



## Certificate of Analysis

**Productname:** Methylis salicylas

**Inspection No:** I02464/0321/536  
**Batchnumber:** 20C03-F04-085596  
**Expiration date:** 18.11.2024  
**Analysed according to:** ČL 2017-Dopl.2020,Ph.Eur.10.0  
**Original Manuf. Date:** 19.11.2019

**Sample Unit:** 1 x 2 ml  
**Batch Size:** 121 x 250 ml

**Identification of producer:** V01558  
**Batch no. of vendor:** RMS1932311

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Colourless or light yellow liquid.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
Identification A	Conform	Conform		IR-spectrum	Fagron CZ
TESTS					
Appearance of solution	Clear, <=Y7	Conform		2 ml/10 ml alcohol	Fagron
Acidity	<=0,4	0,1	ml	0,1M NaOH	Fagron
Relative density	1,182 - 1,188	1,185			Fagron
Refractive index	1,535 - 1,538	1,536			Fagron
Related substances	Conform	Conform		GC	Fagron
Impurity B	<=50	<50	ppm		Fagron
Unspecified impurities	<= 0,10	<0,1	%		Fagron
Total impurities	<=0,5	<0,5	%		Fagron
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					
Methyl salicylate	99,0 - 101,0	100,1	%		Fagron

**Name** Fagron a.s. (CZ)  
 Kontrolní laboratoř č. 536

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**Post Code**

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**Performed by:** Lucie Kubáňová DiS.  
**Responsible:** Ing. Mgr. Kateřina Jokešová, QC  
PharmDr. Ivana Urbánková, QA  
**Date:** 09.04.2021  
**Conclusion:** **APPROVED**

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

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