

Certificate of Analysis

Product name: Carbomerum 974P
Batch number / Weight: 22D07-B05-218223 / 50 G
Analysed according to: Monograph
Number of analysis / Inspection Code 22D07-B05 / INS-22-3556
Reference Code / No.: V01689 / 0000108350

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, fluffy powder, hygroscopic	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Identification D	Conform	Conform		
Viscosity	29400 - 39400	32870	mPa.s	
Free acrylic acid	$\leq 0,25$	$<0,05$	%	
Benzene	≤ 2	<2	ppm	
Loss on drying	$\leq 3,0$	0,74	%	
Sulphated ash	$\leq 4,0$	1,78	%	
Ethylacetate	$\leq 0,5$	0,12	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Carboxylic acid groups	56,0 - 68,0	57,9	%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 EL Spol

Release:

Agnieszka Pszczółka

Qualified Person

24-10-2022

Expiration: 10-08-2023

Conclusion: APPROVED

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