NSF International Standard /
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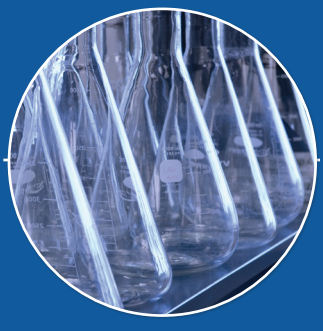
NSF/ANSI 321 - 2010

Goldenseal Root
(Hydrastis canadensis)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Chair, Joint Committee on Dietary Supplements
NSF International
789 North Dixboro Road, P. O. 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: http://www.nsf.org

NSF International Standard/
American National Standard
for Botanical Dietary Supplements —

Goldenseal Root (*Hydrastis canadensis*)

Standard Developer

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Contents

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Foreword[2]

The purpose of this Standard is to serve as an evaluation tool for analyzing the botanical dietary supplement Goldenseal Root (*Hydrastis canadensis*). NSF/ANSI 321 contains requirements for dietary supplements that contain goldenseal root as an ingredient. It allows for the determination that this botanical ingredient is accurately identified, that the product contains the quantity of dietary ingredients and marker constituents as determined by the American Herbal Pharmacopoeia (AHP), that the ingredient does not contain unacceptable quantities of contaminants, conforms to the compliance criteria of the AHP, and can be used to facilitate GMP compliance.

Certification to this Standard serves as a communication tool between manufacturers of ingredients and finished product, retailers, healthcare practitioners, and consumers. This Standard provides test methods and evaluation criteria to allow for the determination that a botanical dietary supplement identified as Goldenseal root contains the ingredients claimed on the label, 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 offers a certification program to this Standard. Products certified by NSF carry the NSF Mark, the leading mark in public health and safety certification around the world. The NSF Mark on a product gives consumers and retailers assurance that the product meets the requirements of the NSF Standard. For more information on the NSF certification program, please contact the General Manager of Dietary Supplements, P.O. Box 130140, Ann Arbor, MI 48113-0140 or at 1-800-NSF-MARK (800-673-6275).

This Standard was developed by the NSF Joint Committee on Dietary Supplements using the NSF Consensus process accredited by the American National Standards Institute.

Suggestions for improvement of this Standard are welcome. Comments should be sent to Chair, Dietary Supplements, c/o NSF International, Standards Department, P.O. Box 130140, Ann Arbor, MI 48113-0140, USA.

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NSF International Standard
for Botanical Dietary Supplements —

Goldenseal Root (*Hydrastis canadensis*)

1 General

1.1 Purpose

This Standard provides test methods for ensuring the identity, strength, purity, and composition of the dietary supplement ingredient Goldenseal root (*Hydrastis canadensis*) to allow for the determination that this botanical ingredient is accurately identified, that the product contains the quantity of dietary ingredients and marker constituents as determined by the American Herbal Pharmacopoeia (AHP), that the ingredient does not contain unacceptable quantities of contaminants, conforms to the compliance criteria of the AHP, and can be used to facilitate GMP compliance. Other limit tests, such as for metals, microbes, and pesticides, are not included in the monograph.

1.2 Scope

This Standard contains requirements for dietary supplements that contain goldenseal root as an ingredient in a dietary supplement as defined as a dietary substance for use by man to supplement the diet by increasing the total dietary intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients. With appropriate modifications to the testing methodology, this Standard can also apply to extracts of the ingredient.

Products and ingredients deemed a hazard to public health or safety by a regulatory agency having jurisdiction shall be excluded from the scope of this document.

2 Normative references

The following documents contain requirements, which by reference in this text, constitute requirements of this Standard.

AHP, *Goldenseal Root (Hydrastis canadensis): Standards of Analysis, Quality Control, & Therapeutics*[3]

Dietary Supplement Health and Education Act of 1994 (DSHEA), an amendment to the Federal Food, Drug and Cosmetic Act: Public Law 103-417 – Oct. 25, 1994[4]

[3] American Herbal Pharmacopoeia and Therapeutic Compendium. *Goldenseal Root (Hydrastis canadensis): Standard of Analysis, Quality Control, and Therapeutics*, Roy Upton (ed.), American Herbal Pharmacopoeia, Santa Cruz, CA: 2001 www.herbal-ahp.org.

[4] Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002 www.fda.gov.