



**MARSHMALLOW ROOT  
ORAL GUM**

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*Marshmallow root powdered  
extract  
125 mg per oral gum*

**Marshmallow root  
powdered extract**

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*Anklam Extrakt article number:  
00-111-0072-02P*

  
**ANKLAM**EXTRAKT

**AGON**  
PHARMA · GMBH

## QUALITY IS OUR PASSION

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### All from a single source

Anklam Extrakt combines high quality extracts with extraordinary service. We are particularly pleased to present our new exclusive service: **ready-to-sell products containing pharmaceutical extracts with stability data and complete documentation.**

We use only the best plant material for our extracts from selected suppliers of controlled and GACP compliant cultivation.

### Marshmallow ... the root for dry cough

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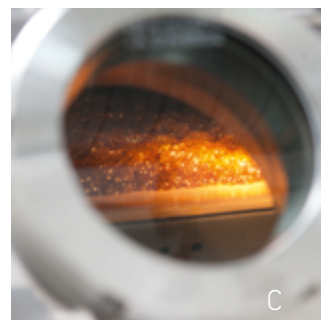
*Althaea* is derived from the Greek "althainein", meaning "to heal". Since Egyptian antiquity, the root has been used in a honey-sweetened confection for the treatment of sore throat. Today, several internationally recognized monographs have been published.

// Images upper left to lower right  
A. Marshmallow plant  
B. Qualified and motivated staff  
with insight  
C. Vacuum belt dryer in use  
D. Percolator

### Quality you can trust

The documentation of raw materials as well as the respective extracts is part of our service – for your product documentation as well as for your market approval documentation. Our specialised employees ensure that the quality of extracts meets the stringent control requirements according to GMP and HACCP standards.

Please do not hesitate to contact us for further information regarding our products and services. We will be pleased to help you.



## Active pharmaceutical ingredient (API)

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- Used plant material
  - Botanical name: *Althaea officinalis* L.
  - Used plant material: unpeeled, whole or cut, dried root
  - Identity: complies with Ph. Eur.
  - Monograph 1126
- Manufacturing data
  - Extraction solvent: Water
  - Drug Extract Ratio (DER) native: 3–9:1
  - Excipients: 17 % maltodextrin, 3 % silicon dioxide

## Marshmallow Root Oral Gum (2 g)

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- 125 mg Marshmallow root extract (native) per oral gum
- Pleasant taste
- PVC / Aluminium blister, 20 or 30 oral gums per package
- API and finished product are produced in Germany under GMP conditions

	dosage
Children (3 - 5 years of age)	1 oral gum, 3 times daily
Children (6 - 11 years of age)	1 - 2 oral gums, 3 times daily
Adolescents, adults and elderly	1 oral gum, several times daily. Maximum daily dose 20 oral gums

## Indication

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Traditional herbal medicinal product used as a demulcent preparation for the symptomatic treatment of oral or pharyngeal irritation and associated dry cough.

## Drug Registration Dossier

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- ICH-compliant. Stability data for API and finished product
- Manufacturing process validation for API and finished product
- Description of production process for API and finished product
- GACP compliant documentation of the herbal raw material

## Regulatory status\*: OTC

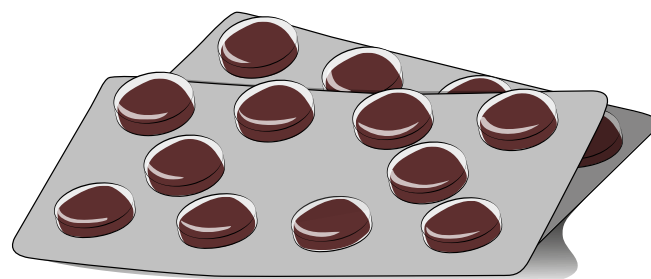
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### Licensing Procedure

Traditional use registration based on the HMPC monograph »*Althaea officinalis* L., radix« dated July 12th, 2016.

### Internationalisation

Depending on the conditions of the agreement, it is possible to use eCTD / English dossier in other countries.



## Marshmallow root Monographs/Literature

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- British Herbal Pharmacopoeia
- Commission E
- EMA Monograph (HMPC)
- ESCOP Monograph
- European Pharmacopoeia
- Hagers Enzyklopädie
- Helvetica Pharmacopoeia
- WHO Monograph

\*Regulatory status in Germany

## 3 strong partners for YOUR success



# ANKLAM EXTRAKT

### ANKLAM Extrakt

Pharmaceutical GMP manufacturer of herbal extracts for the global pharmaceutical industry with production site in Anklam, Germany.

[www.anklam-extrakt.de](http://www.anklam-extrakt.de)

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# AGON

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Approved pharmaceutical laboratory, regulatory affairs, specialised in the preparation of drug registration dossiers for herbal medicinal products.

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### BOLDER Arzneimittel GmbH & Co. KG

BOLDER is the leading contract manufacturing organisation of pastilles, lozenges and oral gums for the international pharmaceutical industry.

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#### Imprint

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#### Disclaimer

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