

Certificate of Analysis

Product name: **Tetracyclini hydrochlor. pond.**

Batch number / Weight: **21K20-B01-219063 / 50 G**

Analysed according to: **Ph. Eur.**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Yellow, crystalline powder	Conform		
Apparent volume	About 18	17,0	ml / 10 g	
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
pH	1,8 - 2,8	2,45		
Specific optical rotation	-240 - - 255	-243,6		
Related substances	Conform	Conform		
Impurity A	<=3,0	1,21	%	
Impurity B	<=1,5	0,57	%	
Impurity C	<=0,5	0,12	%	
Impurity D	<=0,5	0,005	%	
Loss on drying	<= 2,0	0,42	%	
Sulphated ash	<= 0,5	0,02	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	95,0 - 102,0	98,74	%m/m	
Endotoxins	<= 0,5	<0,5	IU / mg	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Dominika Sołtysik
Qualified Person

23-05-2022

Expiration: 17-10-2023

Conclusion: APPROVED

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