



ANKLAM EXTRAKT COUGH ORAL GUM

*75 mg Thyme herb powdered
extract and
37.5 mg Primula root powdered
extract per oral gum*

Thyme herb powdered extract

*Anklam Extrakt article number:
00-115-1140-02P*

Primula root powdered extract

*Anklam Extrakt article number:
00-111-0902-02P*


ANKLAMEXTRAKT

AGON
PHARMA · GMBH

QUALITY IS OUR PASSION

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.

Thyme and Primula ... the perfect combination for cough

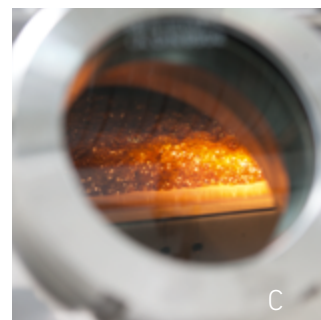
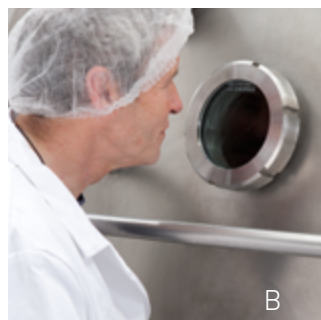
Both Thyme herb and Primula root are well known as expectorants for coughs associated with colds. Whereas Thyme directly influences the membrane of the respiratory tract and facilitates the removal of viscous bronchial secretion, the mode of action of Primula is indirect. The saponins of the Primula root are believed to irritate the gastric mucosa and thereby activate a reflex to stimulate secretion. In combination Thyme herb and Primula root show a perfect synergistic effect.

// Images upper left to lower right
A. Primula, Thyme
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)

Thyme herb powdered extract

- Used plant material
Botanical name: *Thymus vulgaris* L.
and /or *Thymus zygis* L.
Used plant material: whole leaves and flowers separated from the previously dried stems
Identity: complies with Ph. Eur. Monograph 0865
- Manufacturing data
Extraction solvent: Ethanol 70 % (v/v)
Drug Extract Ratio (DER) native: 6 - 10 : 1
Excipients: 17 % maltodextrin, 3 % silicon dioxide
- Assay
Sum of Thymol and Carvacrol, calc. as Thymol on the anhydrous extract: 0.6 - 2.5 %
Rosmarinic acid, calc. on the anhydrous extract: 1 - 10 %

Cough Oral Gum, Primula root & Thyme herb extract (2g)

- 75 mg Thyme herb extract (native) and 37.5 mg Primula root extract (native) per oral gum
- Pleasant taste
- PVC / PVDC / Aluminium blister, 20 or 40 oral gums per package
- API and finished product are produced in Germany under GMP conditions

Indication

The fixed combination of *Thymus vulgaris* L. or *Thymus zygis* L., herba and *Primula veris* L. or *Primula elatior* (L.) Hill, radix (Thyme herb and Primula root) is traditionally used as an expectorant in cough associated with cold.

	dosage
Adolescents, adults and elderly	1 oral gum, 3 times daily

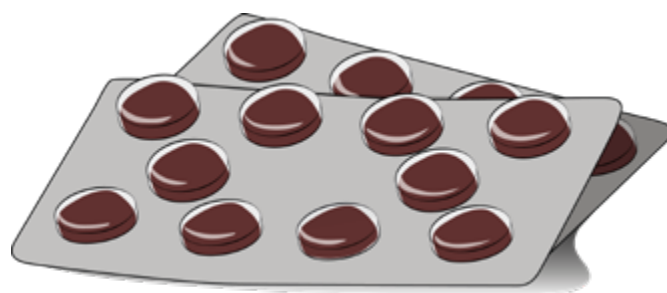
Drug Registration Dossier

- 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 in Germany

Primula root powdered extract

- Used plant material
Botanical name: *Primula elatior* (L.)
or *Primula veris* (L.) Hill
Used plant material: cut and dried rhizome with radix
Identity: complies with Ph. Eur. Monograph 1364
- Manufacturing data
Extraction solvent: Water
Drug Extract Ratio (DER) native: 3.5 - 4.5 : 1
Excipients: 17 % maltodextrin, 3 % silicon dioxide
- Assay
Sum of primula acid I and II calc. as primula acid I and calc. on the dried extract: 0.8 - 22.0 %



Regulatory status*: OTC

Licensing Procedure

Traditional use registration based on the HMPC monograph »Thymi herba / Primulae radix « dated April 5th, 2016.

Internationalisation

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

Thyme herb and Primula root Monographs

- EMA Monograph (HMPC)
- Commission E

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

Contact:

Claudia Pühn
Campus Marienberg
Marienbergstraße 92
90411 Nuremberg
Germany
claudia.puehn@anklam-extrakt.de
+49 911 247901-10

AGON PHARMA · GMBH

AGON Pharma

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

www.agon.de

Contact:

Günter Stephan
Stuttgarter Str. 2
73240 Wendlingen
Germany
gstephan@agon.de
+49 7024 94140



BOLDER Arzneimittel GmbH & Co. KG

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

www.bolder.de

Contact:

Dr. Michelina Gehlbach
Rheinische Allee 11
50858 Cologne
Germany
michelina.gehlabach@bolder.de
+49 2234 379520



Visit our homepage:



Imprint

Anklam Extrakt GmbH

Headquarters
Johann-Friedrich-Böttger-Straße 4
17389 Anklam
Germany

Anklam Extrakt GmbH

Sales office
Campus Marienberg
Marienbergstraße 92
90411 Nuremberg
Germany

sales@anklam-extrakt.com

www.anklam-extrakt.com

Court of registration: Neubrandenburg

Registry number: HRB 17217

Sales tax identification number according to
§ 27a UStG: DE254700277

Managing Director responsible for content:

Claudia Pühn

Disclaimer

The information that is provided regarding our ingredients is not applicable to nor intended to satisfy the requirements of all countries. Anklam Extrakt GmbH supplies ingredients as a raw material to companies that produce a variety of products containing our ingredients. Anklam Extrakt GmbH does not make any claims regarding the use of these finished products and each manufacturer is responsible for ensuring that the claims made for and use of its products comply with the regulatory requirement of the locations in which it is marketed. We accept no liability whatsoever for the content provided.

Print: 03/2018



ANKLAM EXTRAKT