

Certificate of analysis



Article	4684	Tetracyclinhydrochlorid, API (mikrobielle Herkunft)	
Synonym		Tetracyclini hydrochloridum	
Synonym		Tetracycline hydrochloride, API(microbial origin)	
Batch	24000509		
Specification	Ph.Eur.11.0		
Production date	10.2023	Retest date	10.2027

Test	Specification	Result
Characters	According to specification	Complies
Appearance	According to specification	Complies
Solubility	According to specification	Complies
Identification	According to specification	Complies
Thin-layer chromatography	According to specification	Complies
B	According to specification	Complies
C	According to specification	Complies
Tests	According to specification	Complies
pH-Value	1.8 ... 2.8	2.5
Specific optical rotation	-255 ... -240	-245
Related substances	According to specification	Complies
Impurity A	Max. 3.0 %	0.8 %
Impurity B	Max. 1.5 %	0.6 %
Impurity C	Max. 0.5 %	0.1 %
Impurity D	Max. 0.5 %	0.0 %
Loss on drying	Max. 2.0 %	0.2 %
Sulphated ash	Max. 0.5 %	0.0 %
Assay	95.0 ... 102.0 %	98.2 %
Correction factor weighing (f, NRF)	1,000	1,020
Complies specification		Yes

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Release date	11.04.2024	Released by	Frau Apoth. Dr. Schücker, QP
Manufacturer	Ningxia Qiyuan Pharmaceutical CO. LTD.		
Manufacturer batch	231019-62		
Manufacturer street	No.1 Qiyuan Street		
Manufacturer city	750101 Yinchuan, Ningxia		
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 24000509 complies specification.

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