

Certificate of Analysis

Productname: Citronellae etheroleum

Inspection No: I08131/1021/536
Batchnumber: 21117-T06-087147
Expiration date: 07.09.2024
Analysed according to: ČL 2017, Ph.Eur.10.0
Original Manuf. Date: 8.9.2021

Sample Unit: 1 x 1 ml
Batch Size: 235 x 100 ml

Identification of producer: V00201
Batch no. of vendor: 1275878

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Light yellow or brownish yellow liquid.	Conform			Fagron CZ
IDENTIFICATION					
Identification B	Conform	Conform		Chromatographic profile, GC	Contract Lab
TESTS					
Relative density	0,881 - 0,895	0,886			Fagron CZ
Refractive index	1,463 - 1,475	1,470			Fagron CZ
Optical rotation	-4 - +1,5	-3	°		Fagron CZ
Chromatographic profile	Conform	Conform		GC	Contract Lab
limonene	1,0 - 5,0	4,1	%		Contract Lab
citronellal	30,0 - 45,0	36,9	%		Contract Lab
citronellyl-acetate	2,0 - 4,0	2,5	%		Contract Lab
neral	≤2,0	0,3	%		Contract Lab
geranial	≤2,0	0,4	%	Geranial	Contract Lab
geranyl-acetate	3,0 - 8,0	3,2	%		Contract Lab
citronellol	9,0 - 15,0	12,2	%		Contract Lab
geraniol	20,0 - 25,0	21,4	%		Contract Lab
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

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Performed by: Lucie Kubáňová DiS.
Responsible: Ing. Pavel Mišák, QC
PharmDr. Ivana Urbánková, QA
Date: 15.10.2021
Conclusion: APPROVED

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