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FINAL

COMMUNITY HERBAL MONOGRAPH ON *CURCUMA LONGA* L., RHIZOMA

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1. NAME OF THE MEDICINAL PRODUCT

To be specified for the individual finished product.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION [1]

Well-established use	Traditional use
	With regard to the registration application of Article 16d(1) of Directive 2001/83/EC as amended *Curcuma longa* L., rhizoma (turmeric root) i) Herbal substance Not applicable ii) Herbal preparations A) Powdered herbal substance B) Comminuted herbal substance C) Tincture (Ratio of herbal substance to extraction solvent 1:10), extraction solvent ethanol 70% (v/v) D) Dry extract (DER 13-25:1), extraction solvent ethanol 96% (v/v) E) Dry extract (DER 5.5-6.5:1), extraction solvent ethanol 50% (v/v) F) Tincture (Ratio of herbal substance to extraction solvent 1:5), extraction solvent ethanol 70% (v/v)

3. PHARMACEUTICAL FORM

Well-established use	Traditional use
	Comminuted herbal substance as herbal tea for oral use. Herbal preparations in liquid or solid dosage forms for oral use. The pharmaceutical form should be described by the European Pharmacopoeia full standard term.

[1] The declaration of the active substance(s) for an individual finished product should be in accordance with relevant herbal quality guidance

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Well-established use	Traditional herbal medicinal product used to increase bile flow for the relief of symptoms of indigestion (such as sensation of fullness, flatulence, and slow digestion). The product is a traditional herbal medicinal product for use in the specified indication exclusively based upon long-standing use.

4.2. Posology and method of administration

Well-established use	Traditional use **Posology** *Adults and elderly* A) Powdered herbal substance: 1.5-3.0 g daily; B) Comminuted herbal substance for tea preparation: 0.5-1 g, up to 3 times daily as an infusion; C) Tincture (1:10): 0.5-1 ml 3 times daily; D) Dry extract (13-25:1): 80-160 mg, divided in 2-5 partial doses daily; E) Dry extract (5.5-6.5:1): 100-200 mg, 2 times daily; F) Tincture (1:5): 10 ml once daily or 5 ml in 60 ml water 3 times daily; The use in children and adolescents under 18 years of age is not recommended (see section 4.4 'Special warnings and precautions for use') **Duration of use** If the symptoms persist longer than 2 weeks, a doctor or a qualified health care practitioner should be consulted. **Method of administration** Oral use.

4.3. Contraindications

Well-established use	Traditional use Hypersensitivity to the active substance(s).

	Obstruction of bile duct, cholangitis, liver disease, gallstones and any other biliary diseases.

4.4. Special warnings and precautions for use

Well-established use	Traditional use
	The use in children and adolescents is not recommended due to lack of adequate data. If symptoms worsen during the use of the medicinal product a doctor or a qualified health care practitioner should be consulted. For tinctures containing ethanol, the appropriate labelling for ethanol, taken from the 'Guideline on excipients in the label and package leaflet of medicinal products for human use', must be included.

4.5. Interactions with other medicinal products and other forms of interaction

Well-established use	Traditional use
	None reported.

4.6. Pregnancy and lactation

Well-established use	Traditional use
	Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

4.7. Effects on ability to drive and use machines

Well-established use	Traditional use
	No studies on the effect on the ability to drive and use machines have been performed.

4.8. Undesirable effects

Well-established use	Traditional use
	Mild symptoms of dry mouth, flatulence and gastric irritation may occur. The frequency is not known. If other adverse reactions not mentioned above occur, a doctor or a qualified health care practitioner should be consulted.

4.9. Overdose

Well-established use	Traditional use
	No case of overdose has been reported.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.2. Pharmacokinetic properties

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.3. Preclinical safety data

Well-established use	Traditional use
	Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended, unless necessary for the safe use of the product. Adequate tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

6. PHARMACEUTICAL PARTICULARS

Well-established use	Traditional use
	Not applicable.

7. DATE OF COMPILATION/LAST REVISION

9 November 2009