

Certificate of Analysis

Productname: **Magnesii sulfas heptahydr. cr.**
Number of analysis/Inspection Code: 1 / KEUR-185281B
Batchnumber: **20G15-F03-372765**
Reference code / No.: 2183 / MSH 0089
Analysed according to: **PHEUR10.2+**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder or glittering colorless crystals	Conform		
Identification A	White	Conform		Sulphate
Identification B	White	Conform		Magnesium
Appearance of solution	Clear / colourless	Conform		10% <i>m/V</i>
Acidity or alkalinity	Conform	Conform		
Chlorides	<=300	Conform	ppm	
Arsenic	<=2	Conform	ppm	
Iron	<=20	Conform	ppm	
Loss on drying	48,0 - 52,0	49,5	%	110-120°C 1h; 400°C
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CHMP/ICH/82260/2006	Conform		Data producer
Assay Magnesium sulphate	99,0 - 100,5	99,7	% <i>m/m</i>	Dried
Bacterial endotoxins	<=3	Conform	IU/g	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer
CEP	CEP available	Conform		Data producer

Analysis performed by the authorized laboratory Pharma Cosmetic + microbiel.

Release:
Paul Hofman
Pharmacist - Qualified Person

08/25/20

Expiration: 05-2023

Conclusion: APPROVED

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