



## Certificate of Analysis

**Productname:** Clindamycini hydrochloridum  
**Number of analysis/Inspection Code:** 1 / KEUR-88017B  
**Batchnumber:** 12F28-B02-273918 ✓  
**Reference code / No.:** 2022 / P-003-WS12030701  
**Analysed according to:** PH.EUR 7.5

FARMADENT d.o.o. Mitarikova ul. 6 2000 Maribor Prejel: FUJS DRAGO Za: P. L.
Datum pregleda: 28.3.2012
Pregledal: HAROLT Robert, mag. farm. spec.
Datum pregleda: 28.3.2012

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	4,0		10% <i>m/V</i>
Specific optical rotation		+146	°	4% <i>m/V</i> ; anhydrous
Related substances	Conform	Conform		HPLC
Impurity B	<=2,0	0,9	%	
Impurity C	<=4,0	1,4	%	
Any other impurity	<=1,0	0,5	%	
Total impurities	<=6,0	3,4	%	
Water (Karl Fischer)	3,0 - 6,0	4,3	%	
Sulphated ash	<=0,5	0,1	%	
Residual solvents	CPMP/ICH/283/95	Conform		Data producer
Assay Clindamycin hydrochloride	91,0 - 102,0	96,3	% <i>m/m</i>	GC; anhydrous
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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

24-09-12

Expiration: 03-2015 ✓

Conclusion: APPROVED

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