

## Certificate of Analysis

**Product name:** Alc. cetyl. et stear. emuls. B

**Batch number / Weight:** 23H29-B03-228364 / 1 KG

**Analysed according to:** Ph.Eur.11.2

**Number of analysis / Inspection Code** 23H29-B03 / INS-23-6983

**Reference Code / No.:** V01252 / 0027017208

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, waxy granules or flakes	Conform		
Appearance	waxy mass, plates, flakes or granules			
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Identification D	Conform	Conform		
Acid value	$\leq 2,0$	0,06		
Iodine value	$\leq 3,0$	0,30		
Saponification value	$\leq 2,0$	0,21		
Water (Karl Fischer)	$\leq 3,0$	0,50	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Cetostearyl alcohol	$\geq 80,0$	87,96	%m/m	
Assay Sodium lauril sulphate	$\geq 7,0$	8,16	% m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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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:

Agnieszka Pszczółka

Qualified Person

19-10-2023

Expiration: 28-02-2025

Conclusion: APPROVED

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

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