

## Certificate of Analysis

**Product name:** **Bismuthi subnitratis ponderosum**  
**Batch number / Weight:** **19B19-B04-202094 / 250 G**  
**Analysed according to:** **Ph. Eur.**

| Tests                           | Requirement                                  | Result  | Unit | Standard remark |
|---------------------------------|--|---------|------|-----------------|
| Appearance                      | White powder                                 | Conform |      |                 |
| Identification A                | Black / orange                               | Conform |      | Bismuth         |
| Identification B                | Yellow-orange color / orange precipitation   | Conform |      | Bismuth         |
| Identification C                | Violet                                       | Conform |      | Nitrate         |
| Identification D                | $\leq 2,0$                                   | Conform |      | pH              |
| Acidity                         | Conform                                      | Conform |      |                 |
| Chlorides                       | $\leq 200$                                   | Conform | ppm  |                 |
| Copper                          | $\leq 50$                                    | $< 20$  | ppm  | AAS             |
| Lead                            | $\leq 20$                                    | $< 10$  | ppm  | AAS             |
| Silver                          | $\leq 25$                                    | $< 3$   | ppm  | AAS             |
| Substances not precipit. by amm | $\leq 1,0$                                   | Conform | %    |                 |
| Loss on drying                  | $\leq 3,0$                                   | 0,2     | %    | 105 °C          |
| Metallic residues               | CHMP/ICH/353369/2013                         | Conform |      | Data producer   |
| Residual solvents               | CPMP/ICH/82 260/06                           | Conform |      | Data producer   |
| Assay Bismuth                   | 71,0 - 74,0                                  | 72,8    | %m/m | Dried           |
| TSE/BSE-statement:              | No contamination with TSE/BSE-risk materials | Conform |      | Data producer   |

Analysis performed by the authorized lab.

Release:  
 Dominika Sołtysik  
 Qualified Person

06-10-2020

Expiration: 06-09-2023

Conclusion: APPROVED

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