

Pace

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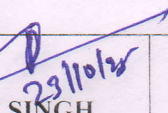
Surajpur, Paonta sahib Dist. Sirmour (H.P)

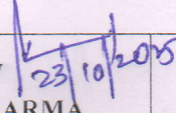
Title : Certificate of Analysis Finished Product

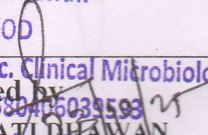
Product Name	MAGSOCAN Injection	A.R. No.	NL/FP/25/208
Generic Name	Magnesium Sulphate Injection IP	Sampled qty.	45 Ampoules
Batch No.	A25202C	Sampled by	Rakesh
Batch Size	50,000 Ampoules	Sampled on	03/10/2025
Mfg. Date	09/2025	Date of Testing	03/10/2025
Exp. Date	08/2027	Date of Release	23/10/2025

S. No.	Tests	Specifications	Observations		
1.	Description	A clear colourless solution filled in clear colour glass ampoule.	A clear colourless solution filled in clear colour glass ampoule.		
2.	Identification	A. It gives the reactions of sulphates. B. It gives the reactions of magnesium.	Complies Complies		
3.	Nominal fill volume	NLT 2ml	2.0 ml		
4.	Extractable Volume	NLT Nominal volume or NMT 110% of Nominal volume.	2.1 ml		
5.	pH (IHS)	5.5 to 7.0	6.10		
6.	Particulate Matter (A.) Light Obscuration Particle Count Test (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (B.) Visual Particle	NMT 6000/Ampoule NMT 600/ Ampoule The solution is free from particles of foreign matter particles that can be observed on visual inspection.	27/Ampoule 0/Ampoule Complies		
7.	Sterility	No microbial growth should be observed.	Complies		
8.	Bacterial Endotoxins	NMT 0.09 EU/mg of magnesium sulphate.	Less than 0.09EU/mcg of magnesium sulphate.		
9.	Assay: (By Titration) Each ml contains:				
Ingredients		Labelled Claim	Found	% of labelled amount	Limits % of labelled amount
Magnesium Sulphate Heptahydrate IP		500 mg	509.22 mg	101.84%	95.0 to 105.0%

Remarks: In the opinion of the undersigned the sample referred to above is/is ~~not~~ of the standard quality as The Drug & Cosmetic Act 1940 and the rules made there under. Complies/~~not~~ complies as per IP/BP/USP/IHS.

Analysis by 
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Checked by 
NAME: NIKHIL SHARMA

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Designation : QC HOD
Qualification : M.Sc. Clinical Microbiology
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Approved by 
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