



Certificate of Analysis

FARMADENT d.o.o.
Minariškova ul. 6
2000 Maribor
Prejel: FUJS DRAGO
Datum prijema: 6.10.14
Pregledal: MAROLT Robert, mag. farm., spec.
Datum pregleda: 6.10.14

Productname: Clindamycini hydrochloridum
Number of analysis/Inspection Code: 2 / KEUR-107147B
Batchnumber: 13J03-B02-291410
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

04/18/14

Expiration: 08-2016

Conclusion: APPROVED

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