

## NATURAL HEALTH PRODUCT

### HOLY BASIL – *OCIMUM TENUIFLORUM* – SEED

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

#### Date

December 18, 2018

#### Proper name(s), Common name(s), Source material(s)

Table 1. Proper name(s), Common name(s), Source material(s)

Proper name(s)	Common name(s)	Source material(s)		
		Proper name(s)	Part(s)	Preparation(s)
<i>Ocimum tenuiflorum</i>	<ul style="list-style-type: none"> <li>▶ Holy basil</li> <li>▶ Rama tulsi</li> <li>▶ Sacred basil</li> <li>▶ Tulsi</li> </ul>	<i>Ocimum tenuiflorum</i>	Seed	Dried

References: Proper name: USDA 2018, McGuffin et al. 2000; Common names: USDA 2018, McGuffin et al. 2000, API 1999; Source material: API 1999.

#### 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 the age category listed in this monograph and specified route of administration are indicated in the Compendium of Monographs Guidance Document.



### Use(s) or Purpose(s)

- ▶ Traditionally used in Ayurveda (as a demulcent) to help relieve cough (Kasa) (Mishra 2004; Kapoor 2001; API 1999).
- ▶ Traditionally used in Ayurveda as a cardi tonic (Hrdya) (API 1999).
- ▶ Traditionally used in Ayurveda to aid digestion (Dipani) (API 1999).

The following combined use(s) or purpose(s) is/are also acceptable:

Traditionally used in Ayurveda (as a demulcent) to help relieve cough (Kasa), as a cardi tonic (Hrdya) and to aid digestion (Dipani) (Mishra 2004; Kapoor 2001; API 1999).

### Note

Claims for traditional use must include the term “Herbal Medicine”, “Traditional Chinese Medicine”, or “Ayurveda”.

### Dose(s)

#### Subpopulation(s)

Adults 18 years and older

#### Quantity(ies)

Methods of preparation: Dry, Powder, Non-Standardised Ethanolic Extracts (Dry extract, Tincture, Fluid extract)

1 - 2 grams of dried seed, per day (Williamson 2002; Kapoor 2001; API 1999).

#### Direction(s) for use

No statement required.

### Duration(s) of use

No statement required.

### Risk information

#### Caution(s) and warning(s)



### *All products*

- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are pregnant, breastfeeding or have a cardiovascular condition (Rai et al. 1997; Agrawal et al. 1996).
- ▶ Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if you are taking any heart or blood pressure medication (Rai et al. 1997; Agrawal et al. 1996).

### *Relief of cough; Digestive aid*

Consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen.

### **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**

No statement required.

### **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.



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