

Certificate of Analysis

Product name: Carbomerum 980
Batch number / Weight: 24A10-B05-237386 / 50 G
Analysed according to: Ph.Eur.11.3
Number of analysis / Inspection Code 24A10-B05 / INS-24-1003
Reference Code / No.: V01419 / 0102660266

Tests	Requirement	Result	Unit	Standard remark
Appearance	White ore almost white, fluffy powder, hygroscopic	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Identification D	Conform	Conform		
Viscosity	40.000 - 60.000	49680	mPa.s	
Free amines	<=0,25	<0,25	%	
Benzene	<= 2	<2	ppm	
Loss on drying	<=3,0	0,37	%	
Ethylacetate	<=0,3	0,15	% (d.p.)	
Cyclohexane	<=2,0	0,04	% (d.p.)	
Sulphated ash	<=4,0	0,01	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	56,0 - 68,0	60,53	%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

26-03-2024

Expiration: 30-07-2025

Conclusion: APPROVED

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