



## NATURAL HEALTH PRODUCT

### TRIPHALA

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 PLA and product 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.
- ▶ 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.

#### Date

June 11, 2014

**Table 1 Medicinal ingredients**

Proper name(s)	Common name(s)	Source material(s)
<i>Phyllanthus emblica</i> L. (Phyllanthaceae [also placed in Euphorbiaceae]) (USDA 2005; McGuffin et al. 2000)  Synonym: <i>Emblica officinalis</i> Gaertn. (Phyllanthaceae [also placed in Euphorbiaceae]) (ITIS 2011; API 2001[1990])	<ul style="list-style-type: none"> <li>• Amalaki (Martindale 2011; API 2001[1990]; McGuffin et al. 2000)</li> <li>• Amla (Martindale 2011; USDA 2005; API 2001[1990]; McGuffin et al. 2000)</li> <li>• Emblic (ITIS 2011; Martindale 2011; USDA 2005)</li> <li>• Emblic myrobalan (Martindale 2011; USDA 2005; API 2001[1990]; McGuffin et al. 2000)</li> <li>• Indian-gooseberry (Martindale 2011; USDA 2005; McGuffin et al. 2000)</li> </ul>	Fruit (API 2001[1990]; Khory and Katrak 1999 [1903])
<i>Terminalia chebula</i> Retz. (Combretaceae) (USDA 2001, API 2001[1990])	<ul style="list-style-type: none"> <li>• Haritaki (API 2001[1990]; USDA 2001)</li> <li>• Harad (API 2001[1990])</li> <li>• Chebulic myrobalan (USDA 2001)</li> </ul>	Mature fruit (API 2001[1990]; Kapoor 2001; Nadkarni 1954)
<i>Terminalia bellirica</i> (Gaertn.) Roxb.	<ul style="list-style-type: none"> <li>• Bibhitaki (USDA 2006)</li> <li>• Belleric (USDA 2006)</li> </ul>	Mature fruit (API 2001[1990])



(USDA 2006)	<ul style="list-style-type: none"> <li>Belleric myrobalan (USDA 2006; API 2001[1990])</li> </ul>	
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**Route(s) of administration**

Oral

**Dosage form(s)**

- ▶ The acceptable pharmaceutical dosage forms include, but are not limited to capsules, chewables (e.g. gummies, tablets), liquids, powders, strips or tablets.
- ▶ This monograph is not intended to include foods or food-like dosage forms such as bars, chewing gums or beverages.

**Use(s) or Purpose(s)** Statement(s) to the effect of

*All products*

- ▶ Traditionally used in Ayurvedic Medicine for the relief of occasional constipation (laxative) (Chouhan et al. 2013; Murthy 2004).
- ▶ Traditionally used in Ayurvedic Medicine as an eye tonic (Chouhan et al. 2013; Murthy 2004).

*Products containing Triphala and/or Amalaki and/or Haritaki*

- ▶ Traditionally used in Ayurvedic Medicine as Rasayana (rejuvenative tonic) (Murthy 2004; API 2001[1990]; Nadkarni 1976).
- ▶ Traditionally used in Ayurvedic Medicine 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 [1903]).

*Products containing Amalaki*

- ▶ Traditionally used in Ayurvedic Medicine to help relieve symptoms such as heartburn and indigestion associated with Amlapitta (hyperacidity or dyspepsia) (Warriar et al. 2003; API 2001[1990]; Gogte 2000).
- ▶ Provides antioxidants (Paranjpe 2005; Williamson 2002; API 2001 [1990]; Kapoor 2001; Duke 1992).

*Products containing Haritaki and/or Bibhitaki*

- ▶ Traditionally used in Ayurvedic Medicine to help expel intestinal worms (vermifuge) (Sukh Dev 2006; Kirtikar and Basu 1981; Nadkarni 1954).



- ▶ Traditionally used in Ayurvedic Medicine to help relieve cough (Sukh Dev 2006; API 2001[1990]).

*Products containing Haritaki*

Traditionally used in Ayurvedic Medicine 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.

**Note**

A claim for traditional use must include the term “Ayurvedic Medicine/Ayurveda”.

**Dose(s)**

**Subpopulation**

Adults ( ≥ 18 years)

**Quantity(ies)**

*Rasayana; Digestive tonic; Eye tonic*

Dry, Powder, Alcoholic non-standardized extracts (Fluid extract, Tincture)

Medicinal Ingredient	Minimum (g/day) dried fruit	Maximum (g/day) dried fruit	References
Amalaki	3	6	API 2001[1990]
Haritaki	1	3	Williamson 2002; API 2001[1990]; Gogte 2000;
Bibhitaki	1	3	Williamson 2002; API 2001[1990]; Gogte 2000;
Triphala (Amalaki +Haritaki + Bibhitaki)	1	3	Tilloston et al. 2001; Gogte 2000
Amalaki + Haritaki or Bibhitaki	2	3	API 2001[1990]; Gogte 2000
Haritaki + Bibhitaki	1	3	Tilloston et al. 2001; ; Gogte 2000



*Laxative; Amlapitta; Carminative; Cough; Vermifuge*

Dry, Powder, Alcoholic non-standardized extracts (Fluid extract, Tincture)

<b>Medicinal Ingredient</b>	<b>Minimum (g/day) dried fruit</b>	<b>Maximum (g/day) dried fruit</b>	<b>References</b>
Amalaki	3	6	API 2001[1990]
Haritaki	2	6	Murthy 1994; API 2001[1990]
Bibhitaka	3	6	API 2001[1990]
Triphala (Amalaki + Haritaki + Bibhitaki)	2	6	Tilloston et al. 2001; Murthy 1994
Any 2 combined together	3	6	Murthy 1994

**Directions for use** Statement(s) to the effect of

*All Products*

Take 2 hours before or after taking other medications or natural health products (Martindale 2008; HC 1994).

*Laxative*

Allow at least 6 to 12 hours for laxative effect to occur (APhA 2002).

**Duration of use**

*Laxative; Vermifuge*

- ▶ For occasional use only.
- ▶ For use beyond 7 days, consult a health care practitioner (Pray 2006; CPhA 2002; HC 1994).

**Risk information** Statement(s) to the effect of

**Caution(s) and warning(s)**

*All products*



- ▶ If you are pregnant or breastfeeding, consult a health care practitioner prior to use.
- ▶ If you have abdominal pain, nausea, fever or vomiting, consult a health care practitioner prior to use (McGuffin et al. 1997; HC 1994).
- ▶ If you experience abdominal pain, cramps, spasms and/or diarrhoea while using this product, reduce dose or discontinue use (Murthy 2004; McGuffin et al. 1997).

*Amlapitta; Stomachic; Laxative; Cough; Carminative; Vermifuge*

If symptoms persist or worsen, consult a health care practitioner.

*Products providing  $\geq 4$  g Triphala dried fruit or  $\geq 4$  g Haritaki dried fruit*

- ▶ If you are taking thiazide diuretics, corticosteroids, licorice root or other medications or health products which may aggravate electrolyte imbalance, consult a health care practitioner prior to use (Murthy 2004; McGuffin et al. 1997).
- ▶ If you have a kidney disorder or are taking cardiac medications (e.g. cardiac glycosides, antiarrhythmic medications), consult a health care practitioner prior to use (McGuffin et al. 1997).

### **Contraindication(s)**

*Products providing  $\geq 4$  g Triphala dried fruit or  $\geq 4$  g Haritaki dried fruit*

If you have abnormal constrictions of the gastrointestinal tract, potential or existing intestinal blockage, atonic bowel, appendicitis, inflammatory colon disease (such as Crohn's disease or ulcerative colitis), abdominal pain of unknown origin, undiagnosed rectal bleeding, severe dehydration with depleted water or electrolytes, do not use this product (Murthy 2004; McGuffin et al. 1997).

### **Known adverse reaction(s)**

*All products except those making laxative claim*

Laxative effect may occur, in which case, discontinue use.

### **Non-medicinal ingredients**

Must be chosen from the current NHPD *Natural Health Products Ingredients Database* (NHPID) and must meet the limitations outlined in the database.

### **Specifications**

- ▶ The finished product specifications must be established in accordance with the requirements described in the NHPD *Quality of Natural Health Products Guide*.



- ▶ The medicinal ingredient must comply with the requirements outlined in the *Natural Health Products Ingredients Database* (NHPID).

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## Appendix 1

### Summary of Acceptable Uses Based on Medicinal Ingredients

<b>Recommended use/purpose</b>	<b>Triphala (Amalaki + Haritaki + Bibhitaki)</b>	<b>Amalaki</b>	<b>Haritaki</b>	<b>Bibhitaka</b>
Laxative	√	√	√	√
Eye tonic	√	√	√	√
Rasayana	√	√	√	
Digestive Tonic	√	√	√	
Heartburn/Amlapitta		√		
Antioxidant		√		
Vermifuge			√	√
Cough			√	√
Carminative			√	