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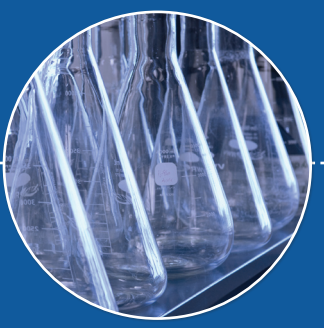
NSF/IPEC/ANSI 363 - 2019

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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Contents

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Foreword[2]

NSF/IPEC/ANSI 363 defines minimum cGMP standards for the manufacture and distribution of pharmaceutical excipients. Certification to this Standard serves as a communication tool between manufacturers of excipients and finished product manufacturers, pharmaceutical regulators, pharmacy organizations, and consumers.

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 11

This revision adds more options for signatures on the Certificate of Analysis is Section 8.2.4.5.

Issue 12

This revision updates the language in Section 6.3.2.1.

Issue 13

This revision removes “waste segregation and disposal” from the form in Section 6.4.

Issue 14

This revision updates the entire standard to be better mapped to the new ISO 9001 format.

This Standard was developed by the NSF Joint Committee on Pharmaceutical Excipients 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 Pharmaceutical Excipients 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/IPEC/ANSI Standard
for Pharmaceutical Excipients –

Good Manufacturing Practices (GMP) for Pharmaceutical Excipients

1 General

1.1 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.

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 third-party audit and certification providers.

NOTE 3 — Each user of a third-party auditing service should make its own determination as to the qualifications of the third 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.

1.2 Purpose

Excipients impact the appearance, stability, and delivery of drug products, and are essential to the safety, quality, and efficacy of these products. It is not possible to assure the consistent quality of excipients by testing alone. Adherence to excipient GMP provides assurance that excipients are suitable for use in drug products. Excipient GMP require a proper quality management system (QMS), test methods, and facilities and controls.

2 Reference documents

2.1 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 shall 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.

WHO, *Guidelines for Drinking-Water Quality*, 4th edition, 2011[4]

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

[4] World Health Organization (WHO). 20 Avenue Appia, 1211 Geneva 27, Switzerland. <www.who.int>