

Certificate of Analysis

Productname: Clindamycini hydrochloridum
Number of analysis/Inspection Code: 1 / KEUR-195867B
Batchnumber: 22A31-F04-382322
Reference code / No.: 3276 / K-211147B
Analysed according to: PH.EUR10.6

| Tests | Requirement | Result | Unit | Standard remark |
|---------------------------------|--|---------|------|----------------------|
| Appearance | (Almost) white, crystalline powder | Conform | | Slightly hygroscopic |
| Identification A | Conform | Conform | | IR-spectrum |
| Identification D | White | Conform | | Chloride |
| pH | 3,0 - 5,0 | 4,4 | | 10%m/V |
| Specific optical rotation | +135 - +150 | +144 | | 4%m/V; anhydrous |
| Related substances | Conform | Conform | | HPLC |
| Impurity B | <=2,0 | 0,7 | % | |
| Impurity C | <=4,0 | 0,9 | % | |
| Any other impurity | <=0,5 | <=0,2 | % | |
| Total impurities | <=6,0 | 2,4 | % | |
| Water (Karl Fischer) | 3,0 - 6,0 | 4,0 | % | |
| Sulphated ash | <=0,5 | 0,1 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CHMP/ICH/82260/2006 | Conform | | |
| Assay Clindamycin hydrochloride | 92,0 - 102,0 | 99,0 | %m/m | HPLC; anhydrous |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |
| CEP | CEP available | Conform | | Data producer |

Analysis performed by the authorized laboratory Quercus BE.

Release:
Anthony Amoureux
Qualified Person

09/30/22

Expiration: 11-2024

Conclusion: APPROVED

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