

SELECT BOTANICAL

ARTICHOKE

Technical-Scientific report

GENERAL INFORMATION

Select Botanical manufactures highest quality extracts following strictest Quality Management System in compliance with the "Good Manufacturing Practices" requirements, carrying on the last manufacturing steps in classified areas (Clean Rooms).

Select Botanical assures the traceability with rigorous analysis from raw material to finished product.

REGISTRY NUMBERS

CAS: 84012-14-6
EINECS: 281-659-3
INCI/ UE: CYNARA SCOLYMUS LEAF EXTRACT

INFORMATION ABOUT PLANT ORIGIN

SPECIFICATIONS/ TECHNICAL CHARACTERISTICS

Raw material

Definition: Leaves of *Cynara scolymus* L.
Description:
- Macroscopic: Complies Ph. Eur. current Ed.
- Microscopic: Complies Ph. Eur. current Ed.
Loss on drying: $\leq 12\%$ w/w
Pesticides: According to Ph. Eur. current ed.
Assay (UV/Vis): Total Polyphenols content in Cynarin (%)

Composition of Extract Preparation

Native dry extract
Maltodextrin (if it is necessary)
Colloidal silicon dioxide

Extract Specifications

Loss on drying: $\leq 6\%$ w/w
Total ash: $\leq 12\%$ w/w
Heavy metals: Analysis of Pb, Hg, Cd and As
Microbiological assay: According to Ph. Eur. current Ed "5.1.8. Point B"
Residual solvents: According to guidelines CPMP/ICH/283/95
Assay (UV/Vis): Total Polyphenols content in Cynarin (%) *

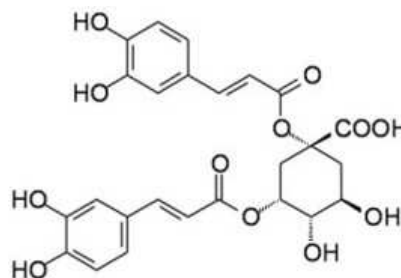
* Select Botanical can offer other qualities upon request.

Botanical Description

The Globe artichoke is a perennial plant up to 2 m. The entire leaf may be up to 70 cm long and 30 cm wide. The lamina is deeply lobed in the upper part and in the lower part the leaf becomes pinnate. All the segments have markedly dentate margins and taper at the apex. Spines are absent. The upper surface of the lamina is green with a fine covering of whitish hairs, the lower surface is pale green or white with long, tangled hairs. The petiole and main veins are flat on the upper surface, prominently raised and longitudinally ridged on the lower surface, with conspicuous hairs on both surfaces. ⁽¹⁾

Analytical marker / Active principle

Cynarin



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PHARMACOLOGICAL STUDIES

- sb** *Blood lipid and cholesterol lowering effects:* In different *in vitro* and *in vivo* experiments, artichoke leaf dry extracts lowered increases in serum and liver cholesterol and prevented the formation of atherosclerotic plaques. In many clinical studies artichoke leaf dry extracts proved a significant lipid-, triglyceride- and phospholipid-lowering effects.^(2, 4)
- sb** *Antidyspeptic and gastrointestinal effects:* In different clinical trials in patients with functional dyspepsia, artichoke leaf dry extract was found to improve the overall symptom with higher improvement in the global quality-of-life scores than with placebo. Digestive complaints declined in a clinically relevant statistically significant manner within 6 weeks.^(2, 4)

PHYTOTHERAPY

Activities

- sb** Hepatoprotective ⁽⁴⁾
- sb** Choleric ⁽⁴⁾
- sb** Antioxidant ⁽⁴⁾
- sb** Anticholesterolemic ⁽⁴⁾
- sb** Digestive ⁽⁴⁾
- sb** Anti-inflammatory ⁽⁴⁾
- sb** Diuretic ⁽⁴⁾

Indications:

Oral use:

- sb** Symptomatic relief of digestive complaints such as dyspepsia with a sensation of fullness, bloating and flatulence; and hepatobiliary disturbances.^(1, 2, 3)
- sb** Adjuvant to a low fat diet in the treatment of mild to moderate hyperlipidaemia.⁽³⁾

Undesirable effects:

- sb** Mild gastro-intestinal disturbances may occur in rare cases.^(2, 3)
- sb** Allergic reactions may occur in sensitized patients.^(2, 3)

Contraindications and special warnings:

- sb** In the absence of sufficient data, the use during pregnancy and lactation is not recommended.^(1, 2, 3)

- sb** Patients with cholelithiasis should take artichoke leaf only after consulting a physician.^(1, 2, 3)
- sb** Contraindicated in case of known allergies to artichokes and obstruction of bile ducts and any other biliary diseases and hepatitis.^(1, 2, 3)

Dosage and administration:

Oral use

Herbal preparations may be found in solid or liquid dosage form or as herbal tea for oral use.

Posology is indicated in the **EMA/HMPC/150218/2009 (traditional use)** and **ESCOP** monographs.^(2, 3)

BIBLIOGRAPHY AND OTHER REFERENCES SOURCES

- Current monograph "1866: Artichoke leaf" of European Pharmacopoeia edition.
- Blumenthal. The Complete German Commission E Monographs. Therapeutic Guide to Herbal Medicines. American Botanical Council. Austin, Texas 1998.
- ESCOP Monographs. Second edition. 2003
- Community Herbal Monograph on *Cynara scolymus* L., folium. EMA/HMPC/150218/2009. September 2011.
- Assessment report on *Cynara scolymus* L., folium. EMA/HMPC/150209/2009. September 2011.



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Revision: 01
November
2016