

SELECT BOTANICAL

MELISSA LEAF

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: 84082-61-1
EINECS: 282-007-0
INCI/ UE: MELISSA OFFICINALIS LEAF EXTRACT

INFORMATION ABOUT PLANT ORIGIN

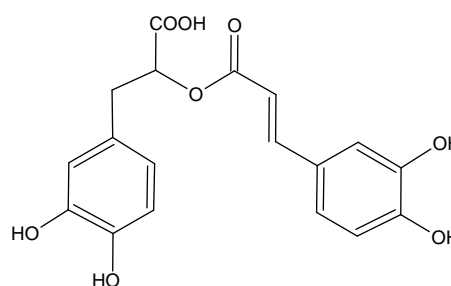
Botanical Description

A herb, up to 70 cm in height, smelling strongly of lemon, with distinctly petiolate, broadly ovate, opposite and decussate leaves on 4-angled stems. Leaf venation very prominent on the lower surface and margin crenate and serrate.

Native in the Eastern Mediterranean region and in Western Asia. ⁽¹⁾

Analytical marker / Active principle

Hydroxycinnamic acid derivatives: Rosmarinic acid



Rosmarinic Acid

SPECIFICATIONS/ TECHNICAL CHARACTERISTICS

Raw material

Definition: Leaf of *Melissa officinalis* 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 (HPLC): Rosmarinic Acid

Composition of Extract Preparation

Native Dry Extract
Maltodextrin
Colloidal Silicon Dioxide

Extract Specifications

Loss on drying: ≤ 6 % w/w

Total ash: ≤ 15 % w/w

Heavy metals: Analysis of Pb,Hg,As and Cd

Microbiological assay: Acc. to Ph. Eur. current Ed. "5.1.8. Point B".

Residual solvents: According to guidelines CPMP/ICH/283/95

Assay (HPLC): Rosmarinic acid

MELISSA LEAF

Technical -Scientific report

PHARMACOLOGICAL STUDIES

- sb Sedative activity: In vivo experiments, aqueous alcoholic extracts of the drug have been shown to have sedative activity. The same extract induced sleep in mice treated with an subhypnotic dose of pentobarbital. ^(1,3,8)
- sb Anti-inflammatory activity: Rosmarinic acid has been shown to inhibit complement-dependent mechanisms of inflammatory reactions. ^(3,8)
- sb Antioxidant activity: antioxidant and free radical scavenging properties have been reported for an aqueous extract. ⁽³⁾
- sb Antiviral activity: Aqueous extract produces antiviral effects on influenza viruses, vaccinia and herpes simplex virus. ⁽³⁾

PHYTOTHERAPY

Activities

Oral use:

- sb Sedative. ^(1, 3, 5, 7)
- sb Mild tranquilizer. ⁽⁴⁾
- sb Carminative. ^(4, 5, 7)
- sb Antispasmodic. ^(3,7)

Topical use:

- sb Antiseptic ⁽⁶⁾
- sb Antiviral. ⁽⁷⁾

Indications:

Oral use:

- sb Traditional herbal medicinal product for relief of mild symptoms of mental stress and to aid sleep. ⁽⁷⁾
- sb Traditional herbal medicinal product for symptomatic treatment of mild gastrointestinal complaints including bloating and flatulence. ⁽⁷⁾
- sb Indicated in the treatment of tenseness, restlessness, irritability and nervous disturbances of sleep. ⁽³⁾
- sb Indicated in the symptomatic treatment of digestive disorders such as minor spasms. ⁽³⁾

Topical use:

- sb Indicated in the treatment of Herpes labialis (cold sores). ⁽³⁾

Undesirable effects:

There are no reported toxic effects or intolerance phenomenon to normal use doses. ^(3,7)

Precautions / Contraindications:

Melissa extract should not be used orally during pregnancy and lactation without medical advice. ^(3, 7)

Dosage and administration:

Oral use:

Melissa Dry Extract may be found formulated in liquid and solid preparations for oral use

- Traditional use: Aqueous and hydroalcoholic extracts (45-53 % v/v) in doses corresponding to 1.5-4.5 g of herbal substance, 1-3 times daily. ⁽⁷⁾
- 2-3 g of the drug as infusion, two or three times daily. Other equivalent preparations. ⁽³⁾

Topical use:

Melissa Dry Extract may be found formulated in creams, among others.

BIBLIOGRAPHY AND OTHER REFERENCE 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. Pons, L., Parra, J. L. Ciencia cosmética. Bases fisiológicas y criterios prácticos. C.G.C.O.F. 1995.
7. Community Herbal Monograph on *Melissa officinalis* L, folium. EMEA/HMPC/196745/2012. EMEA 2012.
8. Assessment report on *Melissa officinalis* L, folium. EMEA /HMPC/196745/2012. EMA 2013.



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
January 2014