



Certificate of Analysis

Productname: Methylis salicylas

Inspection No: K06299/0823/536

Batchnumber: 23G24-T06-106022

Expiration date: 12.10.2026

Analysed according to: ČL2017-Dopl.2020, Ph.Eur.11.0

Original Manuf. Date: 12.10.2021

Sample Unit: 1 x 2 ml

Batch Size: 155 x 100 ml

Identification of producer: V01558

Batch no. of vendor: RMS2128511

	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	0,0	ml	0,1M NaOH	Fagron CZ
Relative density	1,182 - 1,188	1,186			Fagron CZ
Refractive index	1,535 - 1,538	1,536			Fagron CZ
Related substances	Conform	Conform		GC	Fagron PL
Impurity B	<=50	32,2	ppm		Fagron PL
Unspecified impurities	<= 0,10	<0,05	%		Fagron PL
Total impurities	<=0,5	0,003	%		Fagron PL
Microbiology	Conform	Conform			Contract Lab
TAMC	<=2 x 10 ³	<10	CFU/g		Contract Lab
TYMC	<=2 x 10 ²	<10	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	100,03	%		Fagron PL

Quality: API

Performed by: Ludmila Stochlebová

Responsible: Mgr. Zdeňka Šinclová, QC
MVDr. Zdenka Borská, QP

Date: 13.09.2023

Conclusion: **APPROVED**

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