

Certificate of Analysis

Product name: Doxycyclini hyclas

Batch number / Weight: 21I10-B02-221743 / 30 G

Analysed according to: Ph.Eur.10

Number of analysis / Inspection Code 21I10-B02 / INS-21-5467

Reference Code / No.: V01412 / H202106006

Tests	Requirement	Result	Unit	Standard remark
Appearance	Yellow, hygroscopic, crystalline powder	Conform		
Identification A	Conform	Conform		
Identification B	Yellow	Conform		
Identification C	White	Conform		
pH	2,0 - 3,0	2,42		
Lightabsorbing impurities	<=0,07	0,021		
Related substances	Conform	Conform		
Impurity A	<=2,0	1,23	%	
Impurity F	<=1,2	0,74	%	
Impurity B	<=0,5	<0,05	%	
Impurity C	<=0,2	<0,05	%	
Any other impurity	<=0,10	<0,05	%	
Total impurities	<=3,0	1,97	%	
Ethanol	4,3 - 6,0	5,03	%	
Water (Karl Fischer)	1,4 - 2,8	1,95	%	
Sulphated ash	<=0,4	0,03	%	
Endotoxins	<1,14	Conform	IU/mg	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	95,0 - 102,0	98,17	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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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:
Dominika Soltysik
Qualified Person

30-08-2022

Expiration: 09-06-2025

Conclusion: APPROVED

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