

## **Certificate of Analysis**

Hydroxyethylcell. 295 mPa.s Product name:

23H31-B07-226306 / 100 G Batch number / Weight:

Ph.Eur.11.2 Analysed according to:

Number of analysis / Inspection Code 23H31-B07 / INS-23-8238

V01141 / W 2098 Reference Code / No.:

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, yellowish-white or greyish-white powder or granules	Conform		
Identification A	Conform	Conform		
Identification B	Clear	Conform		
рН	5,5 - 8,5	7,34		
Viscosity	221 - 413	318,6	mPa.s	
Chlorides	<=1,0	<1,0	%	
Nitrates	<=3,0	0,8	%	
Aldehydes	<=20	<20	ppm	
Ethylenoxide	<=1	0	ppm	
2-Chloroethanol	<=10	0	ppm	
Loss on drying	<=10,0	4,1	%	
Sulphated ash	<=4,0	1,62	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		
Residual solvents	CPMP/ICH/82 260/06	Conform		
Assay Hydroxyethylcellulose	30,0 - 70,0	38,4	%	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		

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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 FAPL, Eurofins

Release: Ewelina Gadzinowska Qualified Person

08-12-2023

Expiration: 07-08-2025

Conclusion: APPROVED

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