

Certificate of Analysis

Productname: **Methylis salicylas**

Inspection No: I05084/0721/536

Batchnumber: **21E11-T02-087627**

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: 66 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 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					
Methyl salicylate	99,0 - 101,0	99,9	%		Fagron 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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