



Certificate of Analysis

Productname: Clindamycini hydrochloridum
Number of analysis/Inspection Code: 1 / KEUR-90279B
Batchnumber: 12F28-B02-276361 ✓
Reference code / No.:
Analysed according to: PH.EUR 7.5

FARMADENT d.o.o.
Minarikova ul. 6
2000 Maribor
Prejek: FUJS DRAGO
2013
Datum prejeta: 5.3.2013
Pregledal: MAROLJ Robert, mag. farm., spec.
Datum pregleda: 6.2.2013

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

Analyse performed by the authorized lab Proxylabs.

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

30-11-12

Expiration: 03-2015 ✓

Conclusion: APPROVED

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