

Certificate of Analysis

Productname: Clindamycini hydrochloridum
Number of analysis/Inspection Code: 1 / KEUR-196465B
Batchnumber: 22A31-F04-383141
Reference code / No.: 3276 / K-211147B
Analysed according to: PH.EUR10.6

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		Slightly hygroscopic
Identification A	Conform	Conform		IR-spectrum
Identification D	White	Conform		Chloride
pH	3,0 - 5,0	4,4		10%m/V
Specific optical rotation	+135 - +150	+144		4%m/V; anhydrous
Related substances	Conform	Conform		HPLC
Impurity B	<=2,0	0,7	%	
Impurity C	<=4,0	0,9	%	
Any other impurity	<=0,5	<=0,2	%	
Total impurities	<=6,0	2,4	%	
Water (Karl Fischer)	3,0 - 6,0	4,0	%	
Sulphated ash	<=0,5	0,1	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		
Assay Clindamycin hydrochloride	92,0 - 102,0	99,0	%m/m	HPLC; anhydrous
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
CEP	CEP available	Conform		Data producer

Analysis performed by the authorized laboratory Quercus BE.

Manufacturer / Country : Zhejiang Tiantai Pharmaceutica / CN
CEP :

Release:
Anthony Amoureux
Qualified Person

12/07/22

Expiration: 26-11-24

Conclusion: APPROVED

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