

Certificate of Analysis

Product name: Chloramphenicolum

Batch number / Weight: 22H03-B03-222018 / 100 G

Analysed according to: Ph. Eur. 10.8

Number of analysis / Inspection Code 22H03-B03 / INS-22-6467

Reference Code / No.: V01863 / DY0092100055

| Tests | Requirement | Result | Unit | Standard remark |
|---------------------------|--|---------|------|-----------------|
| Appearance | Fine, white, greyish-white | Conform | | |
| Identification A | Conform | Conform | | |
| Acidity or alkalinity | Conform | Conform | | |
| Specific optical rotation | +18,5 - +20,5 | +19,6 | | |
| Related substances | Conform | Conform | | |
| Impurity A | <=0,2 | <0,05 | % | |
| Unspecified impurities | <=0,10 | 0,066 | % | |
| Total impurities | <=0,5 | 0,12 | % | |
| Chlorides | <=100 | Conform | ppm | |
| Loss on drying | <=0,5 | 0,1 | % | |
| Sulphated ash | <=0,1 | 0,01 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| Assay Chloramphenicol | 97,5 - 102,0 (dried substance) | 100,11 | %m/m | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |
| Residual solvents | | | | |
| Methanol | <= 3000 | 16,5 | ppm | |
| Ethanol | <= 5000 | 5,7 | ppm | |
| Isopropanol | <= 5000 | 13,2 | ppm | |
| Chlorobenzene | <= 360 | 0,0 | ppm | |
| Benzene | <= 2 | 0,0 | ppm | |

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All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab FAGRON PL lab

Release:

Ewelina Gadzinowska

Qualified Person

21-10-2022

Expiration: 31-12-2026

Conclusion: APPROVED

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