

SELECT BOTANICAL

DEVIL'S CLAW ROOT

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.

REGISTRY NUMBERS

CAS : 84988-65-8
EINECS: 284-853-6
INCI/ UE: HARPAGOPHYTUM PROCUMBENS
ROOT EXTRACT

INFORMATION ABOUT PLANT ORIGIN

SPECIFICATIONS/ TECHNICAL CHARACTERISTICS

Raw material:

Definition:	Roots of <i>Harpagophytum procumbens</i> DC
Description:	
- Macroscopic	Complies Ph.Eur.current Ed.
- Microscopic	Complies Ph.Eur.current Ed
Loss on drying:	≤ 12 % w/w
Pesticides:	According to Ph. Eur. current Ed.
Assay (HPLC)	Harpagoside

Composition of Extract Preparation

Native Dry Extract
Maltodextrin
Colloidal silicon dioxide

Extract Specifications

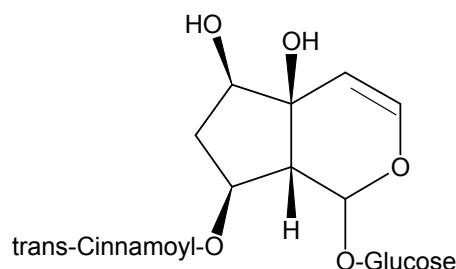
Loss on drying:	≤ 6 % w/w
Total ash:	≤ 15 % w/w
Heavy metals.	Analysis of Pb,As,Cd and Hg
Microbiological assay:	Acc.to Ph. Eur.current Ed "5.1.8. Point B"
Residual solvents:	According to guidelines CPMP/ICH/283/95
Assay (HPLC):	Harpagoside

Botanical Description

Herbaceous trailing perennial; flowers red in axils; fruit with pointed and barbed woody grapples to 2.5 cm long. Native to Kalahari savannas of Southern Africa and Namibia. ⁽²⁾

Analytical marker / Active principle

Iridoid glycosides: Harpagoside



Harpagoside

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PHARMACOLOGICAL STUDIES

- sb Anti-inflammatory activity: After administration of Devil's Claw extracts anti-inflammatory activity has been described. In various animal models of inflammation (carrageenan-induced rat paw oedema, adjuvant-induced arthritis) *Harpagophytum procumbens* shows anti-inflammatory properties when administered by intraperitoneal route only. Clinical studies done in the field of osteoarthritis and low back pain. ^(1,7)
- sb Analgesic activity: Devil's Claw extract exhibited dose-dependent peripheral analgesic effects after intraperitoneal administration into mice. Clinical studies done in the field of osteoarthritis and low back pain. ^(1,7)
- sb Cardiovascular activity: methanolic extract of *Harpagophytum procumbens* exerts hypotensive and bradycardic effects in conscious rats. ^(1,7)

PHYTOTHERAPY

Activities

Oral use:

- sb Anti-inflammatory. ^(1, 3, 6, 7)
- sb Mild analgesic. ^(3, 6, 7)
- sb Antirheumatic. ^(4, 6)
- sb Hypotensive. ^(1,7)
- sb Appetite-stimulating. ^(3, 6)

Topical use:

- sb Anti-inflammatory. ⁽⁵⁾

Indications:

Oral use:

- sb Traditional herbal medicinal product for relief of minor articular pain. ⁽⁸⁾
- sb Traditional herbal medicinal product used for the relief of mild digestive disorders such as bloating and flatulence and where there is loss of appetite. ⁽⁸⁾
- sb Indicated in the symptomatic treatment of painful osteoarthritis and relief of low back pain. ⁽¹⁾
- sb Indicated in the symptomatic treatment of loss of appetite and dyspepsia. ⁽¹⁾

Topical use:

- sb Indicated in the treatment of rheumatic disease, arthrosis, sores, ulcer, boils and skin lesions. ^(5,6)

Undesirable effects:

There are no reported toxic effects or intolerance phenomenon to normal use doses.

Mild gastro-intestinal disturbances may occur in sensitive individuals especially at higher dosage levels. ⁽¹⁾

Precautions/Contraindications:

As a general precaution, patients with gastric or duodenal ulcer should not use devil's claw root preparations. Caution should be taken when *Harpagophytum* is administered to patients affected by cardiovascular disorders. Devil's Claw Dry Extract should not be used during pregnancy and lactation. ⁽⁸⁾

Dosage and administration:

Oral use:

Devil's Claw Dry Extract may be found formulated in solid and liquid preparations.

The recommended daily dose for oral treatment of painful osteoarthritis is 2-5 g of the drug or equivalent aqueous or hydroalcoholic extracts. ⁽¹⁾

For traditional use, posology is indicated in the EMEA/HMPC/251323/2006 monograph. ⁽⁸⁾

Topical use:

Devil's Claw Dry Extract may be found formulated in ointments, creams and gels, among others. ^(4, 7)

BIBLIOGRAPHY AND OTHER REFERENCE SOURCES

1. ESCOP Monographs. Second edition. 2003.
2. Leung, A. Y., Foster, S. Encyclopedia of Common Natural Ingredients Used in Food, Drugs and Cosmetics. John Wiley & Sons, Inc. 2nd. Edition. USA. 1996
3. Blumenthal. The Complete German Commission E Monographs. Therapeutic Guide to Herbal Medicines. American Botanical Council. Austin, Texas 1998.
4. Newall, A. C., Anderson, L. A., Phillipson, D. J. Herbal Medicines. The Pharmaceutical Press. 1996.
5. Pons, L., Parra, J. L. Ciencia cosmética. Bases fisiológicas y criterios prácticos. C.G.C.O.F. 1995.
6. Blumenthal/Goldberg/Brinckmann. Herbal Medicine. Expanded Commission E Monographs. 2000.
7. Assessment report on *Harpagophytum procumbens* DC and/or *Harpagophytum zeyheri* Decne, radix. EMEA/HMPC/251324/2006.
8. Community Herbal Monograph on *Harpagophytum procumbens* DC and/or *Harpagophytum zeyheri* Decne, radix. EMEA/HMPC/251323/2006. EMA 2008.

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