



ANKLAM EXTRAKT COUGH TABLET (SUGAR-COATED)

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

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

wiewelhove
Contract Manufacturing of Solid Forms

 **DS Pharma**
Always one idea ahead

QUALITY IS OUR PASSION

All from a single source

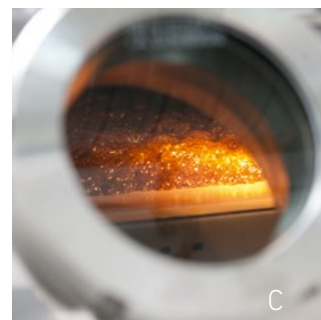
Anklam Extrakt combines high quality extracts with extraordinary service. We are particularly pleased to present our new exclusive service: **ready-to-sell products containing pharmaceutical extracts with stability data and complete documentation.**

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



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 Tablet, Primula root & Thyme herb powdered extract

- 75 mg Thyme herb extract (native) and 37.5 mg Primula root extract (native) per tablet
- Easy to swallow
- PVC / PVDC / Aluminium blister, 30, 60 or 120 tablets 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.

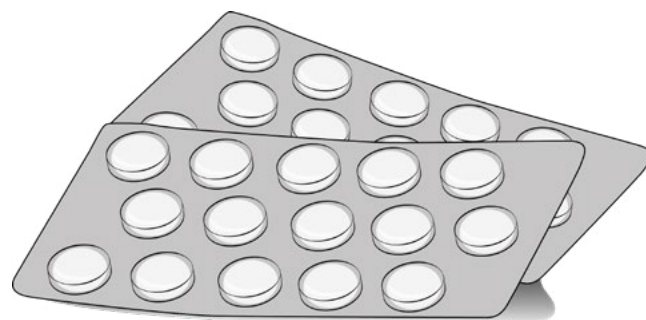
	dosage
Adolescents, adults and elderly	1 tablet, 3 times daily

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

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 - pharmacy only

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

*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

Contact:

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



Wiewelhove

GMP certified contract manufacturer of solid forms, e.g. capsules, tablets and pellets with production site in Ibbenbüren, Germany.
www.wiewelhove.de

Contact:

Dirk Meyer
Dörnebrink 19
49479 Ibbenbüren
Germany
d.meyer@wiewelhove.de
+49 5451 9401-434



DS Pharma

Innovative service partner to the pharmaceutical industry with approved pharmaceutical laboratory and regulatory affairs, specialised in the preparation of drug registration dossiers for herbal medicinal products.
www.ds-pharma.de

Contact:

Dr. Nicole Kordek
Gildestraße 39
49477 Ibbenbüren
Germany
n.kordek@ds-pharma.de
+49 5451 9401 0



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