

## NATURAL HEALTH PRODUCT

### TURMERIC – *CURCUMA LONGA*

#### Oral

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLA) 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 and/or statements are synonymous. Either term or statement may be selected by the applicant.
- As enhanced absorption formulations are often used for Turmeric, 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.
- This monograph supports native extracts of Turmeric rhizome (also termed crude or genuine extracts). The traditional references and herbal medicine textbooks used to build this monograph support the use of native extracts with a maximum extract ratio of 10:1 (dry extracts) or 1:10 (liquid extracts). It should be noted that the ‘Concentrated Turmeric extracts and isolates (curcuminoids/curcumin)’ monograph supports concentrated extracts containing  $\geq 75\%$  curcuminoids based on non-traditional methods of preparation and modern scientific evidence.

#### Date

September 27, 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)
<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

References: Proper name: USDA 2023; Common names: USDA 2023, PPRC 2015; McGuffin et al. 2000; Source information: PPRC 2015, ESCOP 2003, Blumenthal et al. 2000.

## Route of administration

Oral (ESCOP 2003; Blumenthal et al. 2000)

## 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 Compensial applications.

## Use(s) or Purpose(s)

- Source of antioxidants/Provides antioxidants (ESCOP 2003; Blumenthal et al. 2000; Mills and Bone 2000).
- Source of antioxidants/Provides antioxidants that help 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).
- Used in Herbal Medicine to aid digestion (ESCOP 2003; Williamson 2003; Blumenthal et al. 2000; Mills and Bone 2000).
- (Traditionally) used in Herbal Medicine to help relieve flatulent dyspepsia (carminative) (Mills and Bone 2005; Blumenthal et al. 2000; Wren 1907).
- Used in Herbal Medicine as a hepatoprotectant/liver protectant (Boon and Smith 2004; Williamson 2003).
- Used in Herbal Medicine to increase bile excretion by the liver (choloretic) and stimulate contraction of the gallbladder (cholagogue) (Mills and Bone 2005; Boon and Smith 2004; Wichtl 2004; Blumenthal et al. 2000; Mills and Bone 2000).
- (Traditionally) used in Herbal Medicine (as an anti-inflammatory) to help relieve joint pain (Winston and Kuhn 2008; Blumenthal et al. 2000; WHO 1999).
- Used in Traditional Chinese Medicine (TCM) to eliminate blood stasis, promote the flow of qi, relieve pain of menstruation due to blood stasis (PPRC 2015; Bensky et al. 2004).

### Notes:

- The above claims can be combined on the product label if from the same traditional or non-traditional system of medicine (e.g. Used in Herbal Medicine to help relieve flatulent dyspepsia (carminative) and to help relieve joint pain).
- **For multi-ingredient products:**
  - To prevent the product from being represented as a "traditional medicine," any indicated traditional use claim must refer to the specific medicinal ingredient(s) and recognized traditional system of medicine from which the claim originates when 1) both traditional and modern claims are present or 2) when claims originate from



- multiple systems of traditional medicine (e.g. Turmeric is traditionally used in Herbal Medicine to help relieve flatulent dyspepsia (carminative)).
- When ALL of the medicinal ingredients (MIs) in the product are used within the SAME identified system of traditional medicine AND the product makes ONLY traditional claims, listing of MIs in the traditional claim(s) is not required.

### Dose(s)

### Subpopulation(s)

Adults 18 years and older

### Quantity(ies)

**Note:** When ‘decoction’ or ‘infusion’ is listed as an acceptable method of preparation, ‘decoction concentrate’ or ‘infusion concentrate’ is also allowed. This would also apply to standardized methods of preparations.

#### *Antioxidant*

Methods of preparation: Dry, powder, Non-Standardized Extracts (Dry extract\*, Tincture, Fluid extract, Decoction, Infusion)

Not to exceed 9 grams of dried rhizome, per day; For dry extracts, maximum ratio is 10:1 (ESCOP 2003; Williamson 2003; Blumenthal et al. 2000).

**\*Note:** Solvents allowed for the method of preparation “Non-Standardized Extracts (Dry extract)” as part of this monograph are ethanol and/or water only.

Methods of preparation: Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)

Extract providing up to 35% Curcuminoids; Quantity crude equivalent: not to exceed 9 grams of dried rhizome, per day (Meng et al. 2018; Bagchi 2012; Li et al. 2011; ESCOP 2003; Williamson 2003; Blumenthal et al. 2000).

**Note:** Optional: The potency constituent, curcumin, can be included.



*Digestive aid; Relief of flatulent dyspepsia; Hepatoprotectant; Bile excretion; Joint pain*

Methods of preparation: Dry, Powder, Non-Standardized Extracts (Dry extract\*, Tincture, Fluid extract, Decoction, Infusion)

1 – 9 grams of dried rhizome, per day; For dry extracts, maximum ratio is 10:1 (Mills and Bone 2005; Wichtl 2004; ESCOP 2003; Williamson 2003; Blumenthal et al. 2000).

**\*Note:** Solvents allowed for the method of preparation “Non-Standardized Extracts (Dry extract)” as part of this monograph are ethanol and/or water only.

Methods of preparation: Standardized Extracts (Dry extract, Tincture, Fluid extract, Decoction, Infusion)

Extract providing up to 35% Curcuminoids; Quantity crude equivalent: 1 – 9 grams of dried rhizome, per day (Meng et al. 2018; Bagchi 2012; Li et al. 2011; Mills and Bone 2005; Wichtl 2004; ESCOP 2003; Williamson 2003; Blumenthal et al. 2000).

**Note:** Optional: The potency constituent, curcumin, can be included.

### *TCM*

Methods of preparation: Decoction, Decoction concentrate

3 – 9 grams of dried rhizome, per day; For dry extracts, maximum ratio is 10:1 (PPRC 2015; Bensky et al. 2004).

### **Direction(s) for use**

No statement required.

### **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 (EMA 2018; Brinker 2010; ESCOP 2003; McGuffin et al. 1997).**

*All uses except for Source of antioxidants and Hepatoprotectant*

**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.

**EXAMPLE OF PRODUCT FACTS:**

Consult the Guidance Document, [Labelling of Natural Health Products](#) for more details.

<b>Product Facts</b>	
<b>Medicinal ingredient</b> in each capsule	
<i>Curcuma longa</i> (Turmeric) extract	XX mg
Providing YY% curcuminoids (including ZZ% curcumin)	
Equivalent to XX g of dried rhizome	
OR	
<i>Curcuma longa</i> (Turmeric) (X:1 extract)	XX mg
Equivalent to XX g of dried rhizome	
<b>Uses</b>	
<ul style="list-style-type: none"> <li>• Source of antioxidants.</li> <li>• Source of antioxidants that help protect cell against free radicals.</li> <li>• Used in Herbal Medicine to aid digestion.</li> <li>• Used in Herbal Medicine as a liver protectant.</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 disorder.	
<b>Ask a health care practitioner if symptoms persist or worsen<sup>2</sup>.</b>	
<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 “As a digestive aid:” may be included on the label to inform consumers.

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