

Certificate of analysis



Article	2552	Prednison, mikronisiert, API (mikrobielle Herkunft)	
Synonym		Prednisonum	
Synonym		Prednisone, micronized, API(microbial origin)	
Batch	21003706		
Specification	Ph.Eur.10.3		
Production date	08.2021	Retest date	07.2026

Test	Specification	Result
Characters	According to specification	Complies
Appearance	According to specification	Complies
Solubility	According to specification	Complies
Identification	According to specification	Complies
IR spectrophotometry	According to specification	Complies
HPLC	According to specification	Complies
Tests	According to specification	Complies
Specific optical rotation	183 ... 191	187
Related substances	According to specification	Complies
Impurity A	Max. 0,5 %	0,3 %
Impurity E	Max. 0,2 %	0,0 %
Impurity D	Max. 0,15 %	< 0,05 %
Each unspecified impurity	Max. 0,10 %	0,07 %
Total of all impurities	Max. 1,0 %	0,4 %
Loss on drying	Max. 1,0 %	0,0 %
Assay	97,0 ... 102,0 %	99,7 %
Correction factor weighing (f, NRF)		1,003
Complies specification		Yes

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Release date	20.01.2022	Released by	Frau Dr. Haßel, QP, LQK
Manufacturer	Henan Lihua Pharmaceutical CO. LTD.		
Manufacturer batch	K03C20210902M		
Manufacturer street	Middle of Huanghe Street,		
Manufacturer city	455 000 Anyang, Henan Province		
Manufacturer country	Volksrepublik China		

GMP-compliant production and testing of the active pharmaceutical ingredients

Results marked with # were taken from the manufacturer's certificate.

The batch 21003706 complies specification.

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