

Certificate of Analysis

Productname: Doxycyclini hyclas
Number of analysis/Inspection Code: 1 / KEUR-181632B
Batchnumber: 20A30-F01-368707
Reference code / No.: 2074 / 1811023
Analysed according to: PH.EUR10.0

Tests	Requirement	Result	Unit	Standard remark
Appearance	Yellow, crystalline powder	Conform		Hygroscopic
Identification A	Conform	Conform		HPLC
Identification B	Yellow	Conform		
Identification C	White	Conform		
pH	2,0 - 3,0	2,4		1%m/V
Lightabsorbing impurities	<=0,07	0,03		490 nm HCl/MeOH; anhydr-/ethanolfree
Related substances	Conform	Conform		HPLC
Impurity A	<=2,0	1,4	%	
Impurity F	<=1,2	1,1	%	
Impurity B	<=0,5	<0,05	%	
Impurity C	<=0,2	<0,05	%	
Any other impurity	<=0,10	<0,05	%	
Total impurities	<=3,0	2,5	%	
Ethanol	4,3 - 6,0	4,6	%	GC
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	CHMP/ICH/82260/2006	Conform		Data producer
Assay Doxycycline hydrochloride	95,0 - 102,0	97,9	%m/m	HPLC; water- and EtOH-free
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic + microbiel.

Release:
Wai Lung Chung
Pharmacist - Qualified Person

03/31/20

Expiration: 11-2022

Conclusion: APPROVED

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