

## Certificate of Analysis

**Product name:** **Nicotinamidum**

**Batch number / Weight:** **22G28-B02-221760 / 1 KG**

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

**Number of analysis / Inspection Code** **22G28-B02 / INS-22-6473**

**Reference Code / No.:** **V01204 / OP12108006**

| Tests                  | Requirement   | Result  | Unit | Standard remark |
|------------------------|---|---------|------|-----------------|
| Appearance             | (Almost) white, crystalline powder or colourless crystals | Conform |      |                 |
| Identification B       | Conform   | Conform |      |                 |
| Appearance of solution | Clear ≤BY7  | Conform |      |                 |
| pH                     | 6,0 - 7,5   | 6,63    |      |                 |
| Related substances     | Conform   | Conform | %    |                 |
| Any other impurity     | ≤0,10   | <0,05   | %    |                 |
| Total impurities       | ≤0,2  | 0,00    | %    |                 |
| Loss on drying         | ≤0,5  | 0,20    | %    |                 |
| Sulphated ash          | ≤ 0,1   | 0,03    | %    |                 |
| Metallic residues      | CHMP/ICH/353369/2013                                      | Conform |      | Data producer   |
| Residual solvents      | CPMP/ICH/82 260/06  | Conform |      | Data producer   |
| Assay Nicotinamide     | 99,0 - 101,0  | 100,60  | %m/m |                 |
| TSE/BSE-statement:     | No contamination with TSE/BSE-risk materials              | Conform |      | Data producer   |

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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

07-09-2022

Expiration: 04-08-2024

Conclusion: APPROVED

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