

# Triphala

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Extracted: 2025-08-26T06:38:22.822016

Triphala (PDF Version - 73 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 This monograph may be used to support single ingredient or multi-ingredient products containing any medicinal ingredient from Table 1. However, the name "Triphala" is restricted to combination that contains the three medicinal ingredients indicated in Table 1. Therefore, brand name and use or purpose can only mention the name Triphala if these three medicinal ingredients are present in the product. 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 the statements are synonymous. Either term or statement may be selected by the applicant on the label. Date November 29, 2024 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) Phyllanthus emblica Amalaki Amla Emblic Emblic myrobalan Indian gooseberry Myrobalan Phyllanthus emblica Fruit Dry Terminalia bellirica Beach-almond Beleric myrobalan Belleric Belleric myrobalan Bibhitaki Bahera Myrobalan Terminalia bellirica Fruit Dry Terminalia chebula Harad Haritaki Terminalia chebula Fruit Dry References: Proper names: ITIS 2024; USDA 2024; API 2001; McGuffin et al. 2000; Common names: ITIS 2024; USDA 2024; API 2001; McGuffin et al. 2000; Source information: API 2001; Kapoor 2001; Khory and Katrak 1999; Nadkarni 1954. Route of Administration Oral Dosage Form(s) This monograph is not intended to include 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) All products Traditionally used in Ayurveda as a mild laxative for the relief of occasional constipation (Chouhan et al. 2013; Murthy 2004). Traditionally used in Ayurveda as an eye tonic (Chouhan et al. 2013; Murthy 2004). Products containing Triphala and/or Amalaki and/or Haritaki Traditionally used in Ayurveda as Rasayana (rejuvenative tonic) (Murthy 2004; API 2001; Nadkarni 1976). Traditionally used in Ayurveda as a digestive tonic to promote digestive fire, increase appetite and aid in digestion (stomachic) (Paranjpe 2005; Sudarshan 2005; Warriar et al. 2003; Kapoor 2001; Gogte 2000; Khory and Katrak 1999). Products containing Amalaki Traditionally used in Ayurveda to help relieve symptoms such as heartburn and indigestion associated with Amlapitta (hyperacidity/dyspepsia) (Warriar et al. 2003; API 2001; Gogte 2000). Source of antioxidants/Provides antioxidants (Duke 2024; Paranjpe 2005; Williamson 2002; API 2001; Kapoor 2001). Source of antioxidants/Provides antioxidants that help fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals (Duke 2024; Paranjpe 2005; Williamson 2002; API 2001; Kapoor 2001). Products containing Haritaki and/or Bibhitaki Traditionally used in Ayurveda to help expel intestinal worms (vermifuge) (Sukh Dev 2006; Kirtikar and Basu 1981; Nadkarni 1954). Traditionally used in Ayurveda to help relieve cough (Sukh Dev 2006; API 2001). Products containing Haritaki Traditionally used in Ayurveda to help relieve colic pain and flatulence (carminative) (Sukh Dev 2006; Khare 2004). Permitted combinations All ingredients included in this monograph may be combined together as long as combined dose is within the dose limits indicated below. Notes The laxative claim is based on the Ayurvedic Medicine; however, this is not a stimulant laxative nor a bulk-forming laxative. The mode of action is unclear and the laxative effect is mild. The above uses can be combined on the product label if from the same traditional or non-traditional system of medicine (e.g. Traditionally used in Ayurveda as a mild laxative for the relief of occasional constipation and to help relieve symptoms such as heartburn and indigestion associated with Amlapitta (hyperacidity/dyspepsia)). 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. Triphala is traditionally used in Ayurveda as a mild laxative for the relief of occasional constipation). 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) Antioxidants Methods of preparation: Dry, Powdered, Non-standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract) Not to exceed 6 grams of Amalaki, per day (API 2001). Rasayana; Digestive tonic; Eye tonic Methods of preparation: Dry, Powdered, Non-standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract) Table 2: Dose information presented as dose per day Medicinal Ingredients Dried fruit (grams/day) Minimum Maximum Amalaki 3 6 Haritaki 1 3 Bibhitaki 1 3 Amalaki + Haritaki + Bibhitaki (Triphala) 1 3 Amalaki + Haritaki or Bibhitaki 2 3 Haritaki + Bibhitaki 1 3 References: Amalaki: API 2001; Haritaki: Williamson 2002, API 2001, Gogte 2000; Bibhitaki: Williamson 2002, API 2001, Gogte 2000; Triphala: Tilloston et al. 2001, Gogte 2000; Amalaki + Haritaki or Bibhitaki: API 2001, Gogte 2000; Haritaki + Bibhitaki: Tilloston et al. 2001, Gogte 2000. Laxative; Amlapitta; Carminative; Cough; Vermifuge Methods of preparation: Dry, Powdered, Non-standardized Ethanolic Extracts (Dry extract, Tincture, Fluid extract) Table 3: Dose information presented as dose per day Medicinal Ingredients Dried fruit (grams/day) Minimum Maximum Amalaki 3 6 Haritaki 2 6 Bibhitaki 3 6 Amalaki + Haritaki + Bibhitaki (Triphala) 2 6 Any 2 combined together 3 6 References: Amalaki: API 2001; Haritaki: API 2001, Murthy 1994; Bibhitaki: API 2001; Triphala (Amalaki +Haritaki + Bibhitaki): Tilloston et al. 2001, Murthy 1994; Any 2 combined together: Murthy 1999 Direction(s) for use All Products Take a few hours before or after taking other medications or health products (HC 2009). Duration(s) of Use Vermifuge For occasional use only. Risk Information Caution(s) and warning(s) All products Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding (HC 2009). Amlapitta; Stomachic; Carminative; Vermifuge Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Laxative Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms worsen or if laxative effect does not occur within 7 days (HC 2009; Pray 2006; CPhA 2002). Cough Ask a health care practitioner/health care provider/health care professional/doctor/physician if cough worsens or persists for more than 1 week. Contraindication(s) Laxative Do not use if you have fever or any undiagnosed gastrointestinal trouble (HC 2009). Known adverse reaction(s) All products except those making laxative claim When using this product you may experience a laxative effect. 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, 1st edition, Part I, Volume I. Delhi (IN): The Controller of Publications; 2001 [Reprint of 1990 publication]. Chouhan B, Kumawat RC, Kotecha M, Ramamurthy A, Nathani S. Treiphla: A Comprehensive Ayurvedic Review. International Journal of Research in Ayurveda and Pharmacy; 2013;4(4): 612-617. CPhA 2002: Repchinsky C, editor-in-chief. Patient Self-Care: Helping Patients Make Therapeutic Choices. 1st edition. Ottawa (ON): Canadian Pharmacists Association; 2002. Duke 2024: Dr. Duke's Phytochemical and Ethnobotanical Databases. Chemicals and their Biological Activities in: *Phyllanthus emblica* L. (Euphorbiaceae) - Emblic, Myrobalan. [Accessed 2024 January 12]. Available from: <https://phytochem.nal.usda.gov/phytochem/search> Gogte VVM. Ayurvedic Pharmacology and Therapeutic Uses of Medicinal Plants. Mumbai (IN): Bharatiya Vidya Bhavan; 2000. HC 2009: Laxatives: General - Laxatives - Labelling Standard. Ottawa (ON): Drugs and Health Products; Health Canada; 2009. [Accessed 2024 January 12]. 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Silver Spring (MD): American Herbal Products Association; 2000. Murthy KRS. Bhavaprakasa of Bhavamisra. Volume 1. Varanasi (IN): Chowkhamba Krishnadas Academy; 2004. Murthy KRS. Bhavaprakasha of Bhavamisra, Volume 1. Varanasi (IN): Chowkhamba Krishnadas Academy; 2004. Nadkarni AK. India Materia Medica. Volume 1, 3rd edition. Panvel, Bombay (IN): Popular book depot, Dhootpapeshwar Prakashan Ltd.; 1954. Paranjpe P. Indian Medicinal Plants: Forgotten Healers: A Guide to Ayurvedic Herbal Medicine. Delhi (IN): Chaukhamba Sanskrit Pratishthan; 2005. Pray WS. Non-Prescription Product Therapeutics, 2nd edition. New York (NY): Lippincott Williams & Wilkins; 2006. Sudarshan SR. Encyclopaedia of Indian Medicine, Materia Medica - Herbal Drugs. Volume 4. Bangalore (IN): Popular Prakashan; 2005. Sukh Dev. Prime Ayurvedic Plant Drugs. New Delhi (IN):

Anamaya Publishers; 2006. Tillotson A, Khalasa KPS, Caldecott T: Triphala. Canadian Journal of Herbalism; 2001 22(2): 16-44. USDA 2024: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN) ) - Global. U.S. National Plant Germplasm System. [Accessed 2024 January 12]. Available from: <https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysearch> Warriar PK, Nambiar VPK, Ramankutty C, editors. Indian Medicinal Plants: a compendium of 500 species. Volume 4. Chennai (IN): Orient Longman Private Limited; 2003. Williamson EM, editor. Major Herbs of Ayurveda. Edinburgh (GB): Churchill Livingstone; 2002. Report a problem on this page Date modified: 2019-03-01

## **MEDICINAL INGREDIENT(S)**

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 the statements are synonymous. Either term or statement may be selected by the applicant on the label.

## **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) All products Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding (HC 2009). Amlapitta; Stomachic; Carminative; Vermifuge Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen. Laxative Ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms worsen or if laxative effect does not occur within 7 days (HC 2009; Pray 2006; CPhA 2002). Cough Ask a health care practitioner/health care provider/health care professional/doctor/physician if cough worsens or persists for more than 1 week. Contraindication(s) Laxative Do not use if you have fever or any undiagnosed gastrointestinal trouble (HC 2009). Known adverse reaction(s) All products except those making laxative claim When using this product you may experience a laxative effect.

## **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 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.

Proper name(s)	Common name(s)	Source information		
Source material(s)	Part(s)	Preparation(s)		
Phyllanthus emblica	AmalakiAmlaEmblicEmblic myrobalanIndian gooseberryMembolan	Phyllanthus emblica	Fruit	Dry
Terminalia chebula	HaradHaritaki	Terminalia chebula	Fruit	Dry

Medicinal Ingredients	Dried fruit (grams/day)	
Minimum	Maximum	
Amalaki	3	6
Haritaki	1	3
Bibhitaki	1	3
Amalaki + Haritaki + Bibhitaki (Triphala)	1	3
Amalaki + Haritaki or Bibhitaki	2	3
Haritaki + Bibhitaki	1	3

Medicinal Ingredients	Dried fruit (grams/day)	
Minimum	Maximum	
Amalaki	3	6
Haritaki	2	6
Bibhitaki	3	6
Amalaki + Haritaki + Bibhitaki (Triphala)	2	6
Any 2 combined together	3	6