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.

SPECIFICATIONS/ TECHNICAL CHARACTERISTICS

<table>
<thead>
<tr>
<th>Raw material</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Definition:</td>
<td>Leaf of Melissa officinalis L.</td>
</tr>
<tr>
<td>Description:</td>
<td></td>
</tr>
<tr>
<td>- Macroscopic</td>
<td>Complies Ph.Eur.current Ed.</td>
</tr>
<tr>
<td>- Microscopic</td>
<td>Complies Ph.Eur.current Ed.</td>
</tr>
<tr>
<td>Loss on drying:</td>
<td>≤ 10 % w/w</td>
</tr>
<tr>
<td>Pesticides:</td>
<td>Acc. to Ph. Eur. current ed.</td>
</tr>
<tr>
<td>Assay (HPLC):</td>
<td>Rosmarinic Acid</td>
</tr>
</tbody>
</table>

Composition of Extract Preparation

Native Dry Extract
Maltodextrin
Colloidal Silicon Dioxide

Extract Specifications

<table>
<thead>
<tr>
<th>Loss on drying:</th>
<th>≤ 6 % w/w</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total ash:</td>
<td>≤ 15 % w/w</td>
</tr>
<tr>
<td>Heavy metals:</td>
<td>Analysis of Pb,Hg,As and Cd</td>
</tr>
<tr>
<td>Microbiological assay:</td>
<td>Acc. to Ph. Eur. current Ed. “5.1.8. Point B”</td>
</tr>
<tr>
<td>Residual solvents:</td>
<td>According to guidelines CPMP/ICH/283/95</td>
</tr>
<tr>
<td>Assay (HPLC):</td>
<td>Rosmarinic acid</td>
</tr>
</tbody>
</table>

REGISTRY NUMBERS

<table>
<thead>
<tr>
<th>CAS:</th>
<th>84082-61-1</th>
</tr>
</thead>
<tbody>
<tr>
<td>EINECS:</td>
<td>282-007-0</td>
</tr>
<tr>
<td>INCL/ UE:</td>
<td>MELISSA OFFICINALIS LEAF EXTRACT</td>
</tr>
</tbody>
</table>

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

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

Rosmarinic Acid
**MELISSA LEAF**  
**Technical -Scientific report**

**PHARMACOLOGICAL STUDIES**
- 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)  
- Anti-inflammatory activity: Rosmarinic acid has been shown to inhibit complement-dependent mechanisms of inflammatory reactions. (3,8)  
- Antioxidant activity: Antioxidant and free radical scavenging properties have been reported for an aqueous extract. (3)  
- Antiviral activity: Aqueous extract produces antiviral effects on influenza viruses, vaccinia and herpes simplex virus. (3)

**PHYTOTHERAPY**

**Activities**

**Oral use:**
- Sedative. (1, 3, 5, 7)  
- Mild tranquilizer. (4)  
- Carminative. (2, 5, 7)  
- Antispasmodic. (3,7)

**Topical use:**
- Antiseptic (6)  
- Antiviral. (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.
- 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**


**Indications:**

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

**Topical use:**
- 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)