

## Certificate of Analysis

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

**Batch number / Weight:** **22I29-B01-223002 / 50 G**

**Analysed according to:** **Ph. Eur. 10.8**

**Number of analysis / Inspection Code** **22I29-B01 / INS-22-8422**

**Reference Code / No.:** **V01618 / 220409-62**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Yellow, crystalline powder	Conform		
Apparent volume	About 18	76,9	ml / 10 g	
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
pH	1,8 - 2,8	2,50		
Specific optical rotation	-240 - - 255	-245,0		
Related substances	Conform	Conform		
Impurity A	<=3,0	1,26	%	
Impurity B	<=1,5	0,57	%	
Impurity C	<=0,5	0,12	%	
Impurity D	<=0,5	0,01	%	
Loss on drying	<= 2,0	0,45	%	
Sulphated ash	<= 0,5	0,06	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	95,0 - 102,0	99,51	%m/m	
Endotoxins	<= 0,5	<0,5	IU / mg	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Residual solvents				
Acetone	not more than 3000 ppm	<5000	ppm	
1-Butanol	<= 5000	<5000	ppm	

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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 FAGRON PL lab

Release:

Ewelina Gadzinowska

Qualified Person

30-11-2022

Expiration: 01-04-2024

Conclusion: APPROVED

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