

Certificate of Analysis

Product name: **Magnesii sulfas heptahydr. cr.**

Batch number / Weight: **23I06-B08-236723 / 1 KG**

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

Number of analysis / Inspection Code **23I06-B08 / INS-23-8178**

Reference Code / No.: **V00225 / MSH 0198**

Tests	Requirement	Result	Unit	Standard remark
Appearance	white or almost white, crystalline powder or brilliant, colourless crystals	Conform		
Identification A	White	Conform		
Identification B	White	Conform		
Appearance of solution	Clear / colourless	Conform		
Acidity or alkalinity	Conform	Conform		
Chlorides	<=300	<300	ppm	
Iron	<=20	<20	ppm	
Loss on drying	48,0 - 52,0	50,57	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay	99,0 - 100,5	99,97	%m/m	
Bacterial endotoxins	<=3	<3	IU/g	
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, EI Spol, CBMiA

Release:

Agnieszka Pszczółka

Qualified Person

20-02-2024

Expiration: 05-05-2026

Conclusion: APPROVED

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