

Certificate of analysis



125 Jahre
 Qualität aus Leidenschaft.

FARMADENT d.o.o. Minarikova ul. 6 2000 Maribor Prejel: FUS DRAGO 21:	
Datum pregleda:	5.9.13
Pregledat:	MAROLT Robert, mag. farm., spec.
Datum pregleda:	6.9.2013

Article	2272	Hydrocortisonacetat, mikronisiert, API
Synonym		Hydrocortisoni acetas
Batch	12330102	
Specification	PH.EUR. 7.0	
Expiry date	10.2014	

Test	Specification	Result
Characters	In accordance	Complies
-Appearance	In accordance	Complies
-Solubility	In accordance	Complies
-Melting point	Ca. 220 °C	219 °C
Identification	In accordance	Complies
-IR spectrophotometry	In accordance	Complies
-Thin-layer chromatography	In accordance	Complies
Tests	In accordance	Complies
-Specific optical rotation	+158 - +167	+164,0
-Related substances	In accordance	Complies
-Loss on drying	Max 0,5 %	0,26 %
Assay	97,0 - 103,0 %	101,06 %
Complies specification	*****	Yes

GMP-conform

Release date	23.11.2012	Head of Quality Control	Fr. Dr.Haßel
Manufacturer	Pharmacia & Upjohn (Fi. d. Pfizer Inc.)		
Manufacturer Batch	F09084		
Manufacturer Country	USA		
Manufacturer City	Kalamazoo, Michigan		

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