

## Certificate of Analysis

**Productname:** **Macrogolum 4000 poeder**  
**Number of analysis/Inspection Code:** 1 / KEUR-180748B  
**Batchnumber:** **19J28-F03-366736**  
**Reference code / No.:** 2673 / 19/45  
**Analysed according to:** **PH.EUR 9.8**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, waxy or paraffin-like powder	Conform		
Identification A	110 - 170	Conform	mPa·s	Dynamic viscosity
Identification B	White	Conform		
Identification C	Blue	Conform		
Appearance of solution	Clear / <=BY6	Conform		25% <i>m/V</i>
Acidity or alkalinity	Conform	Conform		
Dynamic viscosity	110 - 170	112	mPa·s	50% <i>m/V</i> ; 20 °C
Kinematic viscosity	102 - 158	104	mm <sup>2</sup> /s	50% <i>m/V</i> ; 20 °C
Freezing point	53 - 59	54	°C	
Hydroxyl value	25 - 32	28		
Reducing substances	Conform	Conform		
Formaldehyde	<=30	1	ppm	
Ethylenoxide / Dioxane	<=1 / <=10	Conform	ppm	
Water	<= 1,0	0,4	%	Karl Fischer
Sulphated ash	<= 0,2	0,1	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized laboratory Quercus BE.

Release:  
 dr. M.J. Vincenten - van Maanen  
 Pharmacist - Qualified Person

02/26/20

Expiration: 09-2022

Conclusion: APPROVED

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