

Certificate of Analysis

Product name: **Erythromycinum**

Batch number / Weight: **22A15-B11-218019 / 100 G**

Analysed according to: **Ph. Eur.**

| Tests | Requirement | Result | Unit | Standard remark |
|-----------------------------|---|---------|------|-----------------|
| Appearance | White or pale yellow powder slightly hygroscopic | Conform | | |
| Identification A | Conform | Conform | | |
| Specific optical rotation | -71 - -78 (anhydrous substance) | -73,6 | | |
| Related substances | Conform | Conform | | |
| Impurity A | <= 2,0 | 0,57 | % | |
| Impurity B | <= 2,0 | 0,92 | % | |
| Impurity D | <= 1,0 | 0,24 | % | |
| Impurity C | <=3,0 | 1,00 | % | |
| Impurity E | <= 1,0 | <0,2 | % | |
| Impurity F | <= 1,0 | <0,2 | % | |
| Impurity H | <= 1,0 | 0,16 | % | |
| Impurity L | <=0,4 | <0,2 | % | |
| Any impurity | <=0,4 | <0,2 | % | |
| Total impurities | <=7,0 | 2,89 | % | |
| Thiocyanate | <=0,3 | 0,03 | % | |
| Water (Karl Fischer) | <=6,5 | 1,22 | % | |
| Sulphated ash | <=0,2 | 0,1 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| Dichloromethane | <=600 | 4,4 | ppm | |
| Assay Erythromycine (A+B+C) | 93,0 - 102,0 (anhydrous substance) | 96,17 | %m/m | |
| Erythromycine B | <=5,0 (anhydrous substance) | 0,06 | % | |
| Erythromycine C | <=5,0 (anhydrous substance) | 0,12 | % | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

Analysis performed by the authorized lab.

Release:

Dominika Soltysik

Qualified Person

26-04-2022

Expiration: 31-08-2024

Conclusion: APPROVED

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