

Certificate of Analysis

Product name: **Biotinum**

Batch number / Weight: **22C02-B01-224362 / 100 MG**

Analysed according to: **Ph. Eur. 10.8**

Number of analysis / Inspection Code **22C02-B01 / INS-22-3501**

Reference Code / No.: **V02008 / CS2-2201101**

| Tests | Requirement | Result | Unit | Standard remark |
|---------------------------|--|---------|------|-----------------|
| Appearance | White, crystalline powder or colourless crystals | Conform | | |
| Identification A | Conform | Conform | | |
| Appearance of solution | Clear / colourless | Conform | | |
| Specific optical rotation | +89 - +93 | +91 | | |
| Related substances | Conform | Conform | | |
| Impurity A | <=0,5 | <0,05 | % | |
| Impurity E | <=0,5 | <0,05 | % | |
| Impurity C | <=0,2 | <0,05 | % | |
| Unspecified impurities | <=0,10 | <0,05 | % | |
| Total impurities | <=2,0 | <0,05 | % | |
| Loss on drying | <=1,0 | 0,02 | % | |
| Sulphated ash | <=0,1 | 0,04 | % | |
| Assay D-Biotin | 98,5 - 101,0 | 99,9 | %m/m | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |
| Residual solvents | | | | |
| Ethanol | <=5000 | <5000 | ppm | |
| Toluene | <= 890 | <890 | | |
| Chloroform | <= 60 | <60 | | |

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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, ElSpol

Release:
Ewelina Gadzinowska
Qualified Person

21-10-2022

Expiration: 11-01-2024

Conclusion: APPROVED

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