

Concentrated turmeric and isolates (curcuminoids/curcumin)

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CONCENTRATED TURMERIC EXTRACTS AND ISOLATES (CURCUMINOIDS/CURCUMIN) 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 - 50 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. As enhanced absorption formulations are often used for Turmeric and its constituents, this is a reminder that enhanced absorption dosage forms/formulations are not covered by Natural and Non-prescription Health Products Directorate's monographs and should be submitted as Class III submissions. Date March 28, 2024 Proper name(s), Common name(s), Source information Table 1. Proper name(s), Common name(s), Source information Proper name(s) Common name(s) Source information Source material(s) Part(s) Preparation(s) Curcuma longa Common turmeric Curcuma Indian-saffron Jianghuang Turmeric Yellow ginger Curcuma longa Rhizome Dry Curcuminoids Curcuminoids Curcuma longa Rhizome Isolate (1E,6E)-1,7-Bis(4-hydroxy-3-methoxyphenyl)-1,6-heptadiene-3,5-dione Curcumin Curcuma longa Rhizome Isolate N/A N/A Synthetic References: Proper names: Curcuminoids: USP-NF 2023; EFSA 2017; Curcumin: RSC 2023; Turmeric: USDA 2023; Common names: Curcuminoids: USP-NF 2023; EFSA 2017; Curcumin: Goel et al. 2008; Boon and Smith 2004; Deodhar et al. 1980; Turmeric: USDA 2023; PPRC 2015; McGuffin et al. 2000; Source information: PPRC 2015; Goel et al. 2008; Boon and Smith 2004; ESCOP 2003; Blumenthal et al. 2000; Deodhar et al. 1980. 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 oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications. Use(s) or Purpose(s) Source of (an) antioxidant(s)/Provides (an) antioxidant(s) (ESCOP 2003; Blumenthal et al. 2000; Mills and Bone 2000). Source of (an) antioxidant(s)/Provides (an) antioxidant(s) that help(s) fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals (ESCOP 2003; Blumenthal et al. 2000; Mills and Bone 2000). Helps relieve joint pain and inflammation (Kuptniratsaikul et al. 2014; Panahi et al. 2014; Deodhar et al. 1980). Note: For source of antioxidant(s) claims, the singular should be used on the label when the product only contains one medicinal ingredient (MI) (single compound) associated with the claim (e.g. curcumin); the plural form should be used when the product formulation contains more than one MI with such properties or one MI containing several compounds with antioxidant properties such as curcuminoids. Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) Concentrated Turmeric Extracts Methods of preparation: Standardized Extracts Antioxidant Extract standardized to 75% Curcuminoids or more; Not to exceed 1500 milligrams curcuminoids per day and 500 milligrams per single dose (USP-NF 2023; Kuptniratsaikul et al. 2014; Panahi et al. 2014). Note: Optional: The potency constituent, curcumin, can be included. Relief of joint pain/inflammation Extract standardized to 75% Curcuminoids or more; Providing 1500 milligrams curcuminoids, per day; Not to exceed 500 milligrams per single dose (USP-NF 2023; Kuptniratsaikul et al. 2014; Panahi et al. 2014). Note: Optional: The potency constituent, curcumin, can be included. Curcuminoids Antioxidant Not to exceed 1500 milligrams curcuminoids per day and 500 milligrams per single dose (USP-NF 2023; Kuptniratsaikul et al. 2014; Panahi et al. 2014). Note: Optional: The potency constituent, curcumin, can be included. Relief of joint pain/inflammation 1500 milligrams curcuminoids, per day; Not to exceed 500 milligrams per single dose (USP-NF 2023; Kuptniratsaikul et al. 2014; Panahi et al. 2014). Note: Optional: The potency constituent, curcumin, can be included. Curcumin Antioxidant Not to exceed 1200 milligrams curcumin per day and 400 milligrams per single dose (Deodhar et al. 1980). Relief of joint pain/inflammation 1200 milligrams curcumin, per day; Not to exceed 400 milligrams per single dose (Boon and Smith 2004; Deodhar et al. 1980). Direction(s) for use No statement required. Combination rules The finished product should not exceed a total amount of curcuminoids of 500 mg per dose and 1500 mg per day. The

finished product should not exceed a total amount of curcumin of 400 mg per dose and 1200 mg per day. Duration(s) of Use No statement required. Risk Information Caution(s) and warning(s) All products Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have a biliary disorder (Brinker 2010; ESCOP 2003; McGuffin et al. 2000). Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are taking blood thinners (Brinker 2010; Mills and Bone 2005). Relief of joint pain/inflammation Ask a health care practitioner/health care provider/health care professional/doctor/physician 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 Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database. Storage conditions Must be established in accordance with the requirements described in the Natural Health Products Regulations. Specifications The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products (NNHPD) Quality of Natural Health Products Guide. The medicinal ingredient must comply with the requirements outlined in the NHPID. The medicinal ingredients may comply with pharmacopoeial monographs. For example, as per USP-NF 2023, curcuminoids is defined as a partially purified natural complex of diaryl heptanoid derivatives isolated from Turmeric, *Curcuma longa* L. The ingredient contains NLT 95.0% of curcuminoids, calculated on the dried basis, as the sum of curcumin, desmethoxycurcumin, and bisdesmethoxycurcumin. It contains not less than 70% and no more than 80% curcumin, NLT 15.0% and NMT 25.0% of desmethoxycurcumin, and NLT 2.5% and NMT 6.5% of bisdesmethoxycurcumin. EXAMPLE OF PRODUCT FACTS: Consult the Guidance Document, Labelling of Natural Health Products for more details. References Cited Blumenthal M, Goldberg A, Brinkmann J, editors. 2000. Herbal Medicine: Expanded Commission E Monographs. Boston (MA): Integrative Medicine Communications. Boon H, Smith M. 2004. The Complete Natural Medicine Guide to the 50 Most Common Medicinal Herbs. Toronto (ON): Robert Rose Inc Brinker F. Herb Contraindications and Drug Interactions, 4th edition. Sandy (OR): Eclectic Medical Publications; 2010. Deodhar SD, Sethi R, Srimal RC. 1980. Preliminary studies on antirheumatic activity of curcumin (di-feruloyl methane). Indian Journal of Medical Research 71:632-634. EFSA 2017: European Food Safety Authority. 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Herbs of Commerce, 2nd edition. Silver Spring (MD): American Herbal Products Association. Mills S, Bone K. 2005. The Essential Guide to Herbal Safety. St. Louis (MO): Elsevier Churchill Livingstone. Mills S, Bone K. 2000. Principles and Practice of Phytotherapy. Toronto (ON): Churchill Livingstone. Panahi Y., Rahimnia AR., Sharafi M., Alishiri G., Saburi A., Sahebkar A. 2014. Curcuminoid treatment for knee osteoarthritis: a randomized double-blind placebo-controlled trial. Phytotherapy Research 28(11):1625-1631. RSC 2023: Royal Society of Chemistry: The Merck Index Online [Accessed 2023 August 14]. Available from: <https://merckindex.rsc.org/> USP-NF 2023: United States Pharmacopeia and the National Formulary. Rockville (MD): United States Pharmacopoeial Convention, Inc.; 2023. Whitehouse Station (NJ): Merck & Co., Inc. [Accessed 2018 June 14]. Available at: <http://www.medicinescomplete.com/mc/merck/current/monographs.htm> References Reviewed Araújo CA, Leon LL. 2001. 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Curcuma longa: a review of preclinical and clinical research. *Alternative Medicine Review* 14(2):141-153. Khory RN, Katrak NN. 1999. *Materia Medica of India and their Therapeutics*. Delhi (IN): Komal Prakashan. Kiso Y, Suzuki Y, Watanabe N, Oshima Y, Hikino H. 1983. Antihepatotoxic principles of *Curcuma longa* rhizomes. *Journal of Medicinal Plant Research* 49:185-187. Kohli K, Ali J, Ansari J, Raheman Z. 2005. Curcumin: a natural antiinflammatory agent. *Indian Journal of Pharmacology* 37(3):141-147. Kulkarni RR, Patki PS, Jog VP, Gandage SG, Patwardhan B. 1991. Treatment of osteoarthritis with a herbomineral formulation: a double-blind, placebo-controlled, cross-over study. *Journal of Ethnopharmacology* 33:91-95. Mills S. 1985. *The Dictionary of Modern Herbals*. Wellingborough (GB): Thorsons Publishers Ltd. Moerman DE. 1998. *Native American Ethnobotany*. Portland (OR): Timber Press. Rivera-Espinoza Y, Muriel P. 2009. Pharmacological actions of curcumin in liver diseases or damage. *Liver International* 29(10):1457-1466. Satoskar RR, Shah SJ, Shenoy SG. 1986. Evaluation of anti-inflammatory property of curcumin (diferuloyl methane) in patients with postoperative inflammation. *International Journal of Clinical Pharmacology, Therapy and Toxicology* 24(12):651-654. Srimal R, Dhawan B. 1973. Pharmacology of diferuloyl methane (curcumin), a non-steroidal antiinflammatory agent. *Journal of Pharmacy and Pharmacology* 25:447-452. Report a problem on this page
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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 Must be established in accordance with the requirements described in the Natural Health Products Regulations.

RISK INFORMATION

Caution(s) and warning(s) All products Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you have a biliary disorder (Brinker 2010; ESCOP 2003; McGuffin et al. 2000). Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are taking blood thinners (Brinker 2010; Mills and Bone 2005). Relief of joint pain/inflammation Ask a health care practitioner/health care provider/health care professional/doctor/physician 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 Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database. Storage conditions Must be established in accordance with the requirements described in the Natural Health Products Regulations.

STORAGE CONDITION(S)

Must be established in accordance with the requirements described in the Natural Health Products Regulations.

SPECIFICATIONS

The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products (NNHPD) Quality of Natural Health Products Guide. The medicinal ingredient must comply with the requirements outlined in the NHPID. The medicinal ingredients may comply with pharmacopoeial monographs. For example, as per USP-NF 2023, curcuminoids is defined as a partially purified natural complex of diaryl heptanoid derivatives isolated from Turmeric, *Curcuma longa* L. The ingredient contains NLT 95.0% of curcuminoids, calculated on the dried basis, as the sum of curcumin, desmethoxycurcumin, and bisdesmethoxycurcumin. It contains not less than 70% and no more than 80% curcumin, NLT 15.0% and NMT 25.0% of desmethoxycurcumin, and NLT 2.5% and NMT 6.5% of bisdesmethoxycurcumin. EXAMPLE OF PRODUCT FACTS:

REFERENCES

Route of Administration Oral

Proper name(s)	Common name(s)	Source information		
Source material(s)	Part(s)	Preparation(s)		
Curcuma longa	Common turmericCurcumaIndian-saffronJiang HuangTurmericYellow ginger		Rhizome	Dry
Curcuminoids	Curcuminoids	Curcuma longa	Rhizome	Isolate
(1E,6E)-1,7-Bis(4-hydroxy-3-methoxyphenyl)-6-methylhepta-1,4-diene-3,5-dione	Curcumin	Curcuma longa	Rhizome	Isolate
N/A	N/A	Synthetic		