NSF International Standard /
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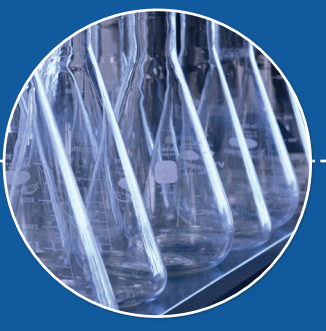
NSF/ANSI 455-4 - 2020

Good Manufacturing Practices for Over-the-Counter Drugs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NSF International Standard /
American National Standard
for Good Manufacturing Practices –

Good Manufacturing Practices for Over-the-Counter Drugs

Standard Developer
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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 13

This revision harmonizes the numbering in Sections 4.2 and 4.3 to that of NSF/ANSI 455-2, *Good Manufacturing Practices for Dietary Supplements*, and NSF/ANSI 455-3, *Good Manufacturing Practices for Cosmetics*, under the ISO Format.

Issue 14

This revision rewords language in Sections 4.2.2 and 4.8.2.

Issue 15

This revision harmonizes the numbering in Section 4.4 to that of NSF/ANSI 455-2, *Good Manufacturing Practices for Dietary Supplements*, and NSF/ANSI 455-3, *Good Manufacturing Practices for Cosmetics*, under the ISO Format.

Issue 17

This revision will add more clarity in Section 4.7.15 on what is required for traceability and mock recalls.

Issue 19

This revision harmonizes the language in Section 5.2 to that of NSF/ANSI 455-2, *Good Manufacturing Practices for Dietary Supplements*, and NSF/ANSI 455-3, *Good Manufacturing Practices for Cosmetics*, under the ISO Format.

Issue 22

This revision harmonizes the language in Section 5.7.3 to that of NSF/ANSI 455-2, *Good Manufacturing Practices for Dietary Supplements*, and NSF/ANSI 455-3, *Good Manufacturing Practices for Cosmetics*, under the ISO Format.

This Standard was developed by the NSF Joint Committee on Good Manufacturing Practices for Over-the-Counter Drugs using the consensus process described by the American National Standards Institute, and with participation from over-the-counter drug manufacturers, public health regulators, and consumers and retailers of over-the-counter 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 Good Manufacturing Practices for Over-the-Counter Drugs at standards@nsf.org, or c/o NSF International, Standards Department, PO Box 130140, Ann Arbor, Michigan 48113-0140, USA.

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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.