



Certificate of Analysis

Productname: **Clindamycini hydrochloridum**
Number of analysis/Inspection Code: 2 / KEUR-107159B
Batchnumber: **13J03-B02-291411** ✓
Reference code / No.: 2022 / P-003-WS13091401
Analysed according to: **PH.EUR 7.8**

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	4,3		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	0,8	%	
Impurity C	≤4,0	0,5	%	
Any other impurity	≤1,0	0,9	%	
Total impurities	≤6,0	3,7	%	
Water (Karl Fischer)	3,0 - 6,0	4,2	%	
Sulphated ash	≤0,5	0,1	%	
Residual solvents	CPMP/ICH/283/95	Conform		Data producer
Assay Clindamycin hydrochloride	91,0 - 102,0	97,8	% <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 Proxylabs.

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

04/22/14

Expiration: 08-2016 ✓

Conclusion: APPROVED



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