

Certificate of Analysis

Product name:	Carbomerum 974P
Batch number / Weight:	22H18-B01-222170 / 50 G
Analysed according to:	Monograph

Number of analysis / Inspection Code 22H18-B01 / INS-22-8563

Reference Code / No.:

V01689 / 0000126560

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	33037	mPa.s	
Free acrylic acid	<= 0,25	<0,05	%	
Benzene	<= 2	<2	ppm	
Loss on drying	<= 3,0	0,95	%	
Sulphated ash	<= 4,0	1,84	%	
Ethylacetate	<= 0,5	0,3	%	
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	58,1	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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Fagron sp. z o.o. ul. Pasternik 26, 31-354 Kraków, Poland tel.: +48 12 3343 512 e-mail: biuro@fagron.pl 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

14-11-2022

Expiration: 23-01-2024

Conclusion: APPROVED

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