ROMAN CHAMOMILE

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.).

Pharmacopeia	Monograph
BP	Chamomile Flowers
Ph. Eur.	Chamomile Flower, Roman

References cited:

BP 2008: British Pharmacopoeia Commission. British Pharmacopoeia 2008, Volume 1. London (GB): The Stationary Office on behalf of the Medicines and Healthcare products Regulatory Agency (MHRA).

BHP 1983: British Herbal Pharmacopoeia. Bournemouth (GB): British Herbal Medicine Association.

Blumenthal M, Busse WR, Goldberg A, Gruenwald J, Hall T, Riggins CW, Rister RS, editors. 1998. Herbal Medicine: Complete Commission E Monographs. Boston (MA): Integrative Medicine Communications.

Bradley PR, editor. 1992. British Herbal Compendium, Volume 1. Bournemouth (GB): British Herbal Medicine Association.

Brinker F. 2001. Herb Contraindications and Drug Interactions, 3rd edition. Sandy (OR): Eclectic Medical Publications.

Ellingwood F. 1919. The American Materia Medica, Therapeutics and Pharmacognosy. Sandy (OR): Eclectic Medical Publications.

Felter HW. 1922. The Eclectic Materia Medica, Pharmacology and Therapeutics. Sandy (OR): Eclectic Medical Publications.

McGuffin M, Kartesz JT, Leung AY, Tucker AO. 2000. Herbs of Commerce. Silver Spring (MD): American Herbal Products Association.

McGuffin M, Hobbs C, Upton R, Goldberg A, editors. 1997. American Herbal Products Association's Botanical Safety Handbook. Boca Raton (FL): CRC Press.

Mills S, Bone K. 2000. Principles and Practice of Phytotherapy. Toronto (ON): Churchill Livingstone.

Ph. Eur. 2008: European Pharmacopoeia Commission. 2008. European Pharmacopoeia, 6th edition, Volume 2. Strasbourg (FR): Directorate for the Quality of Medicines and HealthCare of the Council of Europe (EDQM).

USDA 2008: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN). [online database]. 2008. *Anthemis nobilis* (L.) All. National Germplasm Resources Laboratory, Beltsville (MD). [Accessed 2009 July 23]. Available at: http://www.ars-grin.gov/cgibin/npgs/html/tax_search.pl

Wichtl M, editor. 2004. Herbal Drugs and Phytopharmaceuticals: A Handbook for Practice on a Scientific Basis. 3rd edition. Stuttgart (DE): Medpharm GmbH Scientific Publishers.

References reviewed:

Barnes J, Anderson LA, Phillipson JD. 2007. Herbal Medicines, 3rd edition. Grayslake (IL): Pharmaceutical Press.

Brinker F. 2008. Online Updates and Additions to Herb Contraindications and Drug Interactions, 3rd edition. Sandy (OR): Eclectic Medical Publications. [Accessed 2009 June 24]. Available from: http://www.eclecticherb.com/emp/updatesHCDI.html

Carnat A, Carnat AP, Fraisse D, Ricoux L, Lamaison JL. 2004. The aromatic and polyphenolic composition of Roman camomile tea. Fitoterapia 75(1):32-38.

Mills S, Bone K. 2005. The Essential Guide to Herbal Safety. Amsterdam (NL): Elsevier.

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)