



Certificate of Analysis

Productname: Balsamum peruvianum

Inspection No: L01676/0624/536

Batchnumber: 23G26-T09-111683

Expiration date: 17.07.2026

Analysed according to: ČL 2017, Ph.Eur.11.0

Original Manuf. Date: 18.7.2023

Sample Unit: 1 x 5 g

Batch Size: 220 x 100 g

Identification of producer: V00201

Batch no. of vendor: 1355386

| | Requirement | Result | Unit | Standard remark | Insp. Site |
|----------------------|--|---------|-------|-----------------|---------------|
| CHARACTERS | | | | | |
| Appearance | Dark brown, viscous liquid which is transparent and yellowish-brown when viewed in a thin layer; it is not sticky, non-drying and does not form threads. | Conform | | | Fagron CZ |
| Solubility | Conform | Conform | | | Fagron CZ |
| IDENTIFICATION | | | | | |
| Identification A | Green/Yellowish green | Conform | | | Fagron CZ |
| Identification B | Conform | Conform | | fatty oils, TLC | Fagron CZ |
| TESTS | | | | | |
| Relative density | 1,14 - 1,17 | 1,15 | | | Fagron CZ |
| Saponification value | 230 - 255 | 232 | | | Fagron CZ |
| Artificial balsams | Conform | Conform | | | Fagron CZ |
| Fatty oils | Conform | Conform | | | Fagron CZ |
| Turpentine | Conform | Conform | | | Fagron CZ |
| Microbiology | Conform | Conform | | | Contract Lab |
| TAMC | <=2 x 10 ³ | <10 | CFU/g | | Contract Lab |
| TYMC | <=2 x 10 ² | <10 | CFU/g | | Contract Lab |
| TSE/BSE | No contamination with TSE/BSE-risk materials. | Conform | | | Data Producer |
| Residual solvents | CPMP/ICH/82 260/2006 | Conform | | | Data Producer |
| Metallic residues | ICH Q3D on elemental impurities | Conform | | | Data Producer |
| ASSAY | | | | | |
| Balsamic esters | 45,0 - 70,0 | 53,3 | % | | Fagron CZ |

Quality: Excipient

Performed by: QC Fagron a.s. (CZ)

Responsible: Mgr. Zdeňka Šinclová, QC
MVDr. Zdenka Borská, QA/ QP

Date: 28.03.2024

Conclusion: **APPROVED**

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