



Certificate of Analysis

Productname: Occluvan™

Inspection No: M02504/0325/536

Batchnumber: 24K28-T05-118243

Expiration date: 31.03.2027

Analysed according to: FSCE-SPEC-0462

Customer: FAGRON a.s.

Sample Unit: 1 x 500 g

Batch Size: 563 x 500 g

	Requirement	Result	Unit	Standard remark
CHARACTERS				
Appearance	Elegant, white to off-white, thick ointment.	Conform		
Odour	Specific, not perfumed.	Conform		
IDENTIFICATION				
Identification A	Conform	Conform		Alpha-tocopheryl acetate, HPLC
TESTS				
Viscosity	25000 - 200000	112200	mPa.s	25+ - 2 °C
Microbiology	Conform	Conform		
TAMC	$\leq 1 \times 10^2$	<10	CFU/g	
TYMC	$\leq 1 \times 10^1$	<10	CFU/g	
Pseudomonas aeruginosa	negative/1g	Conform		
Staphylococcus aureus	negative/1g	Conform		
TSE/BSE	No contamination with TSE/BSE-risk materials.	Conform		
Residual solvents	ICH Q3C	Conform		
Elemental impurities	ICH Q3D	Conform		
ASSAY				
Alpha-tocopheryl acetate	≥ 15	29,2	mg/g	

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

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

Date: 31.03.2025

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.