

## Certificate of Analysis

**Product name:** Tetracyclini hydrochloridum

**Batch number / Weight:** 24B27-B06 / KG

**Analysed according to:** Ph.Eur. 01/2014:1615

**Number of analysis / Inspection Code /**

**Reference Code / No.:** V01618 / 231125-63

Tests	Requirement	Result	Unit	Standard remark
Protocol no		522/S/0324		
Appearance	Yellow, crystalline powder	Conform		
Apparent volume	About 18	17,6	ml / 10 g	
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
pH	1,8 - 2,8	2,56		
Specific optical rotation	-240 - - 255	-245,0		
Related substances	Conform	Conform		
Impurity A	$\leq 3,0$	1,07	%	
Impurity B	$\leq 1,5$	0,76	%	
Impurity C	$\leq 0,5$	0,08	%	
Impurity D	$\leq 0,5$	0,00	%	
Loss on drying	$\leq 2,0$	0,37	%	
Sulphated ash	$\leq 0,5$	0,00	%	
Assay	95,0 - 102,0	96,98	%m/m	
Endotoxins	$\leq 0,5$	<0,5	IU / mg	
TAMC	$\leq 10^3$	<10 <sup>3</sup>	CFU/g	
Total yeasts and moulds (TYMC)	$\leq 10^2$	<10	CFU / g	
Correction factor		1,035		

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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:

Magdalena Łatak

Quality Control Supervisor/Speciali

17-04-2024

Expiration: 24-11-2027

Conclusion: APPROVED

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