



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

Date

March 22, 2013

Proper name(s)

Ocimum tenuiflorum L. (Lamiaceae) (USDA 2007; McGuffin et al. 2000)

Synonym: *Ocimum sanctum* L. (ITIS 2011; McGuffin et al. 2000; API 1999)

Common name(s)

- ▶ Holy basil (USDA 2007; McGuffin et al. 2000)
- ▶ Sacred basil (USDA 2007; McGuffin et al. 2000)
- ▶ Tulasi (McGuffin et al. 2000; API 1999)
- ▶ Tulsi (USDA 2007; McGuffin et al. 2000; API 1999)

Source material(s)

seed (API 1999)

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

- ▶ 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).

Dose(s) Statement(s) to the effect of

Sub-population(s)

adults (≥ 19 years)

Quantity(ies)

1-2 g powdered dry seed, per day (Williamson 2002; Kapoor 2001; API 1999).

Duration of use Statement(s) to the effect of

No statement required.

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 a cardiovascular condition, or are taking any heart or blood pressure medication, consult a health care practitioner prior to use (Rai et al. 1997; Agrawal et al. 1996).

Relief of cough and digestion:

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

Contraindication(s)

No statement required.

Known adverse reaction(s)

No statement required.

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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