

## Certificate of analysis



Article	4684	Tetracyclinhydrochlorid, API (mikrobielle Herkunft)	
Synonym		Tetracyclini hydrochloridum	
Synonym		Tetracycline hydrochloride, API(microbial origin)	
Batch	23000427		
Specification	Ph.Eur.10.0		
Production date	10.2021	Retest date	10.2025

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	-246	#
Related substances	According to specification	Complies	#
Impurity A	Max. 3,0 %	1,0 %	#
Impurity B	Max. 1,5 %	0,4 %	#
Impurity C	Max. 0,5 %	0,1 %	#
Impurity D	Max. 0,5 %	< 0,5 %	#
Loss on drying	Max. 2,0 %	0,2 %	
Sulphated ash	Max. 0,5 %	0,0 %	#
Assay	95,0 ... 102,0 %	98,3 %	#
Correction factor weighing (f, NRF)		1,019	
Complies specification		Yes	

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Release date	05.04.2023	Released by	Frau Dr. Haßel, QP, LQK
Manufacturer	Ningxia Qiyuan Pharmaceutical CO. LTD.		
Manufacturer batch	211019-61		
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 23000427 complies specification.

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