NSF International Standard / American National Standard

NSF/ANSI 455-4 - 2018

Good Manufacturing Practices for Over-the-Counter Drugs
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Foreword

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.

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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, 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 CFR § 211.22, Current Good Manufacturing Practice for Finished Pharmaceuticals: Organization and Personnel – Responsibilities of Quality Control Unit