NSF International Standard /
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NSF/IPEC/ANSI 363 - 2016

Good Manufacturing Practices (GMP) for Pharmaceutical Excipients



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NSF International Standard/
International Pharmaceutical
Excipients Council/
American National Standard
for Pharmaceutical Excipients –

Good Manufacturing Practices (GMP) for Pharmaceutical Excipients

Standard Developer

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For ordering copies or for making inquiries with regard to this Standard, please reference the designation "NSF/IPEC/ANSI 363 – 2016."

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Contents

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Foreword[2]

The purpose of NSF/IPEC/ANSI 363 is to serve as an evaluation tool for analyzing pharmaceutical excipients. Certification to this Standard serves as a communication tool between manufacturers of excipients and finished product, pharmaceutical regulators, pharmacy organizations, and consumers. This Standard provides guidance to allow for the determination that a pharmaceutical excipient is within the specifications stated by the manufacturer, either qualitatively or quantitatively, and that it does not contain specific undeclared contaminants. In some instances, validated laboratory methods are not yet available for analyzing certain ingredients. In such cases, new methods will be added to this Standard as they become available.

NSF/IPEC/ANSI 363 was developed with participation from the pharmaceutical excipients manufacturers, public health regulators, and distributors of pharmaceutical excipients.

This edition of the Standard contains the following revisions:

Issue 2

This revision updated section 4.1.1 regarding regional regulations.

Issue 3

Updates were made to language regarding the use of the terms “product” and “excipient.

Issue 4

Definitions for the terms deviation and sanitary were added to section 3.

Issue 5

This revision provides clarity on language in section 6.3.2.1 and 6.3.3.

Issue 6

Updates to section 7.4.1 were made regarding the purchasing process.

Issue 7

Section 7.2.1 was updated to provide clarity.

Issue 8

This revision made several editorial changes throughout the Standard.

Issue 9

A definition for the term data integrity was added to section 3.

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Issue 10

A definition for the term backup was added to section 3.

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 Pharmaceutical Excipients at standards@nsf.org, or c/o NSF International, Standards Department, P.O. Box 130140, Ann Arbor, Michigan 48113-0140, USA.

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for Pharmaceutical Excipients –

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1 General

1.1 Introduction

The principles outlined in this Standard provide a comprehensive basis for the quality management system used in the manufacture of pharmaceutical excipients. Implementation of these principles shall result in the achievement of three main objectives:

a) achieve excipient realization – the organization shall implement and maintain a system that delivers excipients with the quality attributes necessary to meet the requirements and expectations of customers, pharmaceutical users, and regulatory authorities;

b) establish and maintain a state of control – the organization shall ensure the manufacture and supply of excipients is in accordance with this Standard, thus providing customers with some assurance of continued suitability and reliability of supply; and

c) 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 excipient consistency.

1.2 Scope

This Standard is intended to define Good Manufacturing Practices (GMP) for excipient manufacture and distribution[3] for use in drug products. It sets minimum requirements for GMP applicable to all commercially available excipients.

This Standard includes the minimum requirements of a quality management system for excipient manufacture drawing on principles of GMP and quality systems from other relevant standards such as those referenced in section 2.2.

NOTE 1 — The requirements of this Standard may not be sufficient for all applications of excipients. It is the user's responsibility to determine whether or not this Standard meets the requirements for their intended use.

NOTE 2 — Auditing excipient manufacturers ensures conformance to this Standard. This Standard is also intended to be used by duly accredited or otherwise suitably qualified 3rd parties.

NOTE 3 — Each user of a 3rd party auditing service should make its own determination as to the qualifications of the 3rd party and the applicability of the report and/or certificate issued in satisfying its requirements, including those pertaining to its intended use of the excipient.

[3] GMP applies to distribution per the *Federal Food, Drug, and Cosmetic Act (FD&C Act),* 21 U.S.C. 501(a) (2) (B).