



Certificate of Analysis

Productname: Clindamycini hydrochloridum
Number of analysis/Inspection Code: 2 / KEUR-111790B
Batchnumber: 14D23-B03-296116 ✓
Reference code / No.: 2022 / P-003-CN20140304
Analysed according to: PH.EUR 8.1

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification A	Conform	Conform		IR-spectrum
Identification D	White	Conform		Chloride
pH	3,0 - 5,0	4,4		10% <i>m/V</i>
Specific optical rotation	+135 - +150	+143	°	4% <i>m/V</i> ; anhydrous
Related substances	Conform	Conform		HPLC
Impurity B	<=2,0	<2,0	%	
Impurity C	<=4,0	<4,0	%	
Any other impurity	<=1,0	<1,0	%	
Total impurities	<=6,0	<6,0	%	
Water (Karl Fischer)	3,0 - 6,0	4,1	%	
Sulphated ash	<=0,5	0,0	%	
Residual solvents	CPMP/ICH/283/95	Conform		Data producer
Assay Clindamycin hydrochloride	91,0 - 102,0	97,2	% <i>m/m</i>	GC; anhydrous
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analyse performed by the authorized lab Eurofins Parijs.

Release:
Drs. M.V. Garcia Alia
Pharmacist - QA Manager / QP

08/29/14

Expiration: 03-2017 ✓

Conclusion: APPROVED

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