

Certificate of Analysis

Product name: Hypromellosem 4000mPa.s
Batch number / Weight: 20F09-B01-201598 / 25 G
Analysed according to: Ph. Eur.

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, yellowish-white or greyish-white powder or granules	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Identification D	Conform	Conform		
Identification E	Conform	Conform		
Appearance of solution	<=ref. susp. III / <=Y6	Conform		1%/m , dried
pH	5,0 - 8,0	7,6		2%/m , dried
Viscosity	3000 - 5600	3983	mPa.s	2%/m, 20°C, dried
Loss on drying	<=5,0	1,2	%	1 h 105 °C
Sulphated ash	<=1,5	0,44	%	
Assay of methoxy groups	28,0 - 30,0	28,0	%	Methoxy groups, dried
Assay of hydroxypropoxy groups	7,0 - 12,0	9,3	%	Hydroxypropoxy groups, dried
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:
Dorota Sutkowska
Qualified Person

29-06-2020

Expiration: 15-12-2024

Conclusion: APPROVED

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