

Certificate of analysis



Article	2552	Prednison, mikronisiert, API (mikrobielle Herkunft)	
Synonym		Prednisonum	
Synonym		Prednisone, micronized, API(microbial origin)	
Batch	23000981		
Specification	Ph.Eur.10.3		
Production date	08.2022	Retest date	07.2027

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	190
Related substances	According to specification	Complies
Impurity A	Max. 0,5 %	0,4 %
Impurity E	Max. 0,2 %	< 0,1 %
Impurity D	Max. 0,15 %	< 0,05 %
Each unspecified impurity	Max. 0,10 %	< 0,05 %
Total of all impurities	Max. 1,0 %	0,4 %
Loss on drying	Max. 1,0 %	0,0 %
Assay	97,0 ... 102,0 %	101,4 %
Correction factor weighing (f, NRF)		0,986
Complies specification		Yes

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Release date	30.08.2023	Released by	Frau Dr. Haßel, QP, LQK
Manufacturer	Henan Lihua Pharmaceutical CO. LTD.		
Manufacturer batch	K03C20230208M		
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 23000981 complies specification.

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