

Certificate of Analysis

Product name: Doxycyclini hyclas
Batch number / Weight: 19I12-F01-217133 / 10 G
Analysed according to: Ph. Eur.

Tests	Requirement	Result	Unit	Standard remark
Appearance	Yellow, hygroscopic, crystalline powder	Conform		
Identification	Conform	Conform		
Identification B	Yellow	Conform		
Identification C	White	Conform		
pH	2,0 - 3,0	2,2		
Lightabsorbing impurities	<=0,07	0,01		
Related substances	Conform	Conform		
Impurity A	<=2,0	1,5	%	
Impurity F	<=1,2	1,1	%	
Impurity B	<=0,5	0,1	%	
Impurity C	<=0,2	<0,05	%	
Any other impurity	<=0,10	<0,05	%	
Total impurities	<=0,3	2,8	%	
Ethanol	4,3 - 6,0	5,1	%	
Water (Karl Fischer)	1,4 - 2,8	2,0	%	
Sulphated ash	<=0,4	0,0	%	
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	97,9	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
 Ewelina Gadzinowska
 Qualified Person

10-12-2021

Expiration: 31-01-2023

Conclusion: APPROVED

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