

## Certificate of Analysis

**Productname:** Balsamum peruvianum

**Inspection No:** H08002/0820/536  
**Batchnumber:** 20H11-T05-073274  
**Expiration date:** 02.08.2023  
**Analysed according to:** ČL 2017, Ph.Eur.10.0  
**Original Manuf. Date:** 3.8.2020

**Sample Unit:** 1 x 5 g  
**Batch Size:** 150 x 100 g

**Identification of producer:** V00201  
**Batch no. of vendor:** 1217155

	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>	Conform	CFU/g		Contract Lab
TYMC	<=2 x 10 <sup>2</sup>	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	56,1	%		Fagron CZ

**Performed by:** Lucie Kubáňová DiS.

**Responsible:** Lenka Morávková, QC  
 PharmDr. Ivana Urbánková, QA

**Date:** 02.10.2020

**Conclusion:** APPROVED

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