

SELECT BOTANICAL

PASSION FLOWER

Technical-Scientific report

GENERAL INFORMATION

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

REGISTRY NUMBERS

CAS: 72968-47-9
EINECS: 277-142-7
INCI/ UE: PASSIFLORA INCARNATA EXTRACT

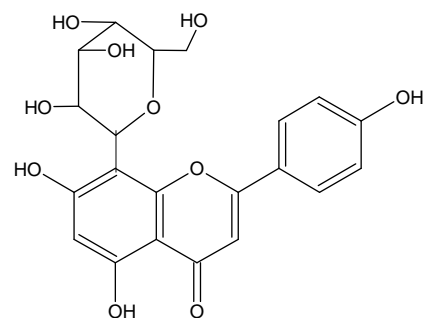
INFORMATION ABOUT PLANT ORIGIN

Botanical Description

A perennial vine with deeply three- to five lobed leaves and large showy flowers; climbing by axillary tendrils to about 9 m.
Native to the United States. ⁽⁴⁾

Analytical marker / Active principle

Flavonoids: Vitexin and Isovitexin.



Vitexin

SPECIFICATIONS/ TECHNICAL CHARACTERISTICS

Raw material

Definition: Aerial part of *Passiflora incarnata* L.
Description:
- Macroscopic: Complies Ph. Eur. current Ed.
- Microscopic: Complies Ph. Eur. current Ed.
Loss on drying: ≤ 10 % w/w
Pesticides: Acc. to Ph. Eur. current Ed
Assay (UV/Vis-Ph.Eur) Total Flavonoids expressed as Vitexin

Composition of Extract Preparation

Native Dry Extract
Maltodextrin
Colloidal Silicon Dioxide

Extract Specifications

Loss on drying: ≤ 5 % w/w
Total ash: ≤ 15 % w/w
Heavy metals: Analysis of Pb,As,Cd and Hg
Microbiological assay: Acc. to Ph. Eur. Current Ed. "5.1.8. Point B"
Residual solvents: According to guidelines CPMP/ICH/283/95
Assay (UV/Vis): Total Flavonoids expressed as Vitexin
Assay (HPLC): Vitexin + Isovitexin

PASSION FLOWER

Technical -Scientific report

PHARMACOLOGICAL STUDIES

- sb Sedative activity: After intraperitoneal administration in rats, an alcohol-free hydroethanolic extract at a dosage of 160 mg/kg significantly prolonged sleeping time induced by pentobarbital and, at a dosage of 50-400 mg/kg, reduced spontaneous locomotor activity. ⁽³⁾
Passionflower depressed motor activity, increases respiration rate and produced a transient reduction in blood pressure. ⁽⁴⁾
- sb Anxyolitic activity: After oral administration in mice of a dry extract of Passionflower containing 2.6% of flavonoids, a significant anxyolitic effect was observed with prolongation of the sleeping time induced by hexobarbital whereas the locomotor activity remained. ⁽³⁾

PHYTOTHERAPY

Activities:

Oral use:

- sb Sedative. ^(3, 4, 6, 7)
- sb Anxyolitic. ^(3, 4, 7)
- sb Analgesic. ⁽⁴⁾
- sb Hypnotic. ^(2, 6)
- sb Antispasmodic. ^(4, 6, 7)

Indications:

Oral use

- sb Indicated in the treatment of tenseness, restlessness, anxiety and irritability with difficulty in falling sleep. ^(3, 7)
- sb Indicated in the treatment of gastrointestinal spasms and gastrointestinal complaints of nervous origin. ^(1, 2, 4)
- sb Traditional herbal medicinal product for relief mild symptoms of mental stress to aid sleep ⁽⁸⁾

Side effects:

There are no reported toxic effects or intolerance phenomenon to normal use doses. If adverse reactions occur, a doctor or a qualified health care practitioner should be consulted. ^(7,8)

Precautions / Contraindications:

Passionflower should not be used during pregnancy and lactation without medical advice. ^(7,8)

Dosage and administration:

Oral use:

Passionflower Extract may be found formulated in liquid and solid preparations for oral use
The recommended daily dose for oral use of Passionflower is 0.5-2 g of drug, one to four times daily; other equivalent preparations. ^(3, 7, 8)

BIBLIOGRAPHY AND OTHER REFERENCES SOURCES

1. Cañigüeral, S., Vila, R., Wichtl, M. Plantas medicinales y drogas vegetales para infusión y tisana. OEMF international srl. Milán 1998.
2. Fitoterapia. Vademecum de prescripción. Masson, S.A. 3º Ed. Barcelona. 1998
3. ESCOP Monographs. Second edition. 2003.
4. Leung, A. Y., Foster, S. Encyclopedia of Common Natural Ingredients Used in Food, Drugs and Cosmetics. John Wiley & Sons, Inc. 2nd. Edition. USA. 1996
5. Blumental. The Complete German Commission E Monographs. Therapeutic Guide to Herbal Medicines. American Botanical Council. Austin, Texas 1998.
6. Newall, A. C. , Anderson, L. A. , Phillipson, D. J. Herbal Medicines. The Pharmaceutical Press. 1996.
7. Blumental/Goldberg/Brinckmann. Herbal Medicine. Expanded Commission E Monographs. 2000.
8. Community Herbal Monograph on *Passiflora incarnata* L herba. EMA / HMPC / 669740 /2013. EMA 2014.



Information contained in this Technical Scientific Report is believed to be accurate and is offered in good faith for the benefit of the user of the product. Select Botanical, SL cannot assume any liability or risk involved in the use of its products since the conditions of the use are beyond our control. The user of our product is responsible for compliance with all legal regulations applying to the use of our products, including patent laws.

Revision: 01
April 2014