

Certificate of Analysis

| Product name: | Argenti vitellinas | | |
|------------------------|--------------------------|--|--|
| Batch number / Weight: | 22C15-B04-222990 / 10 G | | |
| Analysed according to: | Belgium Pharmacopoeia VI | | |
| | | | |

Number of analysis / Inspection Code 22C15-B04 / INS-22-5242

Reference Code / No.:

V00764 / V21-0606

| Tests | Requirement | Result | Unit | Standard remark |
|------------------------|--|------------|------|----------------------|
| Appearance | Brown-black powder or pieces | Conform | | |
| Identification A | Conform | Conform | | |
| Identification B | Conform | Conform | | Purple discoloration |
| Identification C | Conform | Conform | | Purple haze |
| Identification D | Conform | Conform | | Silver |
| Appearance of solution | Conform | Conform | | |
| Alcalinity | Conform | 3,10 ml Na | 0 | |
| Related substances | Conform | Conform | | |
| Chlorides | <=1,0 | <1,0 | % | |
| Free silver | Conform | Conform | | |
| Loss on drying | <=8,0 | 3,53 | % | |
| Metallic residues | CHMP/ICH/353369/2013 | Conform | | Data producer |
| Residual solvents | CPMP/ICH/82 260/06 | Conform | | Data producer |
| Assay Silver | 18,5 - 23,0 | 22,16 | % | |
| TSE/BSE-statement: | No contamination with TSE/BSE-risk materials | Conform | | Data producer |

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Fagron sp. z o.o. ul. Pasternik 26, 31-354 Kraków, Poland tel.: +48 12 3343 512 e-mail: biuro@fagron.pl 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

30-08-2022

Expiration: 31-07-2025

Conclusion: APPROVED

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