

## Certificate of Analysis

**Productname:** Benzyllis benzoas

**Inspection No:** I02500/0421/536  
**Batchnumber:** 21C08-T04-085446  
**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:** 217 x 250 ml

**Identification of producer:** V01100  
**Batch no. of vendor:** 10300312

	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	0,07	ml	0.1 M NaOH	Fagron CZ
Relative density	1,118 - 1,122	1,121			Fagron CZ
Refractive index	1,568 - 1,570	1,569			Fagron CZ
Freezing point	>=17,0	19,0	°C		Fagron CZ
Sulphated ash	<=0,1	0,0	%		Fagron CZ
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 <sup>3</sup>	Conform	CFU/g		Contract Lab
TYMC	<=2 x 10 <sup>2</sup>	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	100,2	%		Fagron CZ

**Performed by:** Bc. Andrea Šmídová

**Responsible:** Ing. Mgr. Kateřina Jokešová, QC  
 PharmDr. Ivana Urbánková, QA

**Date:** 29.03.2021

**Conclusion:** APPROVED

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

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