



## Certificate of Analysis

FARMADENT d.o.o.	
Minarikova ul. 6	
2000 Maribor	
Prejel: F. J. DRAGO	
20.	
Datum prejema:	4.4.14
Prejedal:	MAROLT Robert, mag. farm., spec.
Datum pregleda:	4.4.2014

Productname: **Clindamycini hydrochloridum**  
Number of analysis/Inspection Code: 1 / KEUR-94599B  
Batchnumber: **13C22-B01-285536** ✓  
Reference code / No.: 2022 / P-003-WS13020502  
Analysed according to: **PH.EUR 7.7**

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		+142	°	4% <i>m/V</i> ; anhydrous
Related substances	Conform	Conform		HPLC
Impurity B	<=2,0	1,1	%	
Impurity C	<=4,0	0,4	%	
Any other impurity	<=1,0	0,2	%	
Total impurities	<=6,0	2,2	%	
Water (Karl Fischer)	3,0 - 6,0	3,9	%	
Sulphated ash	<=0,5	0,2	%	
Residual solvents	CPMP/ICH/283/95	Conform		
Assay Clindamycin hydrochloride	91,0 - 102,0	97,4	% <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

10-04-13

Expiration: 03-2016 ✓

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.