

NATURAL HEALTH PRODUCT

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

Date August 5, 2019

Proper name(s), Common name(s), Source material(s)

Table 1. Proper name(s), Common name(s), Source material(s)

Proper name(s)	Common name(s)	Source material(s)	
		Proper name(s)	Part(s)
<i>Solanum lycopersicum</i>	Tomato extract	<i>Solanum lycopersicum</i>	Fruit flesh

References: Proper name: USDA 2019, USP 32 2009; Common name: USP 32 2009, Kucuk et al. 2002, Kucuk et al. 2001; Source material: USP 32 2009, Kucuk et al. 2002.

Route of administration

Oral

Dosage form(s)

This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document.

Acceptable dosage forms for the age category listed in this monograph and specified route of administration are indicated in the Compendium of Monographs Guidance Document.

Use(s) or Purpose(s)

- ▶ Source of/Provides antioxidants (Silaste et al. 2007; Porrini et al. 2005; Matos et al. 2001).



- ▶ Helps to support prostate health (Erdman et al. 2008; Kristal et al. 2008; Schwarz et al. 2008; Mohanty et al. 2005; Giovannucci et al. 2002; Kucuk et al. 2002; Kucuk et al. 2001; Gann et al. 1999).

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Methods of preparation: Standardized extracts

Antioxidant

Not to exceed 30 milligrams of Lycopene, per day (Silaste et al. 2007; Porrini et al. 2005; Kucuk et al. 2002).

Prostate health

6.5 to 30 milligrams of Lycopene, per day (Kristal et al. 2008; Giovannucci et al. 2002; Gann et al. 1999; Giovannucci et al. 1995).

Direction(s) for use

No statement required.

Duration(s) of use

No statement required.

Risk information

Caution(s) and warning(s)

No statement required.

Contraindication(s)

No statement required.



Known adverse reaction(s)

No statement required.

Non-medicinal ingredients

Must be chosen from the current 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 Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide.
- ▶ The medicinal ingredient must comply with the requirements outlined in the NHPID.

References cited

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