

Certificate of Analysis

Productname: **Balsamum peruvianum**

Inspection No: I04253/0621/536
Batchnumber: **21C23-T10-087104**
Expiration date: 10.02.2024
Analysed according to: ČL 2017, Ph.Eur.10.0
Original Manuf. Date: 11.2.2021

Sample Unit: 1 x 5 g
Batch Size: 142 x 100 g

Identification of producer: V00201
Batch no. of vendor: 1243028

	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	231			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	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					
Balsamic esters	45,0 - 70,0	50,7	%		Fagron CZ

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Performed by: Bc. Andrea Šmídová

Responsible: Ing. Mgr. Kateřina Jokešová, QC
PharmDr. Ivana Urbánková, QA

Date: 10.06.2021

Conclusion: **APPROVED**

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