

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

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Meskin MS, Bidlack WR, Davies AJ, Omaye ST. *Phytochemicals in nutrition and health*. CRC Press LLC. Boca Raton, Florida;2002:46-60.

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