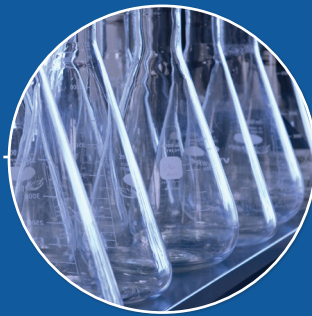




*NSF International Standard /
American National Standard*

NSF/ANSI 455-2 - 2018

Good Manufacturing Practices
for Dietary Supplements



NSF International, an independent, not-for-profit, nongovernmental organization, is dedicated to being the leading global provider of public health and safety-based risk management solutions while serving the interests of all stakeholders.

This Standard is subject to revision.
Contact NSF to confirm this revision is current.

Users of this Standard may request clarifications and interpretations, or propose revisions by contacting:

Chair, Joint Committee on GMP for Dietary Supplements
c/o NSF International
789 North Dixboro Road, PO Box 130140
Ann Arbor, Michigan 48113-0140 USA
Phone: (734) 769-8010 Telex: 753215 NSF INTL
Fax: (734) 769-0109
E-mail: info@nsf.org
Web: www.nsf.org

NSF/ANSI 455-2 – 2018

NSF International Standard /
American National Standard
for Good Manufacturing Practices –
**Good Manufacturing Practices
for Dietary Supplements**

Standard Developer
NSF International

Designated as an ANSI Standard
November 4, 2018
American National Standards Institute

Prepared by
The NSF Joint Committee on GMP for Dietary Supplements

Recommended for adoption by
The NSF Council of Public Health Consultants

Adopted by
NSF International
November 2018

Published by
NSF International
PO Box 130140, Ann Arbor, Michigan 48113-0140, USA

For ordering copies or for making inquiries with regard to this Standard, please reference the designation
"NSF/ANSI 455-2 – 2018."

Copyright 2018 NSF International

Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from NSF International.

Printed in the United States of America.

Disclaimers¹

NSF International (NSF), in performing its functions in accordance with its objectives, does not assume or undertake to discharge any responsibility of the manufacturer or any other party. The opinions and findings of NSF represent its professional judgment. NSF shall not be responsible to anyone for the use of or reliance upon this Standard by anyone. NSF shall not incur any obligation or liability for damages, including consequential damages, arising out of or in connection with the use, interpretation of, or reliance upon this Standard.

NSF Standards provide basic criteria to promote sanitation and protection of the public health. Provisions for mechanical and electrical safety have not been included in this Standard because governmental agencies or other national standards-setting organizations provide safety requirements.

Participation in NSF Standards development activities by regulatory agency representatives (federal, local, state) shall not constitute their agency's endorsement of NSF or any of its Standards.

Preference is given to the use of performance criteria measurable by examination or testing in NSF Standards development when such performance criteria may reasonably be used in lieu of design, materials, or construction criteria.

The illustrations, if provided, are intended to assist in understanding their adjacent standard requirements. However, the illustrations may not include all requirements for a specific product or unit, nor do they show the only method of fabricating such arrangements. Such partial drawings shall not be used to justify improper or incomplete design and construction.

Unless otherwise referenced, the Annexes are not considered an integral part of NSF Standards. The Annexes are provided as general guidelines to the manufacturer, regulatory agency, user, or certifying organization.

¹ The information contained in this Disclaimer is not part of this American National Standard (ANS) and has not been processed in accordance with ANSI's requirements for an ANS. Therefore, this Disclaimer may contain material that has not been subjected to public review or a consensus process. In addition, it does not contain requirements necessary for conformance to the Standard.

This page is intentionally left blank.

Contents

1	General	1	
1.1	Purpose.....	1	
1.2	Scope.....	1	
2	Normative references	1	
3	Definitions	2	
4	Audit requirements.....	2	
4.1	Context of the organization.....	2	
4.2	Leadership	2	
4.3	Planning	3	
4.4	Support	3	
4.5	Operation	6	
4.6	Performance evaluation	11	
4.7	Improvement.....	13	
5	Audit process	13	
5.1	Audit process introduction	13	
5.2	Audit and certification process outline	14	
5.3	Audit preparation.....	15	
5.4	Audit planning	16	
5.5	On-site audit.....	19	
5.6	Reporting / grading	21	
5.7	Nonconformances and corrective action	23	
5.8	Post audit activities	24	
Informative Annex 1			
Additional elements of a certification program for GMP for dietary supplements.....			27
I1.1	General	27	
I1.2	ANSI approved Mark use, marketing and references to the Standard.....	27	
I1.3	Resource requirements – Competence of personnel.....	27	
I1.4	Process requirements.....	29	
I1.5	Listing certified companies	29	
I1.6	Appeals	29	
I1.7	Complaints	30	
I1.8	Advertising	30	
I1.9	Confidentiality	30	
I1.10	References.....	30	

This page is intentionally left blank.

Foreword²

The purpose of NSF/ANSI 455-2 is to serve as an evaluation tool for analyzing good manufacturing practices (GMP) for dietary supplements manufacturers. Certification to this Standard serves as a communication tool between manufacturers of dietary supplements, regulators, retailers, and consumers.

This Standard was developed by the NSF Joint Committee on GMP for Dietary Supplements using the consensus process described by the American National Standards Institute, and with participation from dietary supplement manufacturers, public health regulators, and consumers and retailers of dietary supplements.

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 Dietary Supplements at standards@nsf.org, or c/o NSF International, Standards Department, PO Box 130140, Ann Arbor, Michigan 48113-0140, USA.

² The information contained in this Foreword is not part of this American National Standard (ANS) and has not been processed in accordance with ANSI's requirements for an ANS. Therefore, this Foreword may contain material that has not been subjected to public review or a consensus process. In addition, it does not contain requirements necessary for conformance to the Standard.

This page is intentionally left blank.

NSF/ANSI Standard for Good Manufacturing Practices – Good Manufacturing Practices for Dietary Supplements

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

- **achieve dietary supplement realization:** The organization shall implement and maintain a system that delivers dietary supplements 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 dietary supplements 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 dietary supplements consistency.

1.2 Scope

This Standard is intended to define a standardized approach for auditing to determine the level of compliance of dietary supplement products to 21 CFR Part 111, *Current Good Manufacturing Practices (GMPs) in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements*, as well as incorporating additional retailer requirements. It refers to the requirements for GMP applicable to all dietary supplements. It will assist in the determination of adequate facilities and controls for dietary supplement 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 § 1.511, *General Enforcement Regulations: Foreign Supplier Verification Programs for Food Importers – What FSVP must I have if I am importing a food subject to certain requirements in the dietary supplement current good manufacturing practice regulation?*³

³ US FDA – CFR Code of Federal Regulations Title 21 <www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>