

## NATURAL HEALTH PRODUCT

### CONCENTRATED TURMERIC EXTRACTS AND ISOLATES (CURCUMINOIDS/CURCUMIN)

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 labels at the applicant’s discretion.
- The solidus (/) indicates that the terms are/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)
<i>Curcuma longa</i>	<ul style="list-style-type: none"> <li>• Common turmeric</li> <li>• Curcuma</li> <li>• Indian-saffron</li> <li>• Jianghuang</li> <li>• Turmeric</li> <li>• Yellow ginger</li> </ul>	<i>Curcuma longa</i>	Rhizome	Dry
Curcuminoids	Curcuminoids	<i>Curcuma longa</i>	Rhizome	Isolate
(1E,6E)-1,7-Bis(4-hydroxy-3-methoxyphenyl)-1,6-heptadiene-3,5-dione	Curcumin	<i>Curcuma longa</i>	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 Directorate (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.

<b>Product Facts</b>	
<b>Medicinal ingredient(s)</b> in each capsule	
<i>Curcuma longa</i> (Turmeric) – rhizome extract	XX mg
Providing YY% Curcuminoids (including ZZ% Curcumin)	
AND/OR	
Curcumin ( <i>Curcuma longa</i> – rhizome)	XX mg
AND/OR	
Curcuminoids ( <i>Curcuma longa</i> – rhizome) (including YY mg Curcumin)	XX mg
<b>Uses</b>	
<ul style="list-style-type: none"> <li>• Source of (an) antioxidant(s).</li> <li>• Source of (an) antioxidant(s) that help(s) protect cell against free radicals.</li> <li>• Helps relieve joint pain and inflammation.</li> </ul>	
<b>Warnings</b>	
<b>If applicable<sup>1</sup>:</b>	
<b>Allergens: food allergen, gluten (gluten source), sulphites</b>	
<b>Contains aspartame</b>	
<b>Ask a health care practitioner before use if</b> • you are pregnant or breastfeeding • you have a biliary disease • you are taking blood thinners.	
<b>Ask a health care practitioner if</b> symptoms persist or worsen <sup>2</sup> .	
<b>Directions</b>	
Adults 18 years and older: • Take X capsule(s), X time(s) a day.	
<b>Other information</b>	
(Add storage information)	
<b>Non-medicinal ingredients</b>	
List all NMIs	
<b>Questions?</b> (Call) 1-XXX-XXX-XXXX	

<sup>1</sup>This section can be removed from the table if the product contains no allergen or aspartame.

<sup>2</sup>The qualifier ‘For joint pain and inflammation.’ may be included on the label to inform consumers.

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