

Certificate of Analysis

Product name: Alc. cetyl. et stear. emuls. A

Batch number / Weight: 23J23-B03-233678 / 1 KG

Analysed according to: Ph.Eur.11.2

Number of analysis / Inspection Code 23J23-B03 / INS-23-8872

Reference Code / No.: V01252 / 0027260481

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, waxy granules or flakes	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Identification D	Blue	Conform		
Acid value	$\leq 2,0$	0,03		
Iodine value	$\leq 3,0$	0,27		
Saponification value	$\leq 2,0$	0,42		
Water (Karl Fischer)	$\leq 3,0$	0,33	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
Assay Cetostearyl alcohol	$\geq 80,0$	88,08	%m/m	
Assay Sodium cetostearyl sulph	$\geq 7,0$	8,26	% m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		

All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab FAGRON PL lab

Release:
Ewelina Gadzinowska
Qualified Person

14-12-2023

Expiration: 21-05-2025

Conclusion: APPROVED

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

fagron.pl Fagron Services Northern Europe Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail: fsne@fagron.pl