

Certificate of Analysis

Product name: **Hydroxypropylcellulosum GF**

Batch number / Weight: **23H03-B03-233480 / 10 G**

Analysed according to: **Ph.Eur.11.3**

Number of analysis / Inspection Code **23H03-B03 / INS-23-6520**

Reference Code / No.: **V01388 / 229701**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White or yellowish-white or granules,	Conform		
Appearance	light hygroscopic			
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
pH	5,0 - 8,0	5,77		
Viscosity	225 - 400	293	mPa.s	
	75 - 140	103	%	
Silica	<=0,6	<0,6	%	
Loss on drying	<=5,0	1,8	%	
Sulphated ash	<=0,8	0,06	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Hydroxypropoxy groups	53,4 - 80,5	75,6	%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,Quercus

Release:

Agnieszka Pszczółka

Qualified Person

12-01-2024

Expiration: 24-07-2025

Conclusion: APPROVED

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