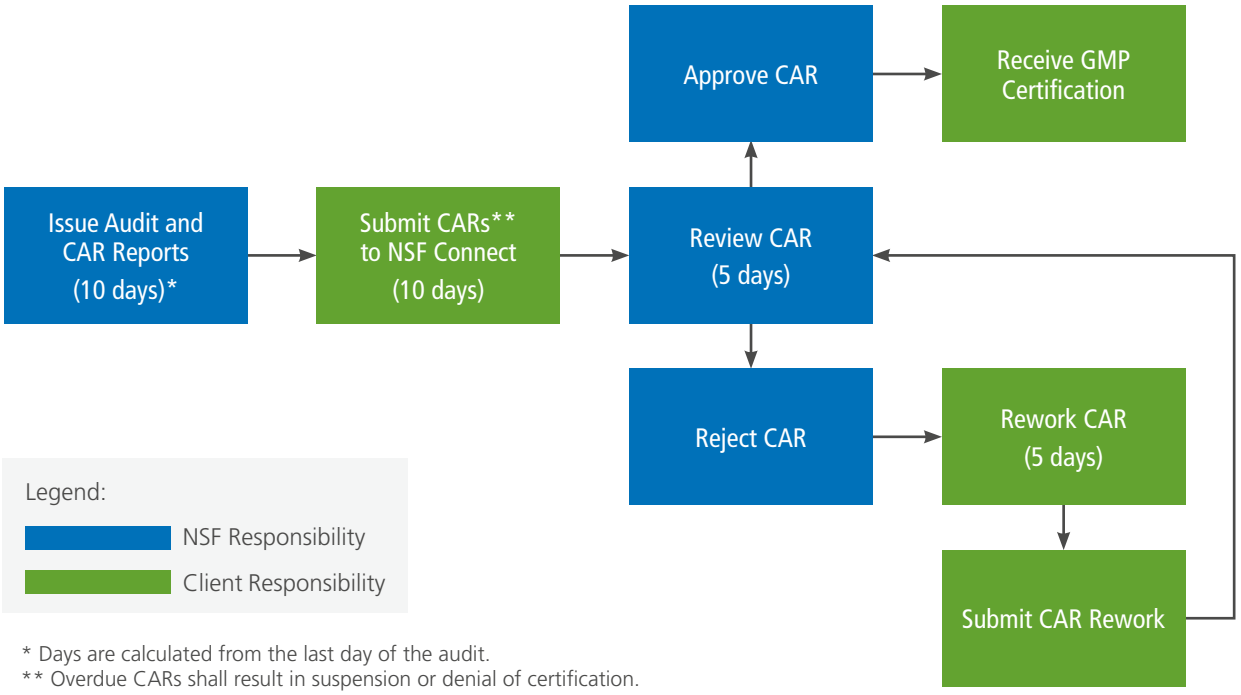
The following are the three (3) levels of nonconformances:[1]:

- Critical nonconformance – A nonconformance or condition which has produced, or may lead to a significant risk of an unsafe or hazardous product which may be harmful and puts the consumer at risk of serious injury or death.
- Major nonconformance – A nonconformance other than critical that results in failure in one or more of the quality sub-systems; or a combination of "minor" nonconformances none of which on their own may be major, but which may together represent a major nonconformance and shall be explained and reported as such.
- Minor nonconformance – A nonconformance where an element of GMP has not been fully met or does not adversely affect the performance, reliability, or use of use of a product; but on the basis of objective evidence does not meet the definition of a major nonconformance. Multiple minor nonconformances when considered collectively may raise the category to a major nonconformance

[1] NSF/ANSI 455-4-2018 – Good Manufacturing Practices for Over-the-Counter Drugs, section 5.5.9

5. Audit Process (cont'd)

Where nonconformances are cited, corrective action must be submitted to NSF for review. Below is the general flow of the corrective action process, post audit.



* Days are calculated from the last day of the audit.
** Overdue CARs shall result in suspension or denial of certification.

5. Audit Process (cont'd)

2. Audit Grade

The auditor submits a draft report for technical review after the audit. At the technical review, the nonconformances are confirmed and the audit grade is determined based on the number and severity of nonconformances cited.

Summary of Grading Model[2]

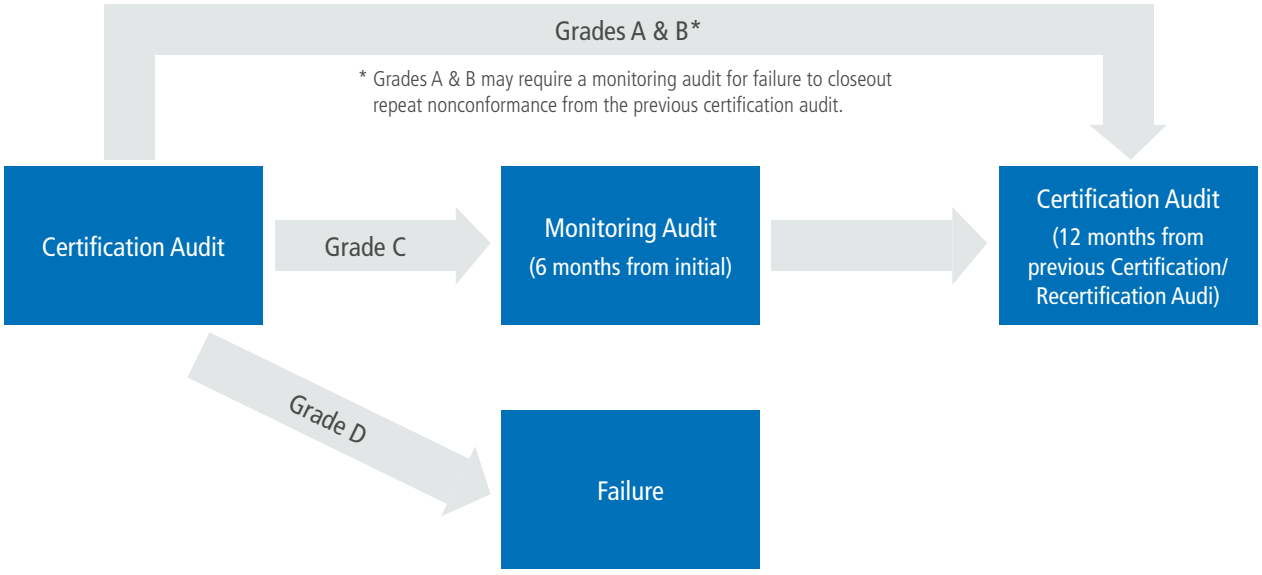
Grade	Critical	Major	Minor
A	0	0	≤ 6
B	0	1	≤ 6
B	0	0	7 to 12
C	0	1	7 to 12
C	0	0	13 to 18
D	≥ 1	–	–
D	0	≥ 2	–
D	0	1	≥ 13
D	0	0	≥ 19

[2] NSF/ANSI 455-4-2018 – Good Manufacturing Practices for Over-the-Counter Drugs, Table 5.2

5. Audit Process (cont'd)

3. Audit Frequency

The frequency of audits is based on the audit grade. Below is the general audit cycle. Please refer to NSF/ANSI 455-4 GMP Section 5 for a more detailed explanation.



6. Comparison of NSF/ANSI 455-4 GMP Standard and Audit Template

To facilitate audit flow, the format of the audit template is rearranged into sections different from the NSF/ANSI 455-4 GMP standard. The table below shows the distribution of NSF/ANSI 455-4 GMP standard elements in the audit template sections.

Audit Template Sections	Title	NSF/ANSI 455-4 GMP Standard Requirement No.				
Section 0	Visit Summary	5.5.1, 5.5.3, 5.5.8				
Section 1	Client Logistics	1.1, 1.2, 1.3, 3.43				
Section A	Administration and Regulatory	4.1.1				
Section B	Quality Management	4.3.6 4.3.7 4.2.4 4.2.3 4.4.1 4.5.1.1 4.2.1 4.4.2	4.3.5 4.2.5 4.2.2 4.8.2 4.7.9 4.8.4 4.8.3 4.3.2	4.3.1 4.3.8 4.5.1.3 4.3.9 4.5.4.1 4.5.4.4 4.6.55 4.5.4.2	4.5.4.3 4.5.4.5 4.5.4.7 4.6.49 4.6.50 4.6.51 4.6.52 4.6.53	4.6.54 4.5.4.6 4.7.15 4.6.6
Section C	Corrective and Preventive Actions & Complaints	4.8.1 4.7.10	4.7.11 4.7.14	4.7.12 4.7.13	4.7.8	
Section D	Supplier Qualification	4.6.2, 4.6.7, 4.6.4, 4.6.5				
Section E	Product Safety	4.5.2.3 4.5.2.20	4.5.1.2 4.5.2.5	4.5.2.6 4.6.10	4.6.20 4.6.23	4.6.31

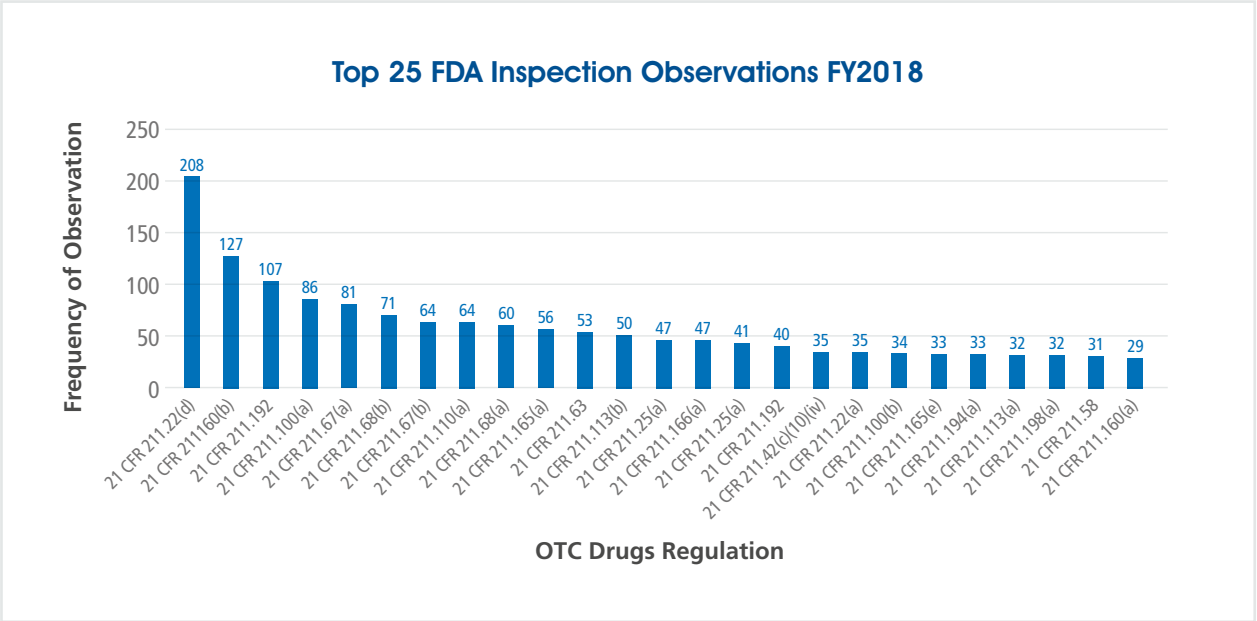
6. Comparison of NSF/ANSI 455-4 GMP Standard and Audit Template (cont'd)

Audit Template Sections	Title	NSF/ANSI 455-4 GMP Standard Requirement No.				
Section F	Facilities	4.5.2.21	4.5.2.16	4.6.25	4.5.2.17	4.6.11
		4.5.2.23	4.6.13	4.6.22	4.5.2.18	4.6.18
		4.5.2.25	4.6.14	4.5.2.28	4.5.2.19	4.5.2.1
		4.5.2.24	4.6.21	4.5.2.11	4.5.2.12	4.5.2.4
		4.5.3.4	4.6.15	4.5.2.9	4.5.2.29	4.5.2.8
		4.5.2.26	4.6.12	4.5.2.10	4.6.19	4.5.2.7
		4.5.2.22	4.5.2.30	4.5.2.13	4.5.3.2	
		4.5.2.27	4.6.24	4.5.2.14	4.5.3.3	
		4.5.2.15	4.6.16	4.5.2.2	4.5.3.1	
Section G	Production and Process Controls – Manufacturing, Packaging Operations & Specification, Product Release and Returns	4.3.3	4.6.34	4.6.39	4.3.4	4.6.28
		4.6.1	4.6.35	4.6.37	4.6.3	4.6.29
		4.6.32	4.6.36	4.6.40	4.7.4	4.6.26
		4.6.56	4.6.41	4.6.42	4.7.16	4.6.30
		4.7.1	4.6.38	4.6.43	4.7.7	4.6.27
		4.6.33	4.6.44	4.6.45	4.7.5	
Section H	Laboratory Controls	4.7.2, 4.7.3, 4.7.6, 4.7.17, 4.7.18				
Section I	Warehouse and Distribution Controls	4.6.46, 4.6.9, 4.6.17, 4.6.47, 4.6.48, 4.6.8				
Section J	NSF Certification Policies	Compliance against NSF certification policies				

7. Top 25 FDA OTC Drugs Inspection Observations

During a FDA inspection of a facility, the inspector may observe conditions or practices that may be deemed to be in violation of FDA's requirements. The graph and table below summarize the top 25 observations in 2018 for OTC drugs against 21 CFR Part 211.

For additional information, please refer to:
https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/inspection-observations



7. Top 25 FDA OTC Drugs Inspection Observations (cont'd)

Top Citations	Reference Number	Short Description	Long Description
1	21 CFR 211.22(d)	Procedures not in writing, fully followed	The responsibilities and procedures applicable to the quality control unit are not [in writing] [fully followed].
2	21 CFR 211.160(b)	Scientifically sound laboratory controls	Laboratory controls do not include the establishment of scientifically sound and appropriate [specifications] [standards] [sampling plans] [test procedures] designed to assure that [components] [drug product containers] [closures] [in-process materials] [labeling] [drug products] conform to appropriate standards of identity, strength, quality and purity.
3	21 CFR 211.192	Investigations of discrepancies, failures	There is a failure to thoroughly review [any unexplained discrepancy] [the failure of a batch or any of its components to meet any of its specifications] whether or not the batch has been already distributed.
4	21 CFR 211.100(a)	Absence of written procedures	There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.
5	21 CFR 211.67(a)	Cleaning / Sanitizing / Maintenance	Equipment and utensils are not [cleaned] [maintained] [sanitized] at appropriate intervals to prevent [malfunctions] [contamination] that would alter the safety, identity, strength, quality or purity of the drug product.
6	21 CFR 211.68(b)	Computer control of master formula records	Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

7. Top 25 FDA OTC Drugs Inspection Observations (cont'd)

Top Citations	Reference Number	Short Description	Long Description
7	21 CFR 211.67(b)	Written procedures not established/ followed	Written procedures are not [established] [followed] for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.
8	21 CFR 211.110(a)	Control procedures to monitor and validate performance	Control procedures are not established which [monitor the output] [validate the performance] of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.
9	21 CFR 211.68(a)	Calibration/ Inspection/Checking not done	Routine [calibration] [inspection] [checking] of [automatic] [mechanical] [electronic] equipment is not performed according to a written program designed to assure proper performance.
10	21 CFR 211.165(a)	Testing and release for distribution	Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the [final specifications] [identity and strength of each active ingredient] prior to release.
11	21 CFR 211.63	Equipment design, size and location	Equipment used in the manufacture, processing, packing or holding of drug products is not [of appropriate design] [of adequate size] [suitably located] to facilitate operations for its [intended use] [cleaning and maintenance].
12	21 CFR 211.113(b)	Procedures for sterile drug products	Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not [established] [written] [followed].

7. Top 25 FDA OTC Drugs Inspection Observations (cont'd)

Top Citations	Reference Number	Short Description	Long Description
13	21 CFR 211.25(a)	Training, Education, Experience overall	Employees engaged in the [manufacture] [processing] [packing] [holding] of a drug product lack the [education] [training] [experience] required to perform their assigned functions.
14	21 CFR 211.166(a)	Lack of written stability program	There is no written testing program designed to assess the stability characteristics of drug products.
15	21 CFR 211.25(a)	Training-operations, GMPs, written procedures	Employees are not given training in [the particular operations they perform as part of their function] [current good manufacturing practices] [written procedures required by current good manufacturing practice regulations].
16	21 CFR 211.192	Written record of investigation incomplete	Written records of investigations into [unexplained discrepancies] [the failure of a batch or any of its components to meet specifications] do not [always] include the conclusions and follow-up.
17	21 CFR 211.42(c)(10)(iv)	Environmental monitoring system	Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.
18	21 CFR 211.22(a)	Lack of quality control unit	There is no quality control unit.
19	21 CFR 211.100(b)	SOPs not followed / documented	Written production and process control procedures are not [followed in the execution of production and process control functions] [documented at the time of performance].
20	21 CFR 211.165(e)	Test methods	The [accuracy] [sensitivity] [specificity] [reproducibility] of test methods have not been [established] [documented].

7. Top 25 FDA OTC Drugs Inspection Observations (cont'd)

Top Citations	Reference Number	Short Description	Long Description
21	21 CFR 211.194(a)	Complete test data included in records	Laboratory records do not include complete data derived from all tests, examinations and assay necessary to assure compliance with established specifications and standards.
22	21 CFR 211.113(a)	Procedures for non-sterile drug products	Procedures designed to prevent objectionable microorganisms in drug products not required to be sterile are not [established] [written] [followed].
23	21 CFR 211.198(a)	Complaint handling procedure	Procedures describing the handling of written and oral complaints related to drug products are [not written or followed] [deficiently written or followed].
24	21 CFR 211.58	Buildings not maintained in good state of repair	Buildings used in the [manufacturing] [processing] [packing] [holding] of a drug product are not maintained in a good state of repair.
25	21 CFR 211.160(a)	Following/ documenting laboratory controls	Established [specifications] [standards] [sampling plans] [test procedures] [laboratory control mechanisms] are not [followed] [documented at the time of performance].

WHAT SHOULD YOU DO?
NSF/ANSI 455-4 GMP STANDARD IS HERE!

Become informed

> Review the NSF materials and tools

- NSF/ANSI 455 GMP Policies
- NSF/ANSI 455-4 GMP Standard
- NSF/ANSI 455-4 GMP ARG
- Audit Template
- Training Videos

> Review regulations and guidelines applicable to OTC Drugs

- 21 CFR Part 11; 21 CFR Part 210 and 21 CFR Part 211
- ICH, Harmonised Tripartite Guideline, Q7: Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients, November 2000
- ICH, Harmonised Tripartite Guideline, Q10: Pharmaceutical Quality System, June 2008

Plan your application for certification

> Review and confirm the scope applicable to your operations

> Communicate the standard requirements to your organization

> Perform a self-assessment and gap analysis of your current operations against the standard

> Contact NSF if you have questions

Submit application for certification to NSF

> Prepare the documents as required by the standard and by NSF include, but are not limited to:

- Company organizational chart
- Site plan
- Process flow diagram
- List of products and technologies included in the scope of the audit
- Typical shift/schedule patterns
- Standard operating procedures index/table of contents
- Regulatory inspection history (past five years)
- Site regulatory registration
- Submit completed and signed documents to NSF

> Contact NSF if you have questions

NSF HAS THE TOOLS

Whether you are currently registered or are looking to newly register, we have the tools to help you prepare for your next certification audit.

Audit Template

Top FDA OTC Drugs Observations

NSF/ANSI 455 Certification Policies

NSF/ANSI 455-4 GMP Standard for OTC Drugs

Webinar

Information Guide

NSF/ANSI 455-4 GMP ARG for OTC Drugs

Regulatory Resource Links

FAQs

10. Implementation Timeline for NSF/ANSI 455-4 GMP Standard

Starting November 2019 NSF is offering certification to NSF/ANSI 455-4 GMP standard. Please contact your account manager to start the certification process for your company.

Annex 1: Detailed Comparison of NSF/ANSI 455-4 GMP Standard & Audit Template

Question Number NSF/ANSI 455-4 GMP Audit Template	Section NSF/ANSI 455-4 GMP Audit Template	NSF/ANSI 455-4 GMP Requirement Number	NSF/ANSI 455-4 GMP Requirement Section
1-7	Visit Summary and Client Logistics	NA	NA
8	Administration and Regulatory	4.1.1	Context of the organization
9	Quality Management	4.3.6	Organization roles, responsibilities, and authorities
10	Quality Management	4.3.7	Organization roles, responsibilities, and authorities
11	Quality Management	4.2.4	Leadership and commitment
12	Quality Management	4.2.3	Leadership and commitment
13	Quality Management	4.4.1	Planning
14	Quality Management	4.5.1.1	Support
15	Quality Management	4.2.1	Leadership and commitment
16	Quality Management	4.4.2	Planning
17	Quality Management	4.3.5	Organization roles, responsibilities, and authorities
18	Quality Management	4.2.5	Leadership and commitment
19	Quality Management	4.2.2	Leadership and commitment
20	Quality Management	4.8.2	Improvement
21	Quality Management	4.7.9	Performance evaluation
22	Quality Management	4.8.4	Improvement
23	Quality Management	4.8.3	Improvement
24	Quality Management	4.3.2	Organization roles, responsibilities, and authorities

Question Number NSF/ANSI 455-4 GMP Audit Template	Section NSF/ANSI 455-4 GMP Audit Template	NSF/ANSI 455-4 GMP Requirement Number	NSF/ANSI 455-4 GMP Requirement Section
25	Quality Management	4.3.1	Organization roles, responsibilities, and authorities
26	Quality Management	4.3.8	Organization roles, responsibilities, and authorities
27	Quality Management	4.5.1.3	Support
28	Quality Management	4.3.9	Organization roles, responsibilities, and authorities
29	Quality Management	4.5.4.1	Support
30	Quality Management	4.5.4.4	Support
31	Quality Management	4.6.55	Operation
32	Quality Management	4.5.4.2	Support
33	Quality Management	4.5.4.3	Support
34	Quality Management	4.5.4.5	Support
35	Quality Management	4.5.4.7	Support
36	Quality Management	4.6.49	Operation
37	Quality Management	4.6.50	Operation
38	Quality Management	4.6.51	Operation
39	Quality Management	4.6.52	Operation
40	Quality Management	4.6.53	Operation
41	Quality Management	4.6.54	Operation
42	Quality Management	4.5.4.6	Support
43	Quality Management	4.7.15	Performance evaluation
44	Quality Management	4.6.6	Operation
45	Corrective and Preventive Actions and Complaints	4.8.1	Improvement
46	Corrective and Preventive Actions and Complaints	4.7.10	Performance evaluation

Question Number NSF/ANSI 455-4 GMP Audit Template	Section NSF/ANSI 455-4 GMP Audit Template	NSF/ANSI 455-4 GMP Requirement Number	NSF/ANSI 455-4 GMP Requirement Section
47	Corrective and Preventive Actions and Complaints	4.7.11	Performance evaluation
48	Corrective and Preventive Actions and Complaints	4.7.14	Performance evaluation
49	Corrective and Preventive Actions and Complaints	4.7.12	Performance evaluation
50	Corrective and Preventive Actions and Complaints	4.7.13	Performance evaluation
51	Corrective and Preventive Actions and Complaints	4.7.8	Performance evaluation
52	Supplier Qualification	4.6.2	Operation
53	Supplier Qualification	4.6.7	Operation
54	Supplier Qualification	4.6.4	Operation
55	Supplier Qualification	4.6.5	Operation
56	Product Safety	4.5.2.3	Support
57	Product Safety	4.5.2.20	Support
58	Product Safety	4.5.1.2	Support
59	Product Safety	4.5.2.5	Support
60	Product Safety	4.5.2.6	Support
61	Product Safety	4.6.10	Operation
62	Product Safety	4.6.20	Operation
63	Product Safety	4.6.23	Operation
64	Product Safety	4.6.31	Operation
65	Facilities	4.5.2.21	Support
66	Facilities	4.5.2.23	Support
67	Facilities	4.5.2.25	Support
68	Facilities	4.5.2.24	Support
69	Facilities	4.5.3.4	Support
70	Facilities	4.5.2.26	Support
71	Facilities	4.5.2.22	Support

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72	Facilities	4.5.2.27	Support
73	Facilities	4.5.2.15	Support
74	Facilities	4.5.2.16	Support
75	Facilities	4.6.13	Operation
76	Facilities	4.6.14	Operation
77	Facilities	4.6.21	Operation
78	Facilities	4.6.15	Operation
79	Facilities	4.6.12	Operation
80	Facilities	4.5.2.30	Support
81	Facilities	4.6.24	Operation
82	Facilities	4.6.16	Operation
83	Facilities	4.6.25	Operation
84	Facilities	4.6.22	Operation
85	Facilities	4.5.2.28	Support
86	Facilities	4.5.2.11	Support
87	Facilities	4.5.2.9	Support
88	Facilities	4.5.2.10	Support
89	Facilities	4.5.2.13	Support
90	Facilities	4.5.2.14	Support
91	Facilities	4.5.2.2	Support
92	Facilities	4.5.2.17	Support
93	Facilities	4.5.2.18	Support
94	Facilities	4.5.2.19	Support
95	Facilities	4.5.2.12	Support
96	Facilities	4.5.2.29	Support
97	Facilities	4.6.19	Operation
98	Facilities	4.5.3.2	Support
99	Facilities	4.5.3.3	Support

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100	Facilities	4.5.3.1	Support
101	Facilities	4.6.11	Operation
102	Facilities	4.6.18	Operation
103	Facilities	4.5.2.1	Support
104	Facilities	4.5.2.4	Support
105	Facilities	4.5.2.8	Support
106	Facilities	4.5.2.7	Support
107	Production and Process Controls – Manufacturing Operations	4.3.3	Organization roles, responsibilities, and authorities
108	Production and Process Controls – Manufacturing Operations	4.6.1	Operation
109	Production and Process Controls – Manufacturing Operations	4.6.32	Operation
110	Production and Process Controls – Manufacturing Operations	4.6.56	Operation
111	Production and Process Controls – Manufacturing Operations	4.7.1	Performance evaluation
112	Production and Process Controls – Manufacturing Operations	4.6.33	Operation
113	Production and Process Controls – Manufacturing Operations	4.6.34	Operation
114	Production and Process Controls – Manufacturing Operations	4.6.35	Operation
115	Production and Process Controls – Packaging Operations	4.6.36	Operation
116	Production and Process Controls – Packaging Operations	4.6.41	Operation
117	Production and Process Controls – Packaging Operations	4.6.38	Operation

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118	Production and Process Controls – Packaging Operations	4.6.44	Operation
119	Production and Process Controls – Packaging Operations	4.6.39	Operation
120	Production and Process Controls – Packaging Operations	4.6.37	Operation
121	Production and Process Controls – Packaging Operations	4.6.40	Operation
122	Production and Process Controls – Packaging Operations	4.6.42	Operation
123	Production and Process Controls – Packaging Operations	4.6.43	Operation
124	Production and Process Controls – Packaging Operations	4.6.45	Operation
125	Production and Process Controls – Specifications, Product Release and Returns	4.3.4	Organization roles, responsibilities, and authorities
126	Production and Process Controls – Specifications, Product Release and Returns	4.6.3	Operation
127	Production and Process Controls – Specifications, Product Release and Returns	4.7.4	Performance evaluation
128	Production and Process Controls – Specifications, Product Release and Returns	4.7.16	Performance evaluation
129	Production and Process Controls – Specifications, Product Release and Returns	4.7.7	Performance evaluation
130	Production and Process Controls – Specifications, Product Release and Returns	4.7.5	Performance evaluation
131	Production and Process Controls – Specifications, Product Release and Returns	4.6.28	Operation
132	Production and Process Controls – Specifications, Product Release and Returns	4.6.29	Operation
133	Production and Process Controls – Specifications, Product Release and Returns	4.6.26	Operation

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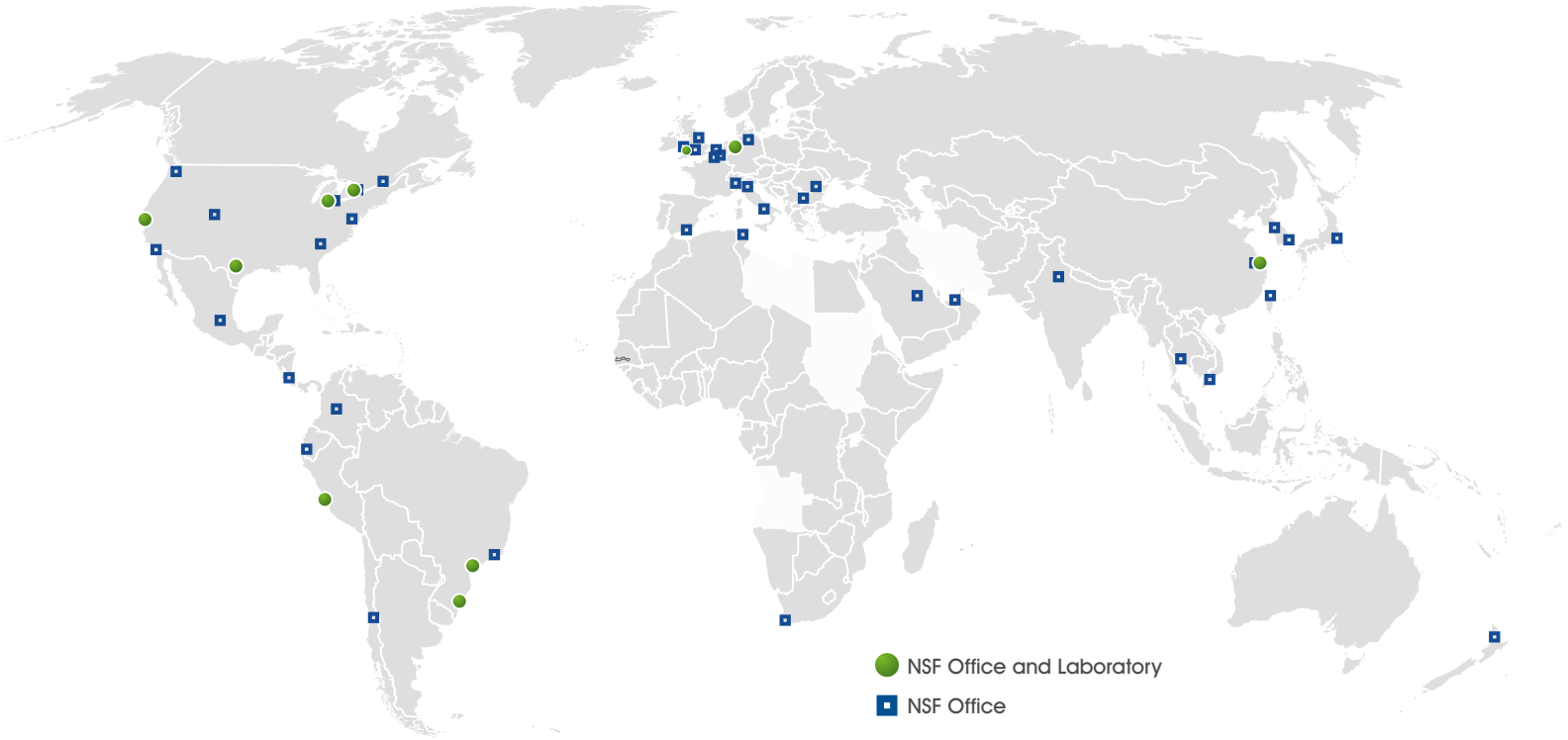
	Production and Process Controls – Specifications, Product Release and Returns	4.6.30	Operation
135	Production and Process Controls – Specifications, Product Release and Returns	4.6.27	Operation
136	Laboratory Controls	4.7.2	Performance evaluation
137	Laboratory Controls	4.7.3	Performance evaluation
138	Laboratory Controls	4.7.6	Performance evaluation
139	Laboratory Controls	4.7.17	Performance evaluation
140	Laboratory Controls	4.7.18	Performance evaluation
141	Warehouse and Distribution	4.6.46	Operation
142	Warehouse and Distribution	4.6.9	Operation
143	Warehouse and Distribution	4.6.17	Operation
144	Warehouse and Distribution	4.6.47	Operation
145	Warehouse and Distribution	4.6.48	Operation
146	Warehouse and Distribution	4.6.8	Operation



NSF International is a global public health organization that operates in more than 175 countries, with worldwide laboratory testing facilities and expert resources across a wide range of professional fields including health sciences, software, food and beverages, sustainability and agriculture.

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