

Certificate of Analysis

Product name: Tetracyclini hydrochloridum
Batch number / Weight: 24J01-B02-007070 / 25 g
Producer / Producer Batch Number: Ningxia Qiyuan Pharmaceutical Co., Ltd. / 240610-61
Analyzed according to: Ph.Eur. 11
Number of Analysis / Certificate no.: 24J01-B02 / QO0012958

	Requirement	Result	Unit	Standard remark
Appearance	Yellow, crystalline powder	Conform		
Apparent volume	About 18ml/10g	17 ml/10g		
Identification	A,B,C	Conform		
pH	1,8 - 2,8	2,46		
Specific optical rotation	(-255) - (-240)	-247,5		
Related substances	Conform	Conform		
Impurity A	<=3,0	1,14	%	
Impurity B	<=1,5	0,55	%	
Impurity C	<=0,5	0,13	%	
Impurity D	<=0,5	0,01	%	
Loss on drying	<= 2,0	0,37	%	
Sulfated ash	<= 0,5	0,00	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
Assay	95,0 - 102,0	97,45	% m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		DP

All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab FSNE LAB

Release:

24-3-2025
 Agnieszka Pszczółka
 Qualified Person

Expiration: 2-6-2026

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.