

## Certificate of Analysis

**Product name:** **Bismuthi subnitras ponderosum**  
**Batch number / Weight:** **19B19-B04-210618 / 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                    | <=2,0  | Conform |      | pH              |
| Acidity                             | Conform                                      | Conform |      |                 |
| Chlorides                           | <=200  | Conform | ppm  |                 |
| Copper                              | <=50   | <20     | ppm  | AAS             |
| Lead                                | <=20   | <10     | ppm  | AAS             |
| Silver                              | <=25   | <3      | ppm  | AAS             |
| Substances not precipit. by ammonia | <=1,0  | Conform | %    |                 |
| Loss on drying                      | <=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:  
 Ewelina Gadzinowska  
 Qualified Person

22-03-2021

Expiration: 06-09-2023

Conclusion: APPROVED

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