



Certificate of Analysis

Productname: Benzylis benzoas

Inspection No: K05106/0823/536

Batchnumber: 23F28-T01-104760

Expiration date: 31.03.2025

Analysed according to: ČL2017-Dopl.2020, Ph.Eur.11.0

Original Manuf. Date: 31.3.2023

Sample Unit: 1 x 2 ml

Batch Size: 61 x 1 l

Identification of producer: V01100

Batch no. of vendor: 10300407

| | Requirement | Result | Unit | Standard remark | Insp. Site |
|-----------------------|---|---------|-------|-----------------|---------------|
| CHARACTERS | | | | | |
| Appearance | (Almost) colourless crystals or (almost) colourless, oily liquid. | Conform | | | Fagron CZ |
| Solubility | Conform | Conform | | | Fagron CZ |
| Boiling point | About 320 °C | 320 | | | Fagron CZ |
| IDENTIFICATION | | | | | |
| Identification A | Conform | Conform | | IR-spectrum | Fagron CZ |
| TESTS | | | | | |
| Acidity | <=0,2 | 0,07 | ml | 0.1 M NaOH | Fagron CZ |
| Relative density | 1,118 - 1,122 | 1,121 | | | Fagron CZ |
| Refractive index | 1,568 - 1,570 | 1,568 | | | Fagron CZ |
| Freezing point | >=17,0 | 17,0 | °C | | Fagron CZ |
| Sulphated ash | <=0,1 | 0,0 | % | | 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 | | | | | |
| Phenylmethyl benzoate | 99,0 - 100,5 | 99,2 | % | | Fagron CZ |

Quality: API

Performed by: Ludmila Stochlebová

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

Date: 30.08.2023

Conclusion: **APPROVED**

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