

Certificate of Analysis

Productname: **Benzylis benzoas**

Inspection No: I07366/0921/536
 Batchnumber: **21G08-T02-090282**
 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: 62 x 1 l

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 10 ³	Conform	CFU/g		Contract Lab
TYMC	<=2 x 10 ²	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**

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

Name	Fagron a.s. (CZ)	Address	Holická 1098/31m, Olomouc	Phone No.	+420585222590
	Kontrolní laboratoř č. 536	Post Code	779 00	Fax No.	+420 585 226 521