

Certificate of Analysis

Productname: Pentravan® (2021)

Inspection No: M09478/1225/536
Batchnumber: 25I02-T14-124182
Expiration date: 31.10.2028
Analysed according to: FSCE-SPEC-0316

Customer: FAGRON a.s.
Sample Unit: 1 x 500 g
Batch Size: 1,304 x 500 g

	Requirement	Result	Unit	Standard remark
CHARACTERS				
Appearance	Stiff, yellow cream.	Conform		
Odour	Slight odour of lecithin.	Conform		
IDENTIFICATION				
Identification A	Conform	Conform		Benzoic acid, HPLC
Identification B	Conform	Conform		Sorbic acid, HPLC
Identification C	Conform	Conform		Lecithin
TESTS				
pH	4,0 - 5,5	4,7		
Yield value	40 - 150	48	Pa	
Viscosity	40000 - 150000	60000	mPa.s	25+ - 2 °C
Microbiology	Conform	Conform		
TAMC	<= 1 x 10 ²	<10	CFU/g	
TYMC	<= 1 x 10 ¹	<10	CFU/g	
Pseudomonas aeruginosa	Absent/1g	Conform		
Staphylococcus aureus	Absent/1g	Conform		
Candida albicans	Absent/1g	Conform		
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform		
Residual solvents	ICH Q3C	Conform		
Elemental impurities	ICH Q3D	Conform		
Nitrosamines	Risk evaluation	Conform		
ASSAY				
Benzoic acid	0,19 - 0,27	0,21	%	HPLC
Sorbic acid	0,17 - 0,33	0,26	%	HPLC

Performed by: QC Fagron a.s. (CZ)

Responsible: Mgr. Kateřina Špičková, QC
Ing. Martina Zemanová,

Date: 19.11.2025

Conclusion: APPROVED