NATURAL HEALTH PRODUCT

RED WINE EXTRACT

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 7, 2014

Proper name(s)

Vitis vinifera L. (Vitaceae) (USDA 2009)

Common name(s)

- Red Wine Extract (Leifert and Abeywardena 2008)
- Red Wine Polyphenol Extract (Leifert and Abeywardena 2008)

Source material(s)

Fruit (Nigdikar et al. 1998; Brouillard et al. 1997)

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

Provides antioxidants (Meskin et al. 2002; Cuevas et al. 2000).

Dose(s)

Statement(s) to the effect of

Subpopulation(s)

Adults (≥ 18 years)

Quantity(ies)

Up to 1 g red wine extract, per day (Chopra et al. 2000; Cuevas et al. 2000; Nigdikar et al. 1998).

Potency (Optional): Up to 95 % polyphenols (Botden et al. 2012; Chopra et al. 2000).

Duration of use

No statement required.

Risk information

Statement(s) to the effect of

Caution(s) and warning(s)

If you are pregnant or breastfeeding, consult a health care practitioner prior to use (Meskin et al. 2002).

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.
Storage conditions

No statement required.

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).

References cited


References reviewed


