

Certificate of Analysis

Product name: **Clindamycini phosphas apyrog.**

Batch number / Weight: **22E09-B07-220372 / 5 G**

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

Number of analysis / Inspection Code **22E09-B07 / INS-22-7400**

Reference Code / No.: **V01874 / 15302000001101**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white powder	Conform		
Identification A	Conform	Conform		
Identification D	Yellow	Conform		
Appearance of solution	Clear / colourless	Conform		
Related substances	Conform	Conform		
Impurity B	$\leq 1,0$	0,52	%	
Impurity L	$\leq 1,0$	0,06	%	
Impurity E	$\leq 0,5$	0,08	%	
Impurity F	$\leq 0,5$	0,21	%	
Impurity G	$\leq 0,2$	$< 0,05$	%	
Impurity I	$\leq 0,2$	$< 0,05$	%	
Impurity J	$\leq 0,2$	0,08	%	
Impurity K	$\leq 0,2$	$< 0,05$	%	
Any other impurity	$\leq 0,10$	0,07	%	
Total impurities	$\leq 2,0$	1,07	%	
Water (Karl Fischer)	$\leq 5,0$	3,90	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Clindamycin phosphate	96,0 - 102,0	99,8	%m/m	
Endotoxins	$\leq 0,6$	Conform	IE/mg	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Methanol	≤ 300	< 25	ppm	
Triethylamine	≤ 320	< 10	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, ElSpol

Release:

Ewelina Gadzinowska

Qualified Person

26-10-2022

Expiration: 11-04-2025

Conclusion: APPROVED

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