

Pace

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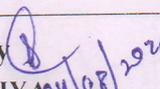
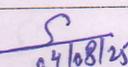
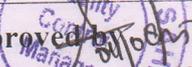
Surajpur, Paonta sahib Dist. Sirmour (H.P)

Title : Certificate of Analysis Finished Product

Product Name	Magsocan 50% Injection	A.R. No.	NL/FP/25/127
Generic Name	Magnesium Sulphate Injection IP 2ml	Sampled qty.	45 Ampoules
Batch No.	A25097A	Sampled by	Vineet
Batch Size	98,000 Ampoules	Sampled on	19/07/2025
Mfg. Date	06/2025	Date of Testing	19/07/2025
Exp. Date	05/2027	Date of Release	04/08/2025

S. No.	Tests	Specifications	Observations		
1.	Description	A clear colourless solution filled in amber colour glass ampoule.	A clear colourless solution filled in amber 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	6.30		
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.	132/Ampoule 4/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/mg of magnesium sulphate.		
9.	Assay: Each ml contains:				
Ingredients		Labelled Claim	Found	% of labelled amount	Limits % of labelled amount
Magnesium Sulphate Heptahydrate IP		500 mg	515.4556 mg	103.09%	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  NAME: SANDHYA 04/08/2025	Checked by  NAME: SUFIYAN ANSARI	Approved by  NAME: SWATI DHAWAN
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