

Certificate of analysis



Article	2272	Hydrocortisonacetat, mikronisiert, API
Synonym		Hydrocortisoni acetat (mikrobielle Herkunft)
Synonym		Hydrocortisone acetate, micronized, API
Batch	160954	
Specification	PH.EUR. 8.0	
Expiry date	11.2018	

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 %	0,1 %	
Assay	97,0 - 102,0 %	99,8 %	#
Correction factor weighing (f, NRF)	*****	1,003	
Complies specification	*****	Yes	

Certificate of analysis



Article	2272	Hydrocortisonacetat, mikronisiert, API
Synonym		Hydrocortisoni acetas (mikrobielle Herkunft)
Synonym		Hydrocortisone acetate, micronized, API
Batch	160954	
Specification	PH.EUR. 8.0	
Expiry date	11.2018	

Test	Specification	Result
GMP-conform		
Release date	20.04.2016	Head of Quality Control
Manufacturer	Pharmacia & Upjohn Company	
Manufacturer Batch	N11965	
Manufacturer City	49001-0199 Kalamazoo, Michigan	
Manufacturer street	7000 Portage Road	
Manufacturer Country	USA	

Result taken from the manufacturer's certificate

This document has been generated automatically and is valid without a signature.