

SELECT BOTANICAL

VALERIAN ROOT

Technical-Scientific report

GENERAL INFORMATION

Definition

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: 8057-49-6
EINECS: 232-501-7
INCI/ UE: VALERIANA OFFICINALIS ROOT EXTRACT

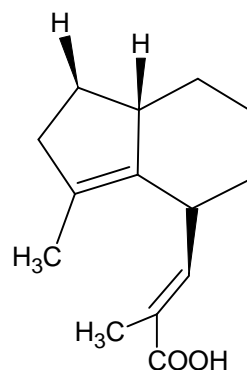
INFORMATION ABOUT PLANT ORIGIN

Botanical Description

Perennial herb up to about 1.5 m high with deeply dissected leaves each bearing seven to ten pairs of lance-shaped leaflets with stems erect.
Native to Europe and Asia. ⁽¹⁾

Analytical marker / Active principle

Valerenic acid and derivatives.



Valerenic acid

SPECIFICATIONS/ TECHNICAL CHARACTERISTICS

Raw material

Definition: Root of *Valeriana Officinalis* L.
Description:
- Macroscopic: Complies Ph. Eur. current Ed.
- Microscopic: Complies Ph. Eur. current Ed.
Loss on drying: ≤ 12 % w/w
Pesticides: Acc. to Ph. Eur. current ed.
Assay (HPLC): Sesquiterpenic acids expressed as valerenic acid

Composition of Extract Preparation

Native Dry Extract
Maltodextrin
Colloidal Silicon Dioxide

Extract Specifications

Loss on drying: ≤ 6 % w/w
Total ash: ≤ 10 % w/w
Heavy metals: Analysis of Pb,As,Cd and Hg
Microbiological assay: Acc. to Ph. Eur. current Ed.
"5.1.8.Point B".
Cat 3B
Residual solvents: According to guidelines CPMP/ICH/283/95
Assay (HPLC): Sesquiterpenic acids expressed as valerenic acid

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PHARMACOLOGICAL STUDIES

- sb** Sedative activity: Biochemical studies have documented that valerenic acid inhibits the enzyme system responsible for the central catabolism of GABA. Increased concentrations of GABA are associated with a decrease in CNS activity and this action may, therefore, be involved in the reported sedative activity of valerenic acid. ⁽⁶⁾
- sb** Antispasmodic activity: Antispasmodic activity on intact and isolated guinea pig has been documented for isovaltrate, valtrate and valeranone. This activity was attributed to a direct action on the smooth muscle receptors rather than ganglion receptors. ⁽⁴⁾

PHYTOTHERAPY

Activities

Oral use:

- sb** Sedative. ^(1, 2, 3, 4, 5, 6, 7)
- sb** Sleep-promoting. ^(5, 7)
- sb** Antispasmodic. ^(2, 4, 6)

Indications:

Oral use:

- sb** Herbal medicinal product indicated for the relief of mild nervous tension and sleep disorders ^(3, 7, 8)
- sb** Traditional herbal medicinal product for relief of mild symptoms of mental stress and to aid sleep. ⁽⁸⁾
- sb** Indicated in the treatment of cramp-like pains in the gastrointestinal region. ^(1, 2, 4, 6)

Undesirable effects:

Gastrointestinal symptoms (e.g. nausea, abdominal cramps) may occur after ingestion of valerian root preparations. The frequency is not known. ⁽⁸⁾

Precautions / Contraindications:

Patients with known hypersensitivity to the active substance should not use valerian root preparations. ⁽⁸⁾
The use is not recommended in children below the age of 12 years. ⁽⁸⁾
Use during pregnancy and lactation is not recommended. ⁽⁸⁾

Dosage and administration:

Valerian Dry Extract may be found formulated in liquid and solid preparations for oral administration.

Oral use:

1. Well established use:

Extracts prepared with ethanol/water (ethanol max. 40 - 70 % V/V) equivalent to 2 to 3 g of the herbal substance.
Maximum daily dose: 4 single dose.

2. Traditional use:

- Dry extracts prepared with water corresponding to 1 to 3 g of the herbal substance
- Valerian tincture corresponding to 0.3 to 1 g of the herbal substance

Maximum daily dose: 4 single dose

BIBLIOGRAPHY AND OTHER REFERENCE SOURCES

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