Tomato Extract

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TOMATO EXTRACT Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section. (PDF Version - 49 KB) 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) Solanum lycopersicum Tomato extract Solanum lycopersicum 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 any age category listed in this monograph for the specified route of administration are listed 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 Erdman JW Jr, Ford NA, Lindshield BL. 2009. Are the health attributes of lycopene related to its antioxidant function? Archives of Biochemistry and Biophysics 483(2):229-235. Gann PH, Ma J, Giovannucci E, Willett W, Sacks FM, Hennekens CH, Stampfer MJ. 1999. Lower prostate cancer risk in men with elevated plasma lycopene levels: results of a prospective analysis. Cancer Research 59(6):1225-1230. Giovannucci E, Rimm EB, Liu Y, Stampfer MJ, Willett WC. 2002. A prospective study of tomato products, lycopene, and prostate cancer risk. Journal of the National Cancer Institute 94(5):391-398. Giovannucci E, Ascherio A, Rimm EB, Stampfer MJ, Colditz GA, Willett WC. 1995. Intake of carotenoids and retinol in relation to risk of prostate cancer. Journal of the National Cancer Institute 87(23):1767-1776. Kristal AR, Arnold KB, Schenk JM, Neuhouser ML, Goodman P, Penson DF, Thompson IM. 2008. Dietary patterns, supplement use, and the risk of symptomatic benign prostatic hyperplasia: results from the prostate cancer prevention trial. The American Journal Epidemiology 167(8):925-934. Kucuk O, Sarkar FH, Djuric Z, Sakr W, Pollak MN, Khachik F, Banerjee M, Bertram JS, Wood DP Jr. 2002. Effects of lycopene supplementation in patients with localized prostate cancer. Experimental Biology and Medicine 227(10):881-885. Kucuk O, Sarkar FH, Sakr W, Djuric Z, Pollak MN, Khachik F, Li YW, Banerjee M, Grignon D, Bertram JS, Crissman JD, Pontes EJ, Wood DP Jr. 2001. Phase II randomized clinical trial of lycopene supplementation before radical prostatectomy. Cancer Epidemiology, Biomarkers & Prevention 10(8):861-868. Matos HR, Capellozzi VL, Gomes QF, Mascio PD, Medeiros MH. 2001. Lycopene inhibits DNA damage and liver necrosis in rats treated with ferric nitrolotriacetate. Archives of Biochemistry and Biophysics 396(2):171-177. Mohanty NK, Saxena S, Singh UP, Goyal NK, Arora RP. 2005. Lycopene as a chemopreventive agent in the treatment of high-grade prostate intraepithelial neoplasia. Urologic Oncology 23(6):383-385. Porrini M, Riso P, Brusamolino A, Berti C, Guarnieri

S, Visioli F. 2005. Daily intake of formulated tomato drink affects caratenoid plasma and lymphocyte concentrations and improves cellular antioxidant protection. British Journal of Nutrition 93(1):93-99. Schwarz S, Obermüller-Jevic UC, Hellmis E, Koch W, Jacobi G, Biesalski HK. 2008. Lycopene inhibits disease progression in patients with benign prostate hyperplasia. The Journal of Nutrition 138(1):49-53. Silaste ML, Alfthan G, Agro A, Kesäniemi YA, Hörkkö S. 2007. Tomato juice decreases LDL cholesterol levels and increases LDL resistance to oxidation. British Journal of Nutrition 98(6):1251-1258. USDA 2019: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN) [online]. 2019. Lycopersicon esculentum Mill. Beltsville (MD): National Germplasm Resources Laboratory. [Accessed 2019 June 7]. Available from: https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysimple.aspx USP 32: United States Pharmacopeial Convention. 2009. United States Pharmacopeia and the National Formulary (USP 32 - NF 27). Rockville (MD): The United States Pharmacopeial Convention. References Reviewed Christian MS, Schulte S, Hellwig J. 2003. Developmental (embryo-fetal toxicity/teratogenicity) toxicity studies of synthetic crystalline lycopene in rats and rabbits. Food and Chemical Toxicology 41(6):773-783. Higdon J. 2005. Carotenoids: Alpha-Carotene, Beta-Carotene, Beta-Cryptoxanthin, Lycopene, Lutein, and Zeaxanthin [online]. Corvallis (OR): Linus Pauling Institute, Oregon State University. Last updated June 2009. [Accessed 2009 May 20]. Available at: http://lpi.oregonstate.edu/infocenter/phytochemicals/carotenoids/index.html Kim L, Rao AV, Rao LG. 2002. Effect of lycopene on prostate LNCaP cancer cells in culture. Journal of Medicinal Food 5(4):181-187. Shao A, Hathcock JN. 2006. Risk assessment for the carotenoids lutein and lycopene. Regulatory Toxicology and Pharmacology 45(3):289-298. Sharma JB, Kumar A, Kumar A, Malhotra M, Arora R, Prasad S, Batra S. 2003. Effect of lycopene on pre-eclampsia and intra-uterine growth retardation in primigravidas. International Journal of Gynaecology and Obstetrics 81(3):257-262. Report a problem on this page Date modified: 2019-03-01

MEDICINAL INGREDIENT(S)

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.

DOSAGE FORM(S)

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

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.

STORAGE CONDITION(S)

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

Route of Administration Oral

Proper name(s)	Common name(s)	Source material(s)	
Proper name(s)	Part(s)		
Solanum lycopersicum	Tomato extract	Solanum lycopersicum	Fruit flesh