



Certificate of Analysis

Productname: Benzylis benzoas

Inspection No: J02102/0322/536

Batchnumber: 21L21-T06-093710

Expiration date: 31.07.2023

Analysed according to: ČL 2017-Dopl.2020,Ph.Eur.10.0

Original Manuf. Date: 31.7.2021

Sample Unit: 1 x 2 ml

Batch Size: 834 x 100 ml

Identification of producer: V01100

Batch no. of vendor: 10300340

	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	1,120			Fagron CZ
Refractive index	1,568 - 1,570	1,570			Fagron CZ
Freezing point	>=17,0	19,3	°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	100,0	%		Fagron CZ

Quality: API

Performed by:

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

Date: 15.03.2022

Conclusion: **APPROVED**

This document has been produced electronically from our quality system and is valid without signature.

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