NSF International Standard /
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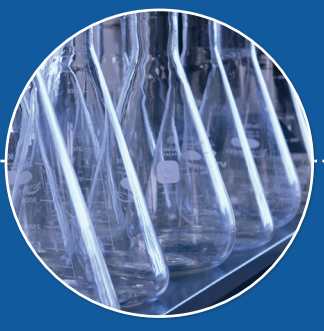
NSF/ANSI 455-4 - 2022

Good Manufacturing Practices for Over-the-Counter Drugs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Chair, Joint Committee on GMP for Over-the-Counter Drugs
c/o NSF International
789 North Dixboro Road, P.O. Box 130140
Ann Arbor, Michigan 48113-0140 U.S.A.
Phone: (734) 769-8010 Fax: (734) 769-0109
Email: info@nsf.org
Web: <www.nsf.org>

NSF International Standard /
American National Standard
for Health Sciences –

Good Manufacturing Practices for Over-the-Counter Drugs

Standard Developer
NSF International

Designated as an ANSI Standard
June 17, 2022
American National Standards Institute

Prepared by
The NSF Joint Committee on GMP for Over-the-Counter Drugs

Recommended for Adoption by
The NSF Council of Public Health Consultants

Adopted by
NSF International
November 2018

Revised November 2020 Revised December 2021 Revised April 2023

Published by
NSF International
P.O. Box 130140, Ann Arbor, Michigan 48113-0140, U.S.A.

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Abbreviations

The following table is provided as a reference for unit abbreviations for common forms of measurement used within NSF documents.

time	second	s
	minute	min
	hour	h
	day	d
	week	wk
	month	mo
	year	yr
length	inch	in
	foot	ft
	yard	yd
	micrometer	µm
	nanometer	nm
	millimeter	mm
	centimeter	cm
	meter	m
	kilometer	km
liquid measure	milliliter	mL
	liter	L
	liters per day	LPD
	liters per minute	LPM
	ounce	oz
	pint	pt
	quart	qt
	gallon	gal
	gallons per minute	GPM
	gallons per day	GPD
weight	microgram	µg
	picogram	pg
	nanogram	ng
	milligram	mg
	centigram	cg
	gram	g
	kilogram	kg
	pounds	lb
	tons	t
	metric tons	mt

Contents

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Foreword[2]

The purpose of NSF/ANSI 455-4 is to serve as an evaluation tool for analyzing good manufacturing practices (GMP) for over-the-counter (OTC) drug manufacturers. Certification to this standard serves as a communication tool between manufacturers of OTC drugs, regulators, retailers, and consumers.

This edition of the standard contains the following revisions:

Issue 32

This revision updates references throughout Section 4.

Issue 37

This revision updates Section 5.8 to redefine the certificate expiration and recertification audit timeline to ensure there are not gaps in certification for certified facilities. It also clarifies the intent and removes redundancy in verbiage.

Issue 38

This revision updates Sections 5.2.a and 5.3.2 to reference Section 2: Normative references rather than list them out. It also removes a link to the documents from Section 5.3.2 since they are available on the FDA website.

Issue 41

This revision clarifies the intent of the requirements by adding new language and removing unclear and unnecessary verbiage in Sections 5.7.1 through 5.7.3.

Issue 42

This revision provides structure around virtual audits in Sections 5.2 through 5.5 and corrects an error which lists “type” instead of “technology” in Section 5.4.3.

This standard was developed by the NSF Joint Committee on GMP for Over-the-Counter Drugs using the consensus process described by the American National Standards Institute.

This standard and the accompanying text are intended for voluntary use by certifying organizations, regulatory agencies, and/or manufacturers as a basis of providing assurances that adequate health protection exists for covered products.

Suggestions for improvement of this standard are welcome. This standard is maintained on a continuous maintenance schedule and can be opened for comment at any time. Comments should be sent to Chair, Joint Committee on Good Manufacturing Practices for Over-the-Counter Drugs at standards@nsf.org, or c/o NSF International, Standards Department, P.O. Box 130140, Ann Arbor, Michigan 48113-0140, U.S.A.

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NSF/ANSI Standard
for Health Sciences –

Good Manufacturing Practices for Over-the-Counter Drugs

1 General

1.1 Purpose

The principles outlined in this standard provide a comprehensive basis for the quality management system used in the manufacture of over-the-counter (OTC) drugs. Implementation of these principles shall result in the achievement of three main objectives:

— **achieve OTC drug realization**: the organization shall implement and maintain a system that delivers OTC drugs with the quality attributes necessary to meet the requirements and expectations of customers, retailers, and regulatory authorities;

— **establish and maintain a state of control**: the organization shall ensure the manufacture and supply of OTC drugs is in accordance with this standard, thus providing customers with some assurance of continued suitability and reliability of supply; and

— **facilitate continual improvement:** the organization shall collect objective evidence to continually develop and enhance the application of these quality management system principles to further assure OTC drug consistency.

1.2 Scope

This standard is intended to define a standardized approach for auditing to determine the level of compliance of OTC drug products to 21 C.F.R. Part 210 *Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General* and 21 C.F.R. Part 211 *Current Good Manufacturing Practice for Finished Pharmaceuticals*, International Council for Harmonisation of Technical Requirements for Pharmaceutical for Human Use (ICH) Quality Guidelines, 1, 7 and 10, 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 drug manufacture with sufficient quality to ensure suitability for intended use.

2 Normative references

The following documents contain requirements that, by reference in this text, constitute requirements of this standard. At the time of publication, the indicated editions were valid. All of the documents are subject to revision and parties are encouraged to investigate the possibility of applying the recent editions of the documents indicated below. The most recent published edition of the document shall be used for undated references.

21 C.F.R. § 11, *Electronic Records; Electronic Signatures*[3]

[3] National Archives and Records Administration, Office of the Federal Register. 7 G Street NW, Suite A-734, Washington, DC 20401. <www.ecfr.gov>