PASSIONFLOWER

Date: March 20, 2008

Proper name(s): Passiflora incarnata L. (Passifloraceae) (EMEA 2007; USDA 2007)

Common name(s): Passionflower (EMEA 2007; USDA 2007)

Source material(s): Aerial parts (EMEA 2007)

Route(s) of administration: Oral

Dosage form(s): Those suited to the allowable route(s) of administration. This monograph is not intended to include 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 Herbal Medicine as a sleep aid (in cases of restlessness or insomnia due to mental stress) (EMEA 2007)

Dose(s):

Subpopulation: Adults, and adolescents ≥ 13 years (EMEA 2007)

Quantity: Preparations equivalent to 0.25-8 g dried aerial parts, per day (EMEA 2007)

See Appendix 1 for examples of appropriate dosage preparations, frequencies of use and directions for use, according to cited references. The purpose of Appendix 1 is to provide guidance to industry.

Duration of use: No statement required.
Risk information: Statement(s) to the effect of:

Caution(s) and warning(s):
- Consult a health care practitioner if symptoms persist or worsen.
- Consult a health care practitioner if sleeplessness persists continuously for more than 3 weeks (chronic insomnia) (Berardi et al. 2002; DiPiro et al. 2002).
- Consult a health care practitioner prior to use if you are pregnant or breastfeeding (EMEA 2007).
- Consumption with alcohol, other medications or natural health products with sedative properties is not recommended (Brinker 2008; EMEA 2007).

Contraindication(s): No statement required.

Known adverse reaction(s):
- Hypersensitivity (e.g. allergy) has been known to occur; in which case, discontinue use (EMEA 2007).
- Some people may experience drowsiness. Exercise caution if operating heavy machinery, driving a motor vehicle or involved in activities requiring mental alertness (EMEA 2007).

Non-medicinal ingredients: Must be chosen from the current NHPD List of Acceptable Non-medicinal Ingredients and must meet the limitations outlined in the list.

Specifications:
- The finished product must comply with the minimum specifications outlined in the current NHPD Compendium of Monographs.
- The medicinal ingredient may comply with the specifications outlined in the Passion Flower Monograph published in the British or the European Pharmacopoeias.

References cited:
References reviewed:

Appendix 1: Examples of appropriate dosage preparations, frequencies of use and directions for use (EMEA 2007)

Dried aerial parts: 0.5-2 g, 1-4 times per day

Infusion: 1-2 g dried aerial parts, 1-4 times per day

   **Directions for use:** Pour 150 ml of boiling water on dried aerial parts and steep for 10 minutes.

Fluidextract:

   - 0.5-2 g dried equivalent, 1-4 times per day
     (1:1, 25% alcohol, 0.5-2 ml)
   - 2 g dried equivalent, 1-3 times per day
     (1:1, 70% alcohol, 2 ml)

Tincture:

   - 0.25-0.5 g dried equivalent, 1-4 times per day
     (1:8, 25% alcohol, 2-4 ml)
   - 0.25 g dried equivalent, 1-3 times per day
     (1:8, 45% alcohol, 2 ml)