

## Certificate of Analysis

**Productname:** Tetracyclini hydrochlor. pond.  
**Number of analysis/Inspection Code:** 1 / KEUR-194666B  
**Batchnumber:** 21D12-F03-382050  
**Reference code / No.:** 2364 / 200616-61  
**Analysed according to:** PHEUR10.4+

Tests	Requirement	Result	Unit	Standard remark
Appearance	Yellow, crystalline powder	Conform		
Apparent volume	About 18	16	ml / 10 g	
Identification A	Conform	Conform		TLC
Identification B	Conform	Conform		
Identification C	Conform	Conform		Chloride
pH	1,8 - 2,8	2,5		1% <i>m/V</i>
Spezifische Drehung	-240 - - 255	-243		1% <i>m/V</i> in HCl 0.1M; dried
Related substances	Conform	Conform		HPLC
Impurity A	<=3,0	2,5	%	
Impurity B	<=1,5	1,0	%	
Impurity C	<=0,5	0,5	%	
Impurity D	<=0,5	0,0	%	
Loss on drying	<= 2,0	0,2	%	3 h 60°C vacuum
Sulphated ash	<= 0,5	0,1	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Tetracycline hydrochloride	95,0 - 102,0	99,4	% <i>m/m</i>	HPLC; dried
Endotoxins	<= 0,5	Conform	IU / mg	LAL-test
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
CEP	CEP available	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic Polen.

Release:  
 Anthony Amoureux  
 Qualified Person

05/17/22

Expiration: 06-2024

Conclusion: APPROVED

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