

SELECT BOTANICAL

ENOXOLONE

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 form raw material to finished product.

Definition:

(20 β)-3 β -Hydroxy-11-oxo-olean-12-en-29-oic acid.

SPECIFICATIONS/ TECHNICAL CHARACTERISTICS

(According to the current monograph "Enoxolone" of the European Pharmacopoeia)

Description:	White or almost white crystalline powder
Solubility:	According to monograph
Identification:	According to monograph
Specific optical rotation:	+145.0 to +154.0
Appearance of solution:	According to monograph
Related substances:	Any impurity: \leq 0.7 % Total impurities: \leq 2.0 %
Loss on drying:	\leq 0.5% w/w
Sulfated ashes:	\leq 0.2 % w/w
Heavy metals:	\leq 20 ppm
Residual solvents:	Ethanol: $<$ 0.5 % w/w
Assay (Potentiometry):	98.0-101.0 % (dried subst.)

INFORMATION ABOUT MANUFACTURING PROCESS

Enoxolone (18- β -Glycyrrhetic Acid) is obtained from the licorice root (*Glycyrrhiza glabra* L.) by extraction and purification methods.

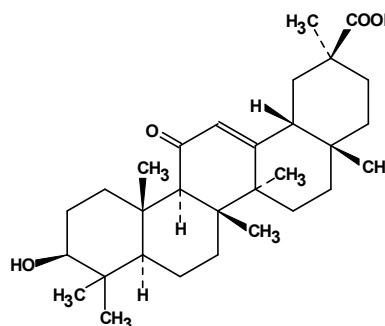
PRODUCT PROPERTIES

sb Solubility: practically insoluble in water, soluble in ethanol, sparingly soluble in methylene chloride.

REGULATORY INFORMATION AND DESCRIPTION

CAS: 471-53-4
EINECS: 207-444-6
INCI/ UE: Glycyrrhetic Acid

Structure:



Molecular formula: C₃₀H₄₆O₄

Relative molecular weight: 470.7

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PROPERTIES

- sb Anti-inflammatory activity: Studies have demonstrated the anti-inflammatory activity of 18-β-Glycyrrhetic Acid (Enoxolone).
- sb Anti-inflammatory effect on 12-O-tetradecanoylphorbol-13-acetate (TPA)-induced mouse ear edema. Preparations of Glycyrrhetic Acid before TPA treatment inhibited edema formation. (7)
- sb Inhibits the production of prostaglandin E₂. (1)

Studies show that 18-β-Glycyrrhetic Acid is a potent inhibitor of the skin enzyme 11-β-hydroxysteroid dehydrogenase which catalyses the conversion of cortisol to the inactive steroid cortisone. The concomitant application of 18-β-glycyrrhetic acid with hydrocortisone has been shown in animal studies potentiate the activity of hydrocortisone in skin. (2)

PRODUCT APPLICATIONS

Oral use:

- sb Anti-inflammatory
- sb Antiviral
- sb Antibacterial

Topical use:

- sb Anti-inflammatory
- sb Healing.
- sb Skin conditioning
- sb Antibacterial

Indications:

Oral use:

- sb Indicated in the treatment of affections of the upper respiratory tract such as aphonia and pharyngitis.

Topical use:

Indicated in the treatment of:

- sb Hemorrhoids and rectal disturbances associated to inflammation.
- sb Various skin diseases as inflamed skin, eczemas, psoriasis, pruritus and sensitive, fragile and irritable skin.
- sb Buccal inflammation affections and sensitive gums.

Undesirable effects:

There are neither reported toxic effects nor intolerance phenomenon to normal use doses. On prolonged use and higher doses sodium and water retention and potassium loss may occur, accompanied by hypertension, edema and hypokalemia. (9)

Precautions / Contraindications:

People suffering from hypertension should avoid excessive consumption. (6)
Enoxolone should not be used during pregnancy and lactation without medical advice. (9)

Dosage and administration:

Oral use:

Enoxolone (18-β-Glycyrrhetic Acid) may be found formulated in preparations for oral use.

Topical use:

Enoxolone (18-β-Glycyrrhetic Acid) may be found formulated in creams, gels, ointments, emulsions, after sun products and toothpastes, among others. Its solubility permits its use in cosmetic preparations with oily base. Moreover, Enoxolone (18-β-Glycyrrhetic Acid) may be found formulated in suppository and antihemorrhoids creams. Recommended dose: 0.5-1.5 % (4)

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