

SELECT BOTANICAL

HAWTHORN

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: 90045-52-6
EINECS: 289-914-0
INCI/ UE: CRATAEGUS MONOGYNA
FLOWER EXTRACT

INFORMATION ABOUT PLANT ORIGIN

SPECIFICATIONS/ TECHNICAL CHARACTERISTICS

Raw material

Definition: Leaves and flowers of *Crataegus sp*
Description:
- Macroscopic: Complies Ph. Eur. current Ed.
- Microscopic: Complies Ph. Eur. current Ed.
Loss on drying: $\leq 10\%$ w/w
Pesticides: According to Ph. Eur. current ed.
Assay (HPLC): Hyperoside+Vitexin 2" Rhamnoside
(UV/Vis): Total flavonoids as hyperoside

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: $\leq 15\%$ 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 (HPLC): Hyperoside + Vitexin 2" Rhamnoside (dry basis)
(UV/Vis): Total flavonoids as hyperoside (dry basis)

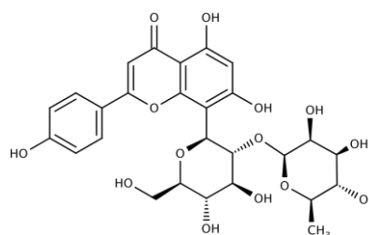
Botanical Description

Hawthorn is a deciduous tree or shrub of up to 10 m in height and is known to live to a great age. It possesses a single seed-vessel to each blossom producing a separate fruit, which when ripe is a brilliant red and this is in miniature a stony apple.

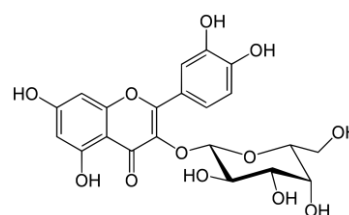
The stems are dark brown and woody with alternate and petiolate leaves, which depending on the species are more or less deeply lobed, slightly serrate or almost entire margined. The lower leaf surface is light greyish green and shows a prominent, dense, reticulate venation. The degree of pubescence is also indicative of the various species. ⁽¹⁾

Analytical marker / Active principle

Vitexin 2" Rhamnoside



Hyperoside



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PHARMACOLOGICAL STUDIES

- sb** *Positive inotropic action:* In clinical *in vitro* investigations the inotropic effect of *Crataegus* dry extract (4-6.6:1, ethanol 45% m/m) and different sub-extracts was observed on the basis of the following results: an increase in force of contraction, an improvement of the frequency-dependent force generation and enhancement of dose-dependent relative shortening of myocytes in the atrium myocardium as well as in the ventricular myocardium. ⁽⁵⁾
- sb** *Vasorelaxation:* Effects have been shown in different *in-vivo* models and *in vitro* experiments, for example, with orally administered ethanol hawthorn extract. ⁽³⁾

PHYTOTHERAPY

Activities

- sb** Increase cardiac contractility, inotropic action ^(2, 3, 4)
- sb** Vasorelaxation ^(2, 3, 4)
- sb** Diuretic. ^(2, 3, 4)
- sb** Tonic ^(2, 3, 4)

Indications:

Oral use:

- sb** Traditional herbal medicinal product used to relieve symptoms of temporary nervous cardiac complaints (e.g. palpitations, perceived extra heart beat due to mild anxiety) after serious conditions have been excluded by a medical doctor. ^(3, 4)
- sb** Traditional herbal medicinal product for relief of mild symptoms of mental stress and to aid sleep. ⁽⁴⁾
- sb** Used for decreasing cardiac output as described in functional Stage II of NYHA. ^(2, 3)

Undesirable effects:

- sb** None known.

Contraindications and special warnings:

- sb** Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended. ^(3, 4)
- sb** If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted. ⁽⁴⁾
- sb** If the ankles or legs become swollen, when pain occurs in the region of the heart, which may spread out to the arms, upper abdomen or the area around the neck, or in case of

respiratory distress (dyspnea), a doctor or a qualified health care practitioner should be consulted immediately. ⁽⁴⁾

Dosage and administration:

Oral use

Hawthorn may be found formulated in liquid and solid preparations.

Posology is indicated in the **EMA/HMPC/159075/2014 (traditional use)** and **ESCOP** monographs. ^(3, 4)

BIBLIOGRAPHY AND OTHER REFERENCES SOURCES

1. Current monograph "1432: Hawthorn leaf and flower" of European Pharmacopoeia edition.
2. Blumenthal. The Complete German Commission E Monographs. Therapeutic Guide to Herbal Medicines. American Botanical Council. Austin, Texas 1998.
3. ESCOP Monographs. Second edition. 2003
4. Community Herbal Monograph on *Crataegus spp.* folium cum flore. EMA/HMPC/159075/2014. April 2016.
5. Assessment report on *Crataegus spp.* folium cum flore. EMA/HMPC/159076/2014. April 2016.



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