This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLA) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredient. It is a referenced document to be used as a labelling standard.

**Note:** Text in parentheses is additional optional information which can be included on the PLA and product labels at the applicants’ discretion. The solidus (/) indicates that the terms are synonyms or that the statements are synonymous. Either term or statement may be selected by the applicant.

**Date:** August 5, 2009

**Proper name(s):** *Chamaemelum nobile* L. All. (*Asteraceae*) Synonym: *Anthemis nobilis* L. (USDA 2008)

**Common name(s):** Roman chamomile (USDA 2008; McGuffin et al. 2000)

**Source material(s):** Flower (Wichtl 2004; Bradley 1992)

**Route(s) of administration:** Oral (Wichtl 2004; Bradley 1992)

**Dosage form(s):** Those pharmaceutical dosage forms suited to oral administration, including but not limited to chewables (eg. gummies, tablets), caplets, capsules, strips, lozenges, powders or liquids where the dose is measured in drops, teaspoons or tablespoons, are acceptable. 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 Herbal Medicine to help relieve mild digestive disturbances (such as dyspepsia, nausea, flatulence) (Wichtl 2004; Mills and Bone 2000; Bradley 1992; BHP 1983; Ellingwood 1983[1919]; Felter 1983[1922]).
**Dose(s):** Preparations equivalent to 1.8-12 g dried flowers, per day (Wichtl 2004; Bradley 1992; BHP 1983)

See Appendix 1 for examples of 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(s) of use:** No statement required.

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

**Caution(s) and warning(s):** Consult a healthcare practitioner if symptoms persist or worsen.

**Contraindication(s):** Do not use if you are allergic to plants of the Asteraceae/Compositae/Daisy family (Mills and Bone 2000; Brinker 2001; Blumenthal et al. 1998).

**Known adverse reaction(s):** Hypersensitivity, such as allergy, has been known to occur in which case, discontinue use (Mills and Bone 2000; Brinker 2001; Blumenthal et al. 1998).

**Non-medicinal ingredients:** Must be chosen from the current NHPD *Natural Health Products Ingredients Database* and must meet the limitations outlined in the database.

**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 pharmacopoeial monographs listed in Table 1 below.

Table 1: Monographs published in the British Pharmacopoeia (BP) and European Pharmacopoeia (Ph. Eur.).

<table>
<thead>
<tr>
<th>Pharmacopeia</th>
<th>Monograph</th>
</tr>
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<tbody>
<tr>
<td>BP</td>
<td>Chamomile Flowers</td>
</tr>
<tr>
<td>Ph. Eur.</td>
<td>Chamomile Flower, Roman</td>
</tr>
</tbody>
</table>
References cited:


References reviewed:


Appendix 1: Examples of dosage preparations, frequencies of use and directions for use

Dried flower:
- 1.5-3 g, 3 times per day (Bradley 1992)
- 1-4 g, 3 times per day (BHP 1983)

Infusion:
- 2-3 g dried flower (Wichtl 2004)
- 1.5-3 g dried flower, three times daily (Bradley 1992)

Directions for use: Pour boiling water over the finely cut dried flower. Steep for 10 min and then strain (Wichtl 2004).

Fluidextract:
- 1.5-3 g dried equivalent, 3 times per day
  (1:1, 70% ethanol, 1.5-3 ml) (Bradley 1992)
- 1-4 g dried equivalent, three times per day
  (1:1, 70% ethanol, 1-4 ml) (BHP 1983)

Tincture: 0.6-1 g dried equivalent, three times per day
(1:5, 1-5 ml) (Bradley 1992)