

## Certificate of Analysis

**Productname:** **Methylis salicylas**
**Inspection No:** I04930/0621/536

**Batchnumber:** **21E11-T02-087144**
**Expiration date:** 12.02.2025

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

**Original Manuf. Date:** 13.2.2020

**Sample Unit:** 1 x 2 ml

**Batch Size:** 15 x 1 l

**Identification of producer:** V01558

**Batch no. of vendor:** RMS2004411

	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 CZ
Acidity	<=0,4	0,1	ml	0,1M NaOH	Fagron CZ
Relative density	1,182 - 1,188	1,182			Fagron CZ
Refractive index	1,535 - 1,538	1,536			Fagron CZ
Related substances	Conform	Conform		GC	Contract Lab
Impurity B	<=50	<50	ppm		Contract Lab
Unspecified impurities	<= 0,10	<0,10	%		Contract Lab
Total impurities	<=0,5	<0,5	%		Contract Lab
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	99,9	%		Fagron CZ

**Name** Fagron a.s. (CZ)  
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**Performed by:** Lucie Kubáňová DiS.  
**Responsible:** Ing. Pavel Mišák, QC  
PharmDr. Ivana Urbánková, QA  
**Date:** 08.07.2021  
**Conclusion:** **APPROVED**

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