



**ARTICHOKE LEAF TABLET
(FILM-COATED)**

*Artichoke leaf powdered extract
600 mg per tablet*

**Artichoke leaf
powdered extract**

*Anklam Extrakt article number:
00-111-1219-04P*


ANKLAMEXTRAKT

wiewelhove
Contract Manufacturing of Solid Forms

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.

Artichoke ... a leaf with healing properties

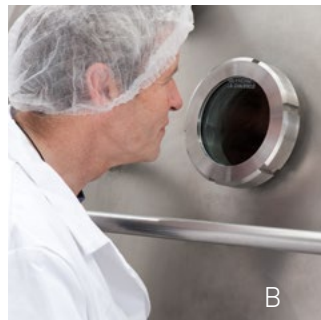
Originated in the Mediterranean region, the ancient Greeks already used Artichoke as healing remedy. Today, Artichoke leaves are well known for their blood lipids lowering and choleric (= stimulating bile production by the liver) properties, being dyspeptic disorders another important indication. Herbal medicine with Artichoke leaves as an API is traditionally used for the symptomatic relief of digestive disorders.

// Images upper left to lower right
A. Artichoke 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)

- Used plant material
Botanical name: *Cynara scolymus* L.
Used plant material: dried, whole or cut leaves
Identity: complies with Ph. Eur. monograph 1866
- Manufacturing data
Extraction solvent: Water
Drug Extract Ratio (DER) native: 4-6:1
Excipients: 17 % maltodextrin, 3 % silicon dioxide
- Assay
Chlorogenic acid, calc. on the dried extract:
≥ 0.6 %

Artichoke Leaf Tablet (Film-Coated)

- 600 mg Artichoke leaf extract (native) per tablet
- 1-2 times daily
- Easy to swallow
- PVC / PVDC / Aluminium blister, 30 or 60 tablets per package
- API and finished product are produced in Germany under GMP conditions

	dosage
<i>Adolescents, adults and elderly</i>	1 tablet, 1-2 times daily

Indication

Traditional herbal medicinal product for the symptomatic relief of digestive disorders such as dyspepsia with a sensation of fullness, bloating and flatulence.

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

Regulatory status*: OTC

Licensing Procedure

Traditional use registration based on the HMPC monograph »*Cynara scolymus* L., folium« dated September 13th, 2011.

Internationalisation

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



Artichoke leaf Monographs/Literature:

- Commission E
- EMA Monograph (HMPC)
- ESCOP Monograph
- European Pharmacopeia
- Hagers Enzyklopädie
- WHO Monograph

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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

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Wiewelhove

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

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AGON Pharma

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

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Disclaimer

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