

## DRIED CRANBERRY JUICE

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 are synonyms or that the statements are synonymous. Either term or statement may be selected by the applicant.

**Date:** March 28, 2011

**Proper name(s):** *Vaccinium macrocarpon* Aiton (Ericaceae) (USDA 2010; McGuffin et al. 2000)

**Common name(s):** Dried cranberry juice (Jepson and Craig 2008; Mills and Bone 2005; Stothers 2002; Upton 2002; Siciliano 1996)

**Source material(s):** Fruit (Jepson and Craig 2008; Mills and Bone 2005; Stothers 2002; Upton 2002; Siciliano 1996)

**Route(s) of administration:** Oral

### Dosage form(s):

- ▶ The acceptable pharmaceutical dosage forms include, but are not limited to chewables (e.g. gummies, tablets), caplets, capsules, strips, lozenges, powders or liquids where the dose is measured in drops, teaspoons or tablespoons.
- ▶ 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 prevent (recurrent) urinary tract infections (UTIs) (Barnes et al. 2007; Bruyère 2006; Blumenthal et al. 2003; Bodel et al. 1959).
- ▶ (Used in Herbal Medicine to) help(s) prevent recurrent urinary tract infections (UTIs) in women (Jepson and Craig 2008; Mills and Bone 2005; Stothers 2002; Walker et al. 1997; Avorn et al. 1994).
- ▶ Provides antioxidants for the maintenance of good health (Valentenova et al. 2007; Ruel et al. 2005; Upton 2002).

**Note:** Claims for traditional use must include the term “Herbal Medicine”.

**Dose(s):**

Antioxidant: Up to 1200 mg dried fruit juice, per day (Valentenova et al. 2007; Upton 2002)

(Recurrent) urinary tract infection:

400-1200 mg dried fruit juice, per day (Mills and Bone 2005; Upton 2002; Walker et al. 1997)

**Note:** Applicants are not to provide a quantity of crude equivalent (QCE) and/or extract ratio.

Refer to 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:**

Antioxidant: No statement required.

(Recurrent) urinary tract infection:

Use for a minimum of 4 weeks to see beneficial effects (Jepson and Craig 2008; Blumenthal et al. 2003; Walker et al. 1997; Avorn et al. 1994).

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

**Caution(s) and warning(s):**

All uses:

- ▶ Consult a health care practitioner prior to use if you have a history of kidney stones (Gettman et al. 2005; Terris et al. 2001).
- ▶ Consult a health care practitioner prior to use if you are taking blood thinners (Brinker 2010; Aston et al. 2006; Rindone and Murphy 2005; Grant 2004).

(Recurrent) urinary tract infection:

Consult a health care practitioner if symptoms persist or worsen.

**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* 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 Cranberry Liquid Preparation published in the US Pharmacopeia (USP).

**Note:** The information detailed in this section is not to be submitted with a compendial PLA, although it may be requested at Health Canada's discretion.

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

- ▶ 200 mg dried cranberry juice, 2 times per day (Valentenova et al. 2007)
- ▶ 400 mg dried cranberry juice, 2 times per day (Valentenova et al. 2007)
- ▶ 400-800 mg dry concentrate (25:1), per day (Mills and Bone 2005)
- ▶ 400 mg cranberry dry extract, 2-3 times per day (Upton 2002)
- ▶ 400 mg cranberry concentrate / concentrated cranberry extract, 2 times per day (Walker et al 1997)