

Certificate of Analysis

Product name: **Magnesii chloridum hexahyd.**

Batch number / Weight: **23K16-B04-236009 / 250 G**

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

Number of analysis / Inspection Code **23K16-B04 / INS-23-9041**

Reference Code / No.: **V00225 / M4381**

Tests	Requirement	Result	Unit	Standard remark
Appearance	Colourless crystals or white,	Conform		
Identification A	Conform	53,16	%	
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Appearance of solution	Clear / colourless	Conform		
Acidity or alkalinity	Conform	Conform		
	<= 0,3 ml HCl (0,01M) or NaOH (0,01M)	(NaOH) 0,05 ml		
Bromides	<= 500	<500	ppm	
Sulphates	<=100	<100	ppm	
Aluminium	<= 1	<0,5	ppm	
Calcium	<= 0,1	<0,1	%	
Iron	<=10	<10	ppm	
Potassium	<=500	<50	ppm	
Water (Karl Fischer)	51,0 - 55,0	53,16	%	
Assay	98,0 - 101,0	100,60	%m/m	
Endotoxins	<= 3	<3	IU / g	
Total aerobic microbial count (TA)	<=10	<1	CFU / g	
Total yeasts and moulds (TYMC)	<=1	<1	CFU / g	
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

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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:
Ewelina Gadzinowska
Qualified Person

22-03-2024

Expiration: 07-10-2026

Conclusion: APPROVED

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