



## Certificate of Analysis

**Productname:** Balsamum peruvianum

**Inspection No:** L00636/0124/536

**Batchnumber:** 23G26-T09-111246

**Expiration date:** 17.07.2026

**Analysed according to:** ČL 2017, Ph.Eur.11.0

**Original Manuf. Date:** 18.7.2023

**Sample Unit:** 1 x 5 g

**Batch Size:** 46 x 100 g

**Identification of producer:** V00201

**Batch no. of vendor:** 1355386

	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	232			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 <sup>3</sup>	<10	CFU/g		Contract Lab
TYMC	<=2 x 10 <sup>2</sup>	<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	53,3	%		Fagron CZ

Quality: Excipient

**Performed by:** Ludmila Stochlebová

**Responsible:** Mgr. Zdeňka Šinclová, QC  
Ing. Martina Zemanová, QA

**Date:** 06.02.2024

**Conclusion:** **APPROVED**

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