

Certificate of analysis



125 Jahre
 Qualität aus Leidenschaft.

FARMADENT d.o.o.
 Minarikova ul. 6
 2000 Maribor
 Prejel: FJJS DRAGO
 Datum pregleda: 15.4.15
 Pregledal: MAROLT Robert, mag. farm. spec.
 Datum pregleda: 15.4.15

Article 3021 Hydrophobes Basisgel
 Synonym Gelatum basalis hydrophobicum
 Batch 150557 ✓
 Specification DAC 2011 ✓
 Expiry date 01.2017 ✓

Test	Specification	Result
Characters	In accordance	Complies
-Appearance	In accordance	Complies
-Odour	In accordance	Complies
Identification	In accordance	Complies
-Freezing point-rotating thermometer	68 - 78 °C	71,3 °C
-B	In accordance	Complies
Tests	In accordance	Complies
-Acidity or alkalinity	In accordance	Complies
-Refractive index	1,475 - 1,495	1,4835
-Fraction insoluble in petroleum ether	4,5 - 5,5 %	4,69 %
-Appearance	In accordance	Complies
-Total ash	Max 0,1 %	0,01 %
Stabilizer	Amount/Name	None
Complies specification	*****	Yes

Release date 25.02.2015 Head of Quality Control Hr.Apoth.Bartschat

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Article	2272	Hydrocortisonacetat, mikronisiert, API
Synonym		Hydrocortisoni acetas (mikrobielle Herkunft)
Batch	143014 <i>01V</i>	
Specification	PH.EUR. 8.0	
Expiry date	03.2017	

Test	Specification	Result
Characters	In accordance	Complies
-Appearance	In accordance	Complies
-Solubility	In accordance	Complies
Identification	In accordance	Complies
-IR spectrophotometry	In accordance	Complies
-HPLC	In accordance	Complies
-Raman spectrophotometry	In accordance	Complies
Tests	In accordance	Complies
-Specific optical rotation	+158 - +167	+ 166
-Related substances	In accordance	Complies
-Loss on drying	Max 0,5 %	0,0 %
Assay	97,0 - 102,0 %	99,0 %
Correction factor weighing (f, NRF)	*****	1,010
Complies specification	*****	Yes

GMP-conform according to §11 ApBetrO

Release date	27.11.2014	Head of Quality Control	Fr. Dr. Haßel
Manufacturer	Pharmacia & Upjohn (Fi. d. Pfizer Inc.)		
Manufacturer Batch	J40117		
Manufacturer Country	USA		
Manufacturer City	Kalamazoo, Michigan		

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NATUR COMMERCE d.o.o. Portorož

Sončna pot 48, 6320 Portorož

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Št. analize: 67 / 2014 N

Datum analize: 07. 11. 2014

Oznaka artikla: MILLEFOLII HERBA

Številka serije: 4123

Rok uporabe: 07 / 2016



ANALIZNI CERTIFIKAT

Predpis: - Ph. Eur.

1. Lastnosti: - posušeni, razrezani zgornji cvetoči deli rastline *Achillea millefolium* L., značilnega aromatičnega vonja in značilnega okusa

2. Istovetnost: - makroskopska: ustreza
- mikroskopska: ustreza

3. Preskusi: - tuje primesi: - max. 5 % stebel premera preko 3 mm - 1,8 %
- max. 2 % drugih tujih primesi - 1,1 %
- izguba pri sušenju: max. 12,0 % - 9,0 %
- skupni pepel: max. 10,0 % - 6,0 %
- v klorovodikovi kislini netopni pepel: max. 2,5 % - 1,2 %

4. Vsebnost: - vsebnost eteričnega olja: min. 2 ml / kg - 4,0 ml / kg
- vsebnost proazulena, preračunana na Chamazulen**: min. 0,02 % - 0,012 %

5. Mikrobiološka kakovost: - Ph.Eur. 8 po 5.1.8. A** - ustreza
(Poročilo o mikrobiološki preiskavi, laboratorijska številka 31509 / NL ZOH)

6. Mnenje: - rezultati preiskovanih parametrov ustrezajo zahtevam Ph. Eur. razen vsebnost proazulena.

Oseba odgovorna za sproščanje:
Gordana Flego, mag. farm. spec.



Natur commerce d.o.o.

Sončna pot 48
6320 Portorož

Oseba odgovorna za kontrolo in zagotavljanje kakovosti:

Saša Babič

* - analiza opravljena v dobaviteljevem laboratoriju

** - analiza opravljena v zunanjem pogodbenem laboratoriju