NSF International Standard /
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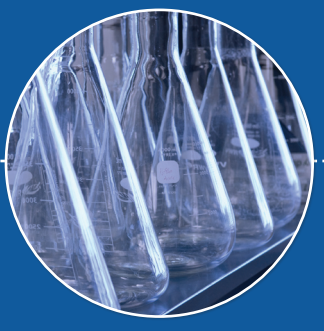
NSF/ANSI 455-3 - 2022

Good Manufacturing Practices for Cosmetics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NSF International Standard /
American National Standard
for Health Sciences –

Good Manufacturing Practices for Cosmetics

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Abbreviations

The following table is provided as a reference for unit abbreviations for common forms of measurement used within NSF documents.

time	second	s
	minute	min
	hour	h
	day	d
	week	wk
	month	mo
	year	yr
length	inch	in
	foot	ft
	yard	yd
	micrometer	µm
	nanometer	nm
	millimeter	mm
	centimeter	cm
	meter	m
	kilometer	km
liquid measure	milliliter	mL
	liter	L
	liters per day	LPD
	liters per minute	LPM
	ounce	oz
	pint	pt
	quart	qt
	gallon	gal
	gallons per minute	GPM
	gallons per day	GPD
weight	microgram	µg
	picogram	pg
	nanogram	ng
	milligram	mg
	centigram	cg
	gram	g
	kilogram	kg
	pound	lb
	ton	t
	metric ton	mt

Contents

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Foreword[2]

The purpose of NSF/ANSI 455-3 is to serve as an evaluation tool for analyzing good manufacturing practices (GMP) for cosmetics manufacturers. Certification to this standard serves as a communication tool between manufacturers of cosmetics, regulators, retailers, and consumers.

This edition of the standard contains the following revisions:

Issue 30

This revision updates Section 5.8 to redefine the certificate expiration and recertification audit timeline to ensure there are not gaps in certification for certified facilities. It also clarifies the intent and removes redundancy in verbiage.

Issue 31

This revision clarifies the intent of the requirements by adding new language and removing unclear and unnecessary verbiage in Sections 5.7.1 through 5.7.3.

Issue 32

This revision updates Sections 5.2.a and 5.3.2 to reference Section 2: Normative references rather than list them out. It also removes a link to the documents from Section 5.3.2 since they are available on the FDA website.

Issue 34

This revision updates Section 5.5.9 to align between the 455 standards.

Issue 36

This revision removes Sections 4.4.25 and 4.4.26, adds Sections 4.5.9 and 4.5.42, and updates Section 4.5.41. In the current language, calibration and preventive maintenance are covered in both Sections 4.4.25 and 4.5.41.

Issue 37

This revision updates Section 4.6.1 and removes Section 4.6.6 to combine the requirements into Section 4.6.1 for cohesiveness.

Issue 38

This revision updates training requirements in Sections 4.4.27, 4.4.28, and 4.4.30 (now 4.4.29) to clarify language. It also removes Section 4.4.29 to eliminate duplication.

Issue 39

This revision adds language to Section 5.4.4 to provide structure around virtual audits. It also corrects an error that lists “type” instead of “technology” in Section 5.4.3.

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This standard was developed by the NSF Joint Committee on GMP for Cosmetics 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 Good Manufacturing Practices for Cosmetics at standards@nsf.org, or c/o NSF International, Standards Department, P.O. Box 130140, Ann Arbor, Michigan 48113-0140, U.S.A.

NSF/ANSI Standard
for Health Sciences –

Good Manufacturing Practices for Cosmetics

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 cosmetics. Implementation of these principles shall result in the achievement of three main objectives:

— **achieve cosmetics realization**: the organization shall implement and maintain a system that delivers cosmetics 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 cosmetics 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 cosmetics consistency.

1.2 Scope

This standard is intended to define a standardized approach for auditing to determine the level of compliance of cosmetic products to ISO 22716[3] FDA Cosmetic GMP guidance, as well as incorporating additional retailer requirements. It refers to the guidelines for GMPs applicable to all cosmetics. It will assist in the determination of adequate facilities and controls for cosmetic manufacture with sufficient quality to ensure suitability for intended use. The criteria in this standard was structured to be in the ISO 9001:2015[3] format, following a Seven Systems approach.

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.

ISO 22716:2007, *Cosmetics -- Good Manufacturing Practices (GMP) -- Guidelines on Good Manufacturing Practices*[3]

[3] International Organization for Standardization. Chemin de Blandonnet 8, Case Postale 401, 1214 Vernier, Geneva, Switzerland. <www.iso.org>