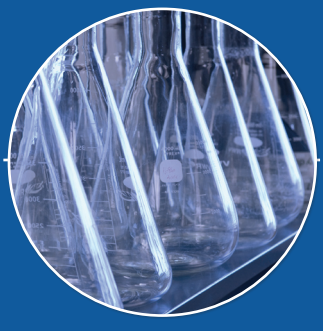
NSF International Standard /
American National Standard

NSF/ANSI 455-4 - 2018

Good Manufacturing Practices for Over-the-Counter Drugs


NSF International, an independent, not-for-profit, non-governmental organization, is dedicated to being the leading global provider of public health and safety-based risk management solutions while serving the interests of all stakeholders.

This Standard is subject to revision.
Contact NSF to confirm this revision is current.

Users of this Standard may request clarifications and interpretations, or propose revisions by contacting:

Chair, Joint Committee on GMP for OTC
c/o NSF International
789 North Dixboro Road, PO Box 130140
Ann Arbor, Michigan 48113-0140 USA
Phone: (734) 769-8010 Telex: 753215 NSF INTL
Fax: (734) 769-0109
E-mail: info@nsf.org
Web: <www.nsf.org>

NSF International Standard /
American National Standard
for Good Manufacturing Practices –

Good Manufacturing Practices for Over-the-Counter Drugs

Standard Developer
NSF International

Designated as an ANSI Standard
July 30, 2018
American National Standards Institute

Prepared by
The NSF Joint Committee on GMP for OTC

Recommended for Adoption by
The NSF Council of Public Health Consultants

Adopted by
NSF International
November 2018

Published by
NSF International
PO Box 130140, Ann Arbor, Michigan 48113-0140, USA

For ordering copies or for making inquiries with regard to this Standard, please reference the designation "NSF/ANSI 455-4 – 2018."

Disclaimers[1]

NSF International (NSF), in performing its functions in accordance with its objectives, does not assume or undertake to discharge any responsibility of the manufacturer or any other party. The opinions and findings of NSF represent its professional judgment. NSF shall not be responsible to anyone for the use of or reliance upon this Standard by anyone. NSF shall not incur any obligation or liability for damages, including consequential damages, arising out of or in connection with the use, interpretation of, or reliance upon this Standard.

NSF Standards provide basic criteria to promote sanitation and protection of the public health. Provisions for mechanical and electrical safety have not been included in this Standard because governmental agencies or other national standards-setting organizations provide safety requirements.

Participation in NSF Standards development activities by regulatory agency representatives (federal, local, state) shall not constitute their agency's endorsement of NSF or any of its Standards.

Preference is given to the use of performance criteria measurable by examination or testing in NSF Standards development when such performance criteria may reasonably be used in lieu of design, materials, or construction criteria.

The illustrations, if provided, are intended to assist in understanding their adjacent standard requirements. However, the illustrations may not include all requirements for a specific product or unit, nor do they show the only method of fabricating such arrangements. Such partial drawings shall not be used to justify improper or incomplete design and construction.

Unless otherwise referenced, the annexes are not considered an integral part of NSF Standards. The annexes are provided as general guidelines to the manufacturer, regulatory agency, user, or certifying organization.

[1] The information contained in this Disclaimer is not part of this American National Standard (ANS) and has not been processed in accordance with ANSI's requirements for an ANS. Therefore, this Disclaimer may contain material that has not been subjected to public review of a consensus process. In addition, it does not contain requirements necessary for conformance to the Standard.

This page is intentionally left blank.

Contents

This page is intentionally left blank.

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

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 GMP for OTC at standards@nsf.org, or c/o NSF International, Standards Department, PO Box 130140, Ann Arbor, Michigan 48113-0140, USA.

[2] The information contained in this Foreword is not part of this American National Standard (ANS) and has not been processed in accordance with ANSI's requirements for an ANS. Therefore, this Foreword may contain material that has not been subjected to public review of a consensus process. In addition, it does not contain requirements necessary for conformance to the Standard.

This page is intentionally left blank.

NSF/ANSI Standard
for Good Manufacturing Practices –

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 over-the-counter (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*, 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 CFR § 211.22, *Current Good Manufacturing Practice for Finished Pharmaceuticals: Organization and Personnel – Responsibilities of Quality Control Unit*[3]

[3] USFDA – CFR Code of Federal Regulations Title 21 <www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>