

Certificate of Analysis

Productname: Benzylis benzoas

Inspection No: I07368/0921/536
Batchnumber: 21G08-T02-090280
Expiration date: 30.11.2022
Analysed according to: ČL 2017-Dopl.2020,Ph.Eur.10.0
Original Manuf. Date: 30.11.2020

Sample Unit: 1 x 2 ml
Batch Size: 167 x 250 ml

Identification of producer: V01100
Batch no. of vendor: 10300319

| | 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 | Conform | | | Fagron CZ |
| IDENTIFICATION | | | | | |
| Identification A | Conform | Conform | | IR-spectrum | Fagron CZ |
| TESTS | | | | | |
| Acidity | <=0,2 | 0,1 | ml | 0.1 M NaOH | Fagron CZ |
| Relative density | 1,118 - 1,122 | 1,121 | | | Fagron CZ |
| Refractive index | 1,568 - 1,570 | 1,569 | | | Fagron CZ |
| Freezing point | >=17,0 | 19 | °C | | Fagron CZ |
| Sulphated ash | <=0,1 | 0 | % | | Fagron CZ |
| Microbiology | Conform | Conform | | | Contract Lab |
| TAMC | <=2 x 103 | Conform | CFU/g | | Contract Lab |
| TYMC | <=2 x 102 | Conform | 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 | 99,9 | % | | Fagron CZ |

Performed by: Lucie Kubáňová DiS.

Responsible: Ing. Pavel Mišák, QC
 PharmDr. Ivana Urbánková, QA

Date: 27.09.2021

Conclusion: APPROVED

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