

WE PRODUCE QUALITY.



Documentation package
for our tinctures and fluid extracts.

HÄNSELER 
SWISS PHARMA

DOCUMENTATION

Due to increased customer and regulatory requirements we provide our tinctures and fluid extracts with the following basic documentation.

1.0 Basic documentation:

- 1.1 Monography
- 1.2 Drug Certificate of Origin
- 1.3 Harvest report (fresh plants)
- 1.4 Certificate of analysis raw material
- 1.5 Certificate of analysis of finished product
- 1.6 Stability report

Additional testing:

pesticides, heavy metals, pyrrolizidin alcaloids and microbiology

2.0 Extended documentation:

(additional costs)

- 2.1 Complete production documentation including COC
- 2.2 Validation documentation for residue analysis
- 2.3 Manufacturing validation report

3.0 Documentation for approval:

(additional costs)

- 3.1 Preparation of an ASMF (open and closed part)
- 3.2 Preparation of a CEP

**Enclosed you will find an example of our basic documentation based on our arnica tincture.
Additional documents on request.**



4.5.2021

Arnica flower - European Pharmacopoeia 10.5

[General Notices](#) apply to all monographs and other texts.
See the information section on [general monographs](#).

01/2012:1391

ARNICA FLOWER

Arnicae flos

DEFINITION

Whole or partially broken, dried flower-heads of *Arnica montana* L.

Content: minimum 0.40 per cent *m/m* of total sesquiterpene lactones, expressed as dihydrohelenalin tiglate (dried drug).

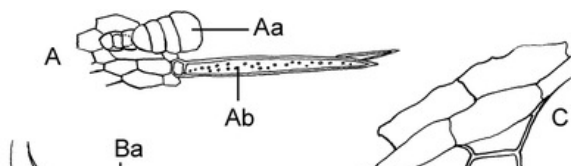
CHARACTERS

Aromatic odour.

The capitulum, when spread out, is about 20 mm in diameter and about 15 mm deep, and has a peduncle 2-3 cm long. The involucre consists of 18-24 elongated lanceolate bracts, with acute apices, arranged in 1-2 rows: the bracts, about 8-10 mm long, are green with yellowish-green external hairs visible under a lens. The receptacle, about 6 mm in diameter, is convex, alveolate and covered with hairs. Its periphery bears about 20 ligulate florets 20-30 mm long; the disc bears a greater number of tubular florets about 15 mm long. The ovary, 4-8 mm long, is crowned by a pappus of whitish bristles 4-8 mm long. Some brown achenes, crowned or not by a pappus, may be present.

IDENTIFICATION

- A. The involucre consists of elongated oval bracts with acute apices; the margin is ciliated. The ligulate floret has a reduced calyx crowned by fine, shiny, whitish bristles, bearing small coarse trichomes. The orange-yellow corolla bears 7-10 parallel veins and ends in 3 small lobes. The stamens, with free anthers, are incompletely developed. The narrow, brown ovary bears a stigma divided into 2 branches curving outwards. The tubular floret is actinomorphic. The ovary and the calyx are similar to those of the ligulate floret. The short corolla has 5 reflexed triangular lobes; the 5 fertile stamens are fused at the anthers.
- B. Microscopic examination (2.8.23). Separate the capitulum into its different parts. Examine under a microscope using [chloral hydrate solution R](#). The powder shows the following diagnostic characters (Figure 1391.-1): the epidermises of the bracts of the involucre [L, M, O, Q] have stomata [Lb, Oa, Qa] and trichomes, more abundant on the outer (abaxial) surface. There are several different types of trichomes: uniseriate multicellular covering trichomes, varying in length from 50-500 µm, particularly abundant on the margins of the bract, whole [La] or fragmented [P]; secretory trichomes with uni- or biseriate multicellular stalks and with multicellular, globular heads, about 300 µm long, abundant on the outer surface of the bract [Qb]; secretory trichomes with multicellular stalks and with multicellular, globular heads, about 80 µm long, abundant on the inner surface of the bract (surface view [Ob], side view [Ma]). The epidermis of the ligulate corolla [C, G, H, J] consists of lobed or elongated cells covered by a striated cuticle [Ga], a few stomata and trichomes of different types: covering trichomes, with very sharp ends, whose length may exceed 500 µm, consisting of 1-3 proximal, thick-walled cells and 2-4 distal, thin-walled cells [C, Hb]; secretory trichomes with biseriate multicellular heads (surface view [Gb], side view [Ja]); secretory trichomes with multicellular stalks and multicellular globular heads [K]. The ligule ends in rounded papillose cells [Ha]. Fragments of the epidermis of the ovary [A, B, D] are covered with trichomes of 2 types: secretory trichomes with short stalks and multicellular globular heads (surface view [Aa], side view [Da]); twinned covering trichomes usually consisting of 2 longitudinally united cells, with common pitted walls (surface view [Ab], side view [Ba]); their ends are sharp and sometimes bifid. The epidermises of the calyx consist of elongated cells bearing short, unicellular, covering trichomes pointing towards the upper end of the bristle [E]. The pollen grains have a diameter of about 30 µm, are rounded, with a spiny exine, and have 3 germinal pores [F, N].



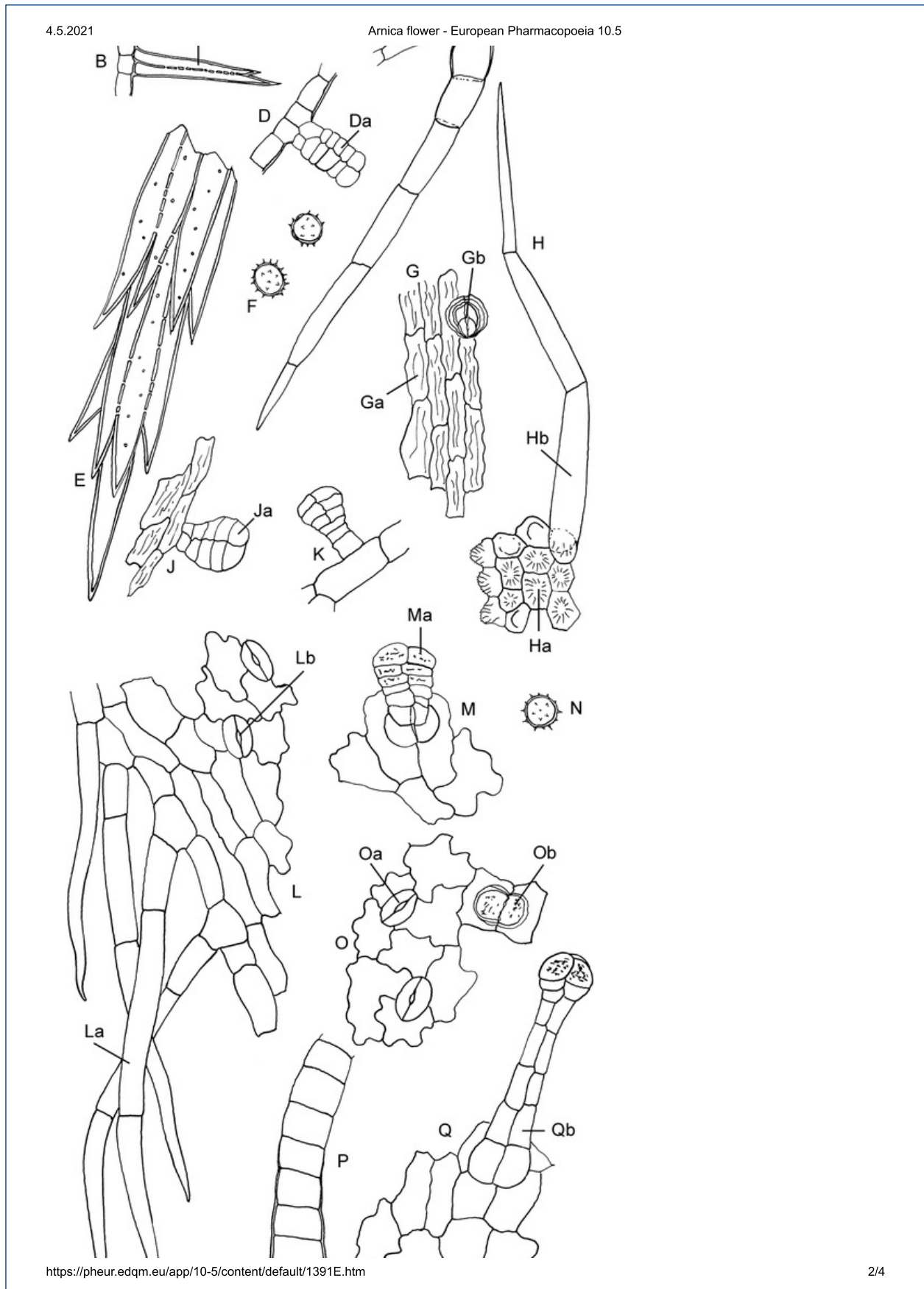
<https://pheur.edqm.eu/app/10-5/content/default/1391E.htm>

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Basic documentation:

1.1 Monography

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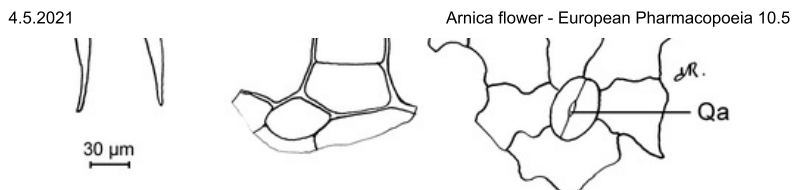


Figure 1391.-1. - Illustration for identification test B of powdered herbal drug of arnica flower

C. Examine the chromatograms obtained in the test for *Calendula officinalis* L. - *Heterotheca inuloides* Cass.

Results: the chromatogram obtained with the test solution shows, in the middle, a fluorescent blue zone corresponding to the zone due to chlorogenic acid in the chromatogram obtained with the reference solution; it shows, above this zone, 3 fluorescent yellowish-brown or orange-yellow zones, and above these 3 zones a fluorescent greenish-yellow zone due to astragalin; the zone located below the astragalin zone is due to isoquercitroside; the zone located just below this zone is due to luteolin-7-glucoside; it also shows a fluorescent greenish-blue zone below the zone due to caffeic acid in the chromatogram obtained with the reference solution.

TESTS

Foreign matter (2.8.2): maximum 5.0 per cent.

***Calendula officinalis* L. - *Heterotheca inuloides* Cass.** Thin-layer chromatography (2.2.27).

Test solution. To 2.00 g of the powdered herbal drug (710) (2.9.12) add 10 mL of **methanol R**. Heat in a water-bath at 60 °C for 5 min with shaking. Cool and filter.

Reference solution. Dissolve 2.0 mg of **caffeic acid R**, 2.0 mg of **chlorogenic acid R** and 5.0 mg of **rutoside trihydrate R** in **methanol R** and dilute to 30 mL with the same solvent.

Plate: TLC silica gel plate R.

Mobile phase: **anhydrous formic acid R**, **water R**, **methyl ethyl ketone R**, **ethyl acetate R** (10:10:30:50 V/V/V/V).

Application: 15 µL as bands.

Development: over a path of 15 cm.

Drying: in air for a few minutes.

Detection: spray with a 10 g/L solution of **diphenylboric acid aminoethyl ester R** in **methanol R**, and then with a 50 g/L solution of **macrogol 400 R** in **methanol R**; heat at 100-105 °C for 5 min, allow to dry in air and examine in ultraviolet light at 365 nm.

Results: the chromatogram obtained with the reference solution shows in the lower part an orange-yellow fluorescent zone due to rutoside, in the middle part a fluorescent zone due to chlorogenic acid and in the upper part a light bluish fluorescent zone due to caffeic acid; the chromatogram obtained with the test solution does not show a fluorescent orange-yellow zone corresponding to the zone due to rutoside in the chromatogram obtained with the reference solution, nor does it show a zone below this.

Loss on drying (2.2.32): maximum 10.0 per cent, determined on 1.000 g of the powdered herbal drug (355) (2.9.12) by drying in an oven at 105 °C for 2 h.

Total ash (2.4.16): maximum 10.0 per cent.

ASSAY

Liquid chromatography (2.2.29).

Internal standard solution. Dissolve immediately before use 0.010 g of **santonin CRS**, accurately weighed, in 10.0 mL of **methanol R**.

Test solution. Introduce 1.00 g of the powdered herbal drug (355) (2.9.12) into a 250 mL round-bottomed flask, add 50 mL of a mixture of equal volumes of **methanol R** and **water R** and heat under a reflux condenser in a water-bath at 50-60 °C for 30 min, shaking frequently. Allow to cool and filter through a paper filter. Add the paper filter, cut into pieces, to the residue in the round-bottomed flask, add 50 mL of a mixture of equal volumes of **methanol R** and **water R** and heat under a reflux condenser in a water-bath at 50-60 °C for 30 min, shaking frequently. Repeat this procedure twice. To the combined filtrates add 3.00 mL of the internal standard solution and evaporate to 18 mL under reduced pressure. Rinse the round-bottomed flask with **water R** and dilute, with the washings, to 20.0 mL. Transfer the solution to a chromatography column about 0.15 m long and about 30 mm in internal diameter containing 15 g of **kieselguhr for chromatography R**. Allow to stand for 20 min. Elute with 200 mL of a mixture of equal volumes of **ethyl acetate R** and **methylene chloride R**. Evaporate the eluate to

Basic documentation:

1.1 Monography

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4.5.2021

Arnica flower - European Pharmacopoeia 10.5

dryness in a 250 mL round-bottomed flask. Dissolve the residue in 10.0 mL of [methanol R](#) and add 10.0 mL of [water R](#). Add 7.0 g of [neutral aluminium oxide R](#), shake for 120 s, centrifuge at 5000 g for 10 min and filter through a paper filter. Evaporate 10.0 mL of the filtrate to dryness. Dissolve the residue in 3.0 mL of a mixture of equal volumes of [methanol R](#) and [water R](#) and filter.

Column:

- size: $l = 0.12$ m, $\varnothing = 4$ mm;
- stationary phase: [octadecylsilyl silica gel for chromatography R](#) (4 μ m).

Mobile phase:

- mobile phase A: [water R](#);
- mobile phase B: [methanol R](#);

Time (min)	Mobile phase A (per cent V/V)	Mobile phase B (per cent V/V)
0 - 3	62	38
3 - 20	62 → 55	38 → 45
20 - 30	55	45
30 - 55	55 → 45	45 → 55
55 - 57	45 → 0	55 → 100
57 - 70	0	100
70 - 90	62	38

Flow rate: 1.2 mL/min.

Detection: spectrophotometer at 225 nm.

Injection: 20 μ L loop injector.

Calculate the percentage content of total sesquiterpene lactones, expressed as dihydrohelenalin tiglate, using the following expression:

$$\frac{S_{LS} \times C \times V \times 1.187 \times 100}{S_S \times m \times 1000}$$

S_{LS}	=	area of all peaks due to sesquiterpene lactones appearing after the santonin peak in the chromatogram obtained with the test solution;
S_S	=	area of the peak due to santonin in the chromatogram obtained with the test solution;
m	=	mass of the herbal drug to be examined, in grams;
C	=	concentration of santonin in the internal standard solution used for the test solution, in milligrams per millilitre;
V	=	volume of the internal standard solution used for the test solution, in millilitres;
1.187	=	peak correlation factor between dihydrohelenalin tiglate and santonin.

Basic documentation:

1.2 Drug Certificate of Origin

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	Form		50527	
			Page 1 of 2	
	Drug Certificate of Origin		Version: 001	
	GACP confirmation		Valid from: 26/03/2021	
				Responsible Department/ Division: Quality Assurance

Article no. <i>Hänseler AG</i>	09-1058-00	Batch number <i>Hänseler AG</i>	2020.12-0574	Supplier no. <i>Hänseler AG</i>	3554
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Article description: FLOR. ARNICAE C.CAL. TOT. (whole Arnica flos with calyx)					
Lot no.	1180A201013	Quantity:	Supply date:		
Harvest period (MM/YY):	06/2020	Country of origin:	UA		
Harvest:	☒ wild collection	☐ cultivation	☐ conventional	☐ organic cultivation	
Harvest stage:	☐ before flowering	☒ flowering	☐ after flowering		
	☐ mature fruit	☐ during dormancy			
Harvest method:	☒ manual	☐ machine			
Drying:	☒ natural	☐ artificial	Duration / Temperature:	h / °C	
Cleaning:	☐ none	☒ by hand	☐ mechanical	☐ washed	
Metal detector:	☒ no	☐ yes			
Sieving:	☒ no	☐ yes			
Comminution:	☒ no	☐ yes			
Disinfestation:	☒ no	☐ yes	Time point:	Active substances:	
Germ reduction:	☒ no	☐ yes	Time point:	Active substances:	
Use of plant protection agents	☒ no	☐ yes	Active substances:		
Genetically modified organisms:	☒ no	☐ yes			
Use of ionising radiation	☒ no	☐ yes			
Use of ethylene oxide, methyl bromide/iodide	☒ no	☐ yes			
Storage:	☒ packed	Packaging material:			
Controlled temperature:	☐ no	☒ yes	max. temperature:	25 °C	
Controlled humidity:	☐ no	☒ yes	max. humidity	75%	
Physico-chemical	☐ no	☒ yes (annex)			
Microbiology	☐ no	☒ yes (annex)			
Other	☐ no	☒ yes (annex)			

We confirm compliance with the guidelines on good agricultural and collection practice (GACP)

We confirm compliance with the guidelines on good manufacturing practice (GMP)

We hereby confirm the completeness and correct transcription of the supplier information:

Head of QC Hänseler AG	Date 25/03/2021	Name: Dr Christoph Titze (QP)	Signature
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Basic documentation:

1.3 Harvest report (fresh plants)

1/2

	Form		QQk50512	
	Harvest protocol for fresh plant GACP confirmation		Page 1 of 2	
			Version: 001 Valid from: 26/03/2021 Responsible Department/ Division: Quality Assurance	

Article no. Hänseler AG		Batch number Hänseler AG		Supplier no. Hänseler AG	
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To be completed by supplier

Supplier		Grower/ Collector		Supply date	
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Latin plant name		German plant name		Delivery quantity	_____ kg
Country of origin		Region		Altitude	
Date of harvest		Time of day		Harvesting method	manual ☐ machine ☐
Cultivation	wild collection ☐ conventional cultivation ☐ organic cultivation ☐ other ☐ _____				
During cultivation	fertilisation no ☐ yes ☐ if yes, what: _____				
During cultivation	use of plant protection agents no ☐ yes ☐ if yes, what: _____				
Weather during harvest	dry ☐ sunny ☐ cloudy ☐ rain ☐ other ☐ _____				
Plant part	flos ☐ herba ☐ radix ☐ semen ☐ cortex ☐ fructus ☐ other ☐ _____				
Harvest stage	Before flowering ☐ at start of flowering ☐ during flowering ☐ after flowering ☐ during dormancy ☐				
Cut	1st cut ☐ 2nd cut ☐ 3rd cut ☐		Precleaning	no ☐ yes ☐ if yes, method: _____	
Packaging	open ☐ net bag ☐ crate ☐ stackable pallet box (wooden/plastic) ☐ other ☐ _____			Number of containers	
Precleaning	no ☐ yes ☐		if yes, method: _____		
Transport	car ☐ lorry ☐ ship ☐ aeroplane ☐ other ☐ _____				Refrigerated: no ☐ yes ☐

GACP confirmation	I hereby confirm this form has been truthfully completed and complies with the guidelines on good agricultural and collection practice (GACP)	Date, Signature Supplier	
Confirmation of harvest	I hereby confirm the fresh plant was not harvested during rain or watered before harvesting (>24h) and that any dew had largely dried before harvesting.	Date, Signature Supplier	
PA confirmation	I hereby confirm that attention was paid during the harvest to ensure no weeds containing pyrrolizidine (e.g. common ragwort) contaminated the harvest.	Date, Signature Supplier	

Basic documentation:

1.3 Harvest report (fresh plants)

2/2

	Form	QQk50512
		Page 2 of 2
	Harvest protocol for fresh plant GACP confirmation	Version: 001
		Valid from: 26/03/2021 Responsible Department/ Division: Quality Assurance

Note: The revision history, distribution list and approval can be deleted when issuing the report.

Approval

	Position	Name	Date	Initials
Issued	Head of Quality Assurance Department	S. Dilettoso		
Checked	Head of Procurement Department	K. Fink		
Approved	Head of Division QM / QP	C. Titze		

1. Revision history

Version	Valid from	Changes
	11/07/2014	Inclusion of Point 10: Confirmation
001	26/03/2021	Full revision, alignment with GACP guidelines

Distribution list:

Head of Department	Manufacture, Quality Control, Procurement, Planning
Group Head	Materials Management, Production, Laboratory
Staff positions	Registration
File	CE60

Basic documentation:

1.4 Certificate of analysis raw material

1/3



Electronically Signed by / Elektronisch signiert von:
Wallimann Stephan
Date/Datum: 2021-01-20 15:58
Reason/Grund: GMP-compliant batch release/
GMP-konforme Chargenfreigabe

Analysenzertifikat vom AZ00039636 Artikel: 09-1058-00 Arnicae flos pro Fabrikation

Seite 1 von 3

Chargennr.	2020.12.0574
Ext. Chargennr.	1180A201013
Qualität	PHEUR
MFD	keine Angaben
Retest	30.09.2023
Ursprungsland	UA
Freigabedatum	20. Januar 2021

Hersteller

Heinrich Klenk GmbH & Co.KG
Aschenhof 35
97525 Schwebheim
Deutschland

Reference: PhEur, 01/2012:1391

Characters: Whole or partially broken, dried flower-heads of Arnica montana L.
with a aromatic odour

Storage: Well closed, protected from light.

Reason for change: Adjusting the testing severity PA according to CC2020.08.0232

Test	Methode		Spezifikation		Soll	Resultat
			Min.	Max.		
Identification (Herbs)						
Macroscopic Identification	E-ID-	MACRO			complies	complies
Microscopic Identification	E-ID-	MICRO			complies	complies
TLC	E2.2.27				complies	complies
Tests (herbals)						
Foreign matter	E2.8.2 1	2)		5.0		1.4 %
TLC	E2.2.27 1				complies	complies
Calendula officinalis L., Heterotheca inuloides						
Loss on drying	E2.2.32			10.0		8.8 %
Total ash	E2.4.16	2)		10.0		6.0 %
Pesticide residues	E2.8.13	2)			complies	complies
Pesticides of which the concentration is above quantification limit will be listed with their individual result (see comments).						
alpha HCH 0.017 mg/kg						
Lindan 0.020 mg/kg						
Folpet/PI 0.069 mg/kg						
Phthalimid 0.034 mg/kg						
Cadmium (AAS)	E2.4.27 CD	2)		1.00		<= 1.00 ppm
entspricht statistischer Absicherung						
Lead (AAS)	E-2.4.27 PB	2)		5.00		0.10 ppm

Hänseler AG
Industriestrasse 35
9100 Herisau

1) Extern im Auftrag HAG
2) Übernommen von Lieferant / Hersteller

Basic documentation:

1.4 Certificate of analysis raw material

2/3



Analysenzertifikat vom AZ00039636 Artikel: 09-1058-00 Arnicae flos pro Fabrikation

Seite 2 von 3

Chargennr. 2020.12.0574
Ext. Chargennr. 1180A201013
Qualität PHEUR
MFD keine Angaben
Retest 30.09.2023
Ursprungsland UA
Freigabedatum 20. Januar 2021

Test	Methode	Min.	Spezifikation		Soll	Resultat
				Max.		
Mercury (AAS) entspricht statistischer Absicherung	E-2.4.27 HG 2)			0.10		<=0.10 ppm
Pyrrolizidinalkaloide (PA) statistically validated	PA2 2)				entspricht	entspricht
Assay						
Assay	E-ASSAY 2)	0.40				1.37 %(m/m)
Of total sesquiterpene lactones, expressed as dihydrohelenalin tiglate (dried drug)						
Microbial Analysis						
TAMC	TAMC / G 2)			10'000'000		132'000 CFU/g
TYMC	TYMC / G 2)			100'000		19'500 CFU/g
E coli	E-MO- 2)			1'000		<100 CFU/g
	E.COLI					
Salmonella	E-MO- 2)				complies	complies
	SALMONEL					
	LA					
in 25 g						
Remarks / Hinweise						
Origin / Ursprungsland	WE22					Ukraine
MFD / Herstellungsdatum	MFD					keine Angaben
Retest / zu überprüfen ab:	RETEST					30.09.2023

Hänseler AG
Industriestrasse 35
9100 Herisau

1) Extern im Auftrag HAG
2) Übernommen von Lieferant / Hersteller

Basic documentation:

1.4 Certificate of analysis raw material

3/3



Analysenzertifikat vom AZ00039636 **Artikel: 09-1058-00 Arnicae flos pro Fabrikation**

Seite 3 von 3

Chargennr.	2020.12.0574
Ext. Chargennr.	1180A201013
Qualität	PHEUR
MFD	keine Angaben
Retest	30.09.2023
Ursprungsland	UA
Freigabedatum	20. Januar 2021

We hereby certify that the above information is authentic and accurate.
This batch has been fabricated/manufactured, including packaging and quality control at the above mentioned site in compliance with the EU-GMP requirements of the local Regulatory Authority except the verification of the compendial analytical method.
The batch processing, packaging and analysis records were reviewed and found to be in compliance with EU-GMP.

This certificate is only valid for closed containers of this specific batch.

No release relevant deviation was observed.

Herisau, 20. Januar 2021
Hänseler AG FvP / QP
i.v. Stephan Wallimann

Hänseler AG
Industriestrasse 35
9100 Herisau

- 1) Extern im Auftrag HAG
- 2) Übernommen von Lieferant / Hersteller

Basic documentation:

1.5 Certificate of analysis of finished product

1/2



Electronically Signed by / Elektronisch signiert von:
Wallimann Stephan
Date/Datum: 2021-01-14 14:02
Reason/Grund: GMP-compliant batch release/
GMP-konforme Chargenfreigabe

Analysenzertifikat vom AZ00039472

Artikel: 25-0551-00 Arnicae tinct

Seite 1 von 2

Packungstext	BULK
Chargennr.	2020.10.0487
Qualität	PHEUR
MFD	04.01.2021
Retest	04.01.2024
Ursprungsland	CH
Freigabedatum	14. Januar 2021

Hersteller
Hänseler AG
Industriestrasse 35
9100 Herisau

Reference: PhEur, 01/2008:1809 corrected 6.3

Characters: Yellowish-brown liquid

Storage: Protected from light

Reason for change: Implementation in Navision 2015

Test	Methode	Spezifikation		Soll	Resultat
		Min.	Max.		
Identification					
TLC	E2.2.27 1			complies	complies
Thin-layer chromatography (2.2.27)					
Purity					
TLC	E2.2.27			complies	complies
Thin-layer chromatography					
Calendula officinalis - Heterotheca inuloides					
TESTS					
Relative density	E2.2.5				0.900
Ethanol content	E2.9.10	61.9			67.4 % (V/V)
Methanol	E2.9.11 2		0.05		<0.05 % (V/V)
2-Propanol	E2.9.11		0.05		<0.05 % (V/V)
Dry residue of extracts	E2.8.16	1.7			2.2 % (m/m)
Assay					
Assay	E-ASSAY	0.04			0.07 %
Not less than 0.04% Sesquiterpene lactones (expressed as dihydrohelenalin tiglate).					
Microbial Analysis					
TAMC	TAMC	1)	10'000		10 CFU/g
TYMC	TYMC	1)	100		<10 CFU/g

Hänseler AG
Industriestrasse 35
9100 Herisau

1) Extern im Auftrag HAG
2) Übernommen von Lieferant / Hersteller

Basic documentation:

1.5 Certificate of analysis of finished product

2/2



Analysenzertifikat vom AZ00039472

Artikel: 25-0551-00 Arnicae tinct

Seite 2 von 2

Packungstext	BULK
Chargennr.	2020.10.0487
Qualität	PHEUR
MFD	04.01.2021
Retest	04.01.2024
Ursprungsland	CH
Freigabedatum	14. Januar 2021

Test	Methode		Spezifikation		Soll	Resultat
			Min.	Max.		
Enterobact. / gram-neg. bact.	E-MO- ENTEROBA CT	1)		100		<10 CFU/g
2.6.13 Escherichia coli	E-MO-E COLI	1)			complies	complies
absence in 1 g Salmonella	E-MO- SALMONEL LA	1)			complies	complies
absence in 25 g						
Remarks / Hinweise						
Drogen Extrakt Verhältnis	DEV					1 : 8.8
Origin / Ursprungsland	WE22					Schweiz
MFD / Herstellungsdatum	MFD					04.01.2021
Retest / zu überprüfen ab:	RETEST					04.01.2024

We hereby certify that the above information is authentic and accurate.
This batch has been fabricated/manufactured, including packaging and quality control at the above mentioned site in compliance with the EU-GMP requirements of the local Regulatory Authority except the verification of the compendial analytical method.
The batch processing, packaging and analysis records were reviewed and found to be in compliance with EU-GMP.

This certificate is only valid for closed containers of this specific batch.

No release relevant deviation was observed.

Herisau, 14. Januar 2021
Hänseler AG FvP / QP
i.v. Stephan Wallimann

Hänseler AG
Industriestrasse 35
9100 Herisau

1) Extern im Auftrag HÄG
2) Übernommen von Lieferant / Hersteller

Basic documentation:

1.6 Stability report

1/5

Article 25-0551-00
Batch 2016.09.0450

Final report on stability testing, ICH / Stress test / Follow-up

1. General Information

Product name	Arnica tincture
Quality	☐ Medicinal product (Swissmedic/ MA no. marketing authorisation number) ☐ Medicinal product (registered in Canton Appenzell Ausser rhoden / MA no. marketing authorisation number) ☐ Narcotic ☐ GID top ten ☐ GID intermediates ☐ TPA Art 9, para 2, letter a-c ☒ Active substances, HAG ☐ Packaged raw materials, HAG
Art. no.	25-0551-00
Batch no.	2016.09.0450
Shelf life at start of testing	3 years

2. Packaging

Container	brown glass bottles
Trading unit size	100 ml
Art. no.	11-0200-01

3. Test

Reason for storage	follow-up
Duration of test	36 months
Test intervals	0/6/12/24/36
Test criteria	Chemical and physical tests: (in accordance with test protocol) • properties • TLC identity • specific gravity • ethanol content • dry residue • assay (expressed as dihydrohelenanin) • methanol and 2-propanol content • microbiology (in accordance with Ph. Eur. 5.1.8 B)

Valid from:	03/02/2020	Issued:	J. Huber	JHr
Replaces form dated:	28/08/2019	Approved:	S. Wallimann	on: 31/01/2020 SWa

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Batch 2016.09.0450

4. Warehousing

Storage conditions	☐ room temperature ☒ environmental chamber at 25 °C / 60% rel. humidity ☐ environmental chamber at 30 °C / 65% rel. humidity ☐ environmental chamber at 40 °C / 75% rel. humidity ☐ refrigerator at 2 - 8 °C ☐ cold room at 10 - 15 °C		
Storage in warehouse	15/12/2016	Removal from warehouse	25/11/2019
Number of samples stored	10	Number of samples removed from storage	3 remaining samples were disposed of

5. DEV and/or OOS

M24: Test date expired, see DEV2019.08.0069

6. Stability study results and analysis

6.1 Stability overview

Table 1: Overview of stability data for batch 2016.09.0450

Stability test overview for Arnica tincture follow-up

Article number: 25 0551-00 Manufacture: 23 09 2016
 Batch: 2016.09.0450 Storage conditions: 25 ± 2°C / 60 ± 5% rel. humidity
 Primary packaging material: brown glass bottles (11-0200-01) Release (bulk) 01/12/2016
 Volume: 100 ml Release (filling):
 Bulk batch: Storage in warehouse: 15/12/2016
 Method: Ph. Eur. 01/2008:1809 corrected 6.3 Shelf life: 3 years

Time	Deadline	Date of conduct	Properties	TLC identity	Specific gravity	Ethanol content [% (v/v)]	Dry residue [%]	Assay (expressed as dihydrohelenanin)	Methanol and 2-propanol content [%]	Microbiology
Method	-	-	-	-	-	-	-	-	Ph. Eur. 2.9.11	Ph. Eur. 5.1.8 B
Spec.	-	-	complies	complies	-	min. 61.9%	min. 1.7%	min. 0.04%	max. 0.05%	-
0 mo.	01 12 2016	01 12 2016	complies	complies	0.898	66.6	2.1	0.10	<0.01	-
6	01 06 2017	14 06 2017	complies	-	0.899	66.3	2.1	0.10 *	-	-
12	01 12 2017	30 11 2017	complies	complies	0.899	66.8	2.0	0.09	<0.01	-
24	01 12 2018	14 01 2019	complies	complies	0.899	65.5	2.1	0.04	<0.01	-
36	01 12 2019	25 11 2019	complies	CC2019 020004	0.899	66.7	2.0	0.04	<0.01	complies

Comments * subsequently corrected, as wrong value (0.12 %) was transcribed

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6.2 Trend analysis for batch 2016.09.0450

Comparison with 5 other batches manufactured from 2009-2015. No significant trend visible within 36 months.
Guaranteed shelf life of 36 months.

6.2.1 Properties

The properties comply with specifications at all times.

☒ no trend ☐ increasing ☐ decreasing

Comments: n.a.

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6.2.2 TLC identity

The TLC identity complies with specifications at all times.

☒ no trend ☐ increasing ☐ decreasing

Comments: TLC identity was not tested after 6 months. The test is dispensed with after 12 months in accordance with CC2019.02.0004

6.2.3 Specific gravity

Specific gravity is a purely informative value. There is no specification.

☒ no trend ☐ increasing ☐ decreasing

Comments: n.a.

6.2.4 Ethanol content

The ethanol content complies with specifications at all times (min. 61.9% (v/v)).

☒ no trend ☐ increasing ☐ decreasing

Comments: n.a.

6.2.5 Dry residue

The dry residue complies with specifications at all times (min. 1.7%).

☒ no trend ☐ increasing ☐ decreasing

Comments: n.a.

6.2.6 Assay (expressed as dihydrohelenanin)

The assay (expressed as dihydrohelenanin) complies with specifications at all times (min. 0.04%).

☒ no trend ☐ increasing ☐ decreasing

Comments: n.a.

6.2.7 Methanol and 2-propanol content

The methanol and 2-propanol content complies with specifications at all times (min. 0.05%).

☒ no trend ☐ increasing ☐ decreasing

Comments: n.a.

6.2.8 Microbiology (in accordance with 5.1.8.B)

Microbiology tests were carried out after 36 months. The test complies with specifications.

☒ no trend ☐ increasing ☐ decreasing

Comments: n.a.

7. Ongoing measures (if required):

☒ not required

Justification: n.a.

8. Assessment of shelf life:

A shelf life of 36 months at 25 ± 2°C / 60 ± 5% rel. humidity can be guaranteed based on the data evaluated in this final report.

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Issued (person responsible for stability testing)

Name: Marie Titze Date: 16. JULY 2020 Signature: *[signature]*

Approved (QP for Medicinal Product Manufacture, otherwise Head of Quality Control):

Name/Function: M. Titze Datum: 20. JULY 2020 Signature: *[signature]*

Client:

Client signature, if contract manufacture: yes ☐ n.a. ☒

Client: / Date: / Signature: /

9. Revision history

29/05/2017 new
06/09/2019 full revision
16/12/2019 Point 5 added, approved by Head of Department QC

Mailing list (status as of 02/10/2019):

Head of Department Quality Control

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HEALTHY GROWTH
THROUGH A FRUITFUL
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