

Certificate of Analysis

Productname: Balsamum peruvianum

Inspection No: I09321/1221/536
Batchnumber: 21J26-T17-091229
Expiration date: 10.10.2024
Analysed according to: ČL 2017, Ph.Eur.10.0
Original Manuf. Date: 11.10.2021

Sample Unit: 1 x 5 g
Batch Size: 403 x 100 g

Identification of producer: V00201
Batch no. of vendor: 1281425

	Requirement	Result	Unit	Standard remark	Insp. Site
CHARACTERS					
Appearance	Dark brown, viscous liquid which is transparent and yellowish-brown when viewed in a thin layer; it is not sticky, non-drying and does not form threads.	Conform			Fagron CZ
Solubility	Conform	Conform			Fagron CZ
IDENTIFICATION					
Identification A	Green/Yellowish green	Conform			Fagron CZ
Identification B	Conform	Conform		fatty oils, TLC	Fagron CZ
TESTS					
Relative density	1,14 - 1,17	1,15			Fagron CZ
Saponification value	230 - 255	230			Fagron CZ
Artificial balsams	Conform	Conform			Fagron CZ
Fatty oils	Conform	Conform			Fagron CZ
Turpentine	Conform	Conform			Fagron CZ
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					
Balsamic esters	45,0 - 70,0	55,6	%		Fagron CZ

Name	Fagron a.s. (CZ) Kontrolní laboratoř č. 536	Address	Holická 1098/31m, Olomouc 779 00	Phone No.	+420585222590
		Post Code		Fax No.	+420 585 226 521

Performed by: Lucie Kubáňová DiS.
Responsible: Ing. Pavel Mišák, QC
MVDr. Zdenka Borská, QA
Date: 02.12.2021
Conclusion: **APPROVED**

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Name	Fagron a.s. (CZ) Kontrolní laboratoř č. 536	Address	Holická 1098/31m, Olomouc	Phone No.	+420585222590
		Post Code	779 00	Fax No.	+420 585 226 521