

Ashwagandha

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ASHWAGANDHA - WITHANIA SOMNIFERA Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section. (PDF Version - 51 KB) This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredient. Notes Text in parentheses is additional optional information which can be included on the label at the applicant's discretion. The solidus (/) indicates that the terms and/or statements are synonymous. Either term or statement may be selected by the applicant on the label. Date February 28, 2025 Proper name(s), Common name(s), Source information Table 1. Proper name(s), Common name(s), Source information Proper name(s) Common name(s) Source information Source material(s) Part(s) Preparation(s) Withania somnifera Asgandh Ashwagandha Asvagandha Winter-cherry Withania Withania somnifera Root Whole plant Dry References: Proper name: USDA 2023; Common names: API 2001, McGuffin et al. 2000; Source information: Winston and Maimes 2007; API 2001. Route of Administration Oral Dosage Form(s) This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document. Acceptable dosage forms for oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications. Use(s) or Purpose(s) Traditionally used in Ayurveda as Rasayana (rejuvenative tonic) (Sukh Dev 2006; API 2001; Upton 2000). Traditionally used in Ayurveda to relieve general debility, especially during convalescence or old age (API 2001; Kapoor 2001). Traditionally used in Ayurveda to help relieve restlessness and/or nervousness (which helps (to) promote sleep) (Khare 2004; Upton 2000). Traditionally used in Ayurveda to balance aggravated Vata (nervine) (Kapoor 2001; Khory and Katrak 1999; Nadkarni 1954). Traditionally used in Ayurveda for memory enhancement (Sukh Dev 2006; Upton 2000; Nadkarni 1954). Used in Herbal Medicine as an adaptogen to help increase energy and resistance to stress over time (e.g. in case of mental and physical fatigue related to stress) (Winston and Maimes 2007; Bone 2003; Williamson 2002). Notes The above claims can be combined on the product label if from the same traditional system of medicine (e.g. Traditionally used in Ayurveda to balance aggravated Vata (nervine) and to relieve general debility, especially during convalescence or old age). For multi-ingredient products: To prevent the product from being represented as a "traditional medicine," any indicated traditional use claim must refer to the specific medicinal ingredient(s) and recognized traditional system of medicine from which the claim originates when 1) both traditional and modern claims are present or 2) when claims originate from multiple systems of traditional medicine (e.g. Ashwagandha is traditionally used in Ayurveda for memory enhancement). When ALL of the medicinal ingredients (MIs) in the product are used within the SAME identified system of traditional medicine AND the product makes ONLY traditional claims, listing of MIs in the traditional claim(s) is not required. Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) Traditional Ayurvedic Claims Methods of preparation: Dry, Powdered, Non-Standardized Extracts (Dry extract*, Tincture, Fluid extract, Decoction, Infusion) 2 - 6 grams of dried root, per day (Williamson 2002; API 2001; Kapoor 2001; Nadkarni 1954). *Note: Solvents allowed for the method of preparation "Non-Standardized Extracts (Dry extract)" as part of this monograph are ethanol and/or water only. Adaptogen Methods of preparation: Dry, Powdered, Non-Standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract) 2.5 - 6.5 grams of dried root/whole plant, per day (Winston and Maimes 2007; Bone 2003; Williamson 2002). Direction(s) for use No statement required. Duration(s) of Use No statement required. Risk Information Caution(s) and warning(s) General debility; Memory enhancement; Adaptogen; Restlessness/nervousness Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. All products Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding (Upton 2000; McGuffin et al. 1997). When using this product exercise caution if you drive or use machinery as you may experience drowsiness (Berardi et al. 2002). Contraindication(s) No statement required. Known adverse reaction(s) No statement required. Non-medicinal ingredients Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database. Storage conditions Must be established in accordance with the requirements described in the Natural Health Products

Regulations . Specifications The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide. The medicinal ingredient must comply with the requirements outlined in the NHPID. **EXAMPLE OF PRODUCT FACTS:** Consult the Guidance Document, Labelling of Natural Health Products for more details. **References Cited** API 2001: The Ayurvedic Pharmacopoeia of India, Part I, Volume I, 1st edition. New Delhi (India): Government of India, Ministry of Health and Family Welfare, Department of Indian Systems of Medicine & Homoeopathy; 2001. Berardi RR, DeSimone EM, Newton GD, Oszko MA, Popovich NG, Rollins CJ, Shimp LA and Tietze KJ, editors. Handbook of Nonprescription Drugs: An Interactive Approach to Self-Care, 13th edition. Washington (DC): American Pharmaceutical Association; 2002. Bone K. A clinical guide to blending liquid herbs: Herbal formulations for the individual patient. St. Louis (MI): Churchill Livingstone; 2003. Dipiro JT, Talbert RL, Yee GC, Matzke GR, Wells BG, Posey LM. Pharmacotherapy: A pathophysiologic approach. 5th edition. New York (NY): The McGraw-Hill Companies, Inc.; 2002. Gennaro AR, editor. Remington: The Science and Practice of Pharmacy, 20th edition. Baltimore (MD): Lippincott Williams and Wilkins; 2000. Kapoor LD. Handbook of Ayurvedic Medicinal Plants: Herbal Reference Library. Boca Raton (FL): CRC Press; 2001. Khare CP. Indian Herbal Remedies: Rational Western Therapy, Ayurvedic and Other Traditional Usage, Botany. New York (NY): Springer; 2004. Khory RN, Katrak NN. Materia Medica of India and Their Therapeutics. Delhi (India): Komal Prakashan; 1999. McGuffin M, Hobbs C, Upton R, Goldberg A, editors. American Herbal Products Association's Botanical Safety Handbook. Boca Raton (FL): CRC Press, LLC; 1997. McGuffin M, Kartesz JT, Leung AY, Tucker AO, editors. Herbs of Commerce, 2nd edition. Silver Spring (MD): American Herbal Products Association; 2000. Nadkarni AK, Nadkarni KM. India Materia Medica with Ayurvedic, Unani-Tibbi, Siddha, Allopathic, Homeopathic, Naturopathic & Home Remedies, Volume 1, 3rd edition. Bombay (India): Popular Book Depot; 1954. Sukh Dev. Prime Ayurvedic Plant Drugs. Tunbridge Wells (UK): Anshan; 2005. Upton R, editor. American Herbal Pharmacopoeia and Therapeutic Compendium: Ashwagandha Root (*Withania somnifera*) - Standards of Analysis, Quality Control, and Therapeutics. Santa Cruz (CA): American Herbal Pharmacopoeia; 2000. USDA 2023: United States Department of Agriculture Agricultural Research Service (USDA ARS), Germplasm Resources Information Network (GRIN) - Global. U.S. National Plant Germplasm System. [Accessed 2023 September 11]. Available from: <https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysearch> Williamson EM, editor. Major Herbs of Ayurveda. London (UK): Churchill Livingstone; 2002. Winston D, Maimes S. Adaptogens: Herbs for strength, stamina and stress relief. Rochester (VT): Healing Arts Press; 2007. Report a problem on this page Date modified: 2019-03-01

DOSAGE FORM(S)

Acceptable dosage forms for oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications.

RISK INFORMATION

Caution(s) and warning(s) General debility; Memory enhancement; Adaptogen; Restlessness/nervousness Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. All products Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding (Upton 2000; McGuffin et al. 1997).When using this product exercise caution if you drive or use machinery as you may experience drowsiness (Berardi et al. 2002). Contraindication(s) No statement required. Known adverse reaction(s) No statement required.

NON-MEDICINAL INGREDIENTS

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database. Storage conditions Must be established in accordance with the requirements described in the Natural Health Products Regulations.

STORAGE CONDITION(S)

Must be established in accordance with the requirements described in the Natural Health Products Regulations.

SPECIFICATIONS

The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide. The medicinal ingredient must comply with the requirements outlined in the NHPID. EXAMPLE OF PRODUCT FACTS: Consult the Guidance Document, Labelling of Natural Health Products for more details.

REFERENCES

Route of Administration Oral

Proper name(s)	Common name(s)	Source information		
Source material(s)	Part(s)	Preparation(s)		
Withania somnifera	AsgandhAshwagandhaAsvagandhaWinter-cherryWithania	Withania somnifera	RootWhole plant	Dry