

Certificate of Analysis

Product name: **Cetrimidum**

Batch number / Weight: **22D22-B01-220572 / 100 G**

Analysed according to: **Ph. Eur. 10.8**

Number of analysis / Inspection Code **22D22-B01 / INS-22-4049**

Reference Code / No.: **V01474 / B/018/22**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, voluminous	Conform		
Appearance	free-flowing powder			
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Identification D	Conform	Conform		
Identification E	White yellow	Conform		
Appearance of solution	Clear / colourless	Conform		
Acidity or alkalinity	Conform	0,1 ml NaOH		
Amines and amine salts	Conform	1,9	ml	
Loss on drying	<=2,0	0,141	%	
Sulphated ash	<=0,5	0,04	%	
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	96,0 - 101,0	97,45	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Acetone	<=5000	<5000	ppm	

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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, ElSpol

Release:
Ewelina Gadzinowska
Qualified Person

18-10-2022

Expiration: 31-01-2026

Conclusion: APPROVED

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