

Title

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Certificate of Analysis Finished Product

Product Name	GLUTACAN 1200 Injection	A.R. No.	NB/FP/25/203
Generic Name	Glutathione for Injection 1200mg	Sampled qty.	45 Vials
Batch No.	N25228A	Sampled by	Rakesh
Batch Size	3000 Vials	Sampled on	11/09/2025
Mfg. Date	09/2025	Date of Testing	11/09/2025
Exp. Date	08/2027	Date of Release	27/09/2025

S. No.	Tests	Specifications	Observations		
1.	Description	A white lyophilized powder filled in clear glass vial.	A white lyophilized powder filled in clear glass vial.		
2.	Identification (By IR)	Compare the spectrum with that obtained with Glutathione RS treated in the same manner or with the reference spectrum of Glutathione.	Complies		
3.	Uniformity of weight	Average weight $\pm 10\%$	-7.41% & +1.90%		
4.	Average weight	Informative $\pm 2\%$.	1313.3 mg		
5.	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/vial NMT 600/ vial The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be seen with naked eye.	1506.67/vial 246.00/vial Complies		
6.	Sterility	No microbial growth should be observed.	Complies		
7.	Bacterial Endotoxins	NMT 0.10 EU/mg of Glutathione.	Less than 0.10 EU/mg of Glutathione.		
8.	Assay: Each vial contains:				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Glutathione (sterile)		1200 mg	1250.17 mg	104.18%	90.0 to 110.0%

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~~. ✓

Name : Mrs. Swati Dhawan

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