

Certificate of Analysis Finished Product

Title	:		
Product Name	GLUTACAN Injection	A.R. No.	NB/FP/24/139
Generic Name	Glutathione for Injection & Vitamin C Injection IP	Sampled qty.	45 Vials
Batch No.	N24099G	Sampled by	Vineet
Batch Size	5000 Vials	Sampled on	20/08/2024
Mfg. Date	07/2024	Date of Testing	20/08/2024
Exp. Date	06/2026	Date of Release	04/09/2024

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 $\pm 10\%$	-5.22% & +1.85%		
4.	Average weight	Informative.	647.6 mg		
5.	Particulate Matter				
	(a.) Sub-Visible particle count (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$	NMT-6000/vial NMT-600/ vial	160/vial 2/vial		
	(b.) Visual	The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally.	Complies		
6.	Sterility	No microbial growth should be observed.	Complies		
7.	Bacterial Endotoxins	NMT- 0.58 EU/mg of Glutathione.	Less than- 0.58 EU/mg Glutathione.		
8.	Assay: Each vial Contains :				
Ingredients		Labeled Claim	Found	% of labeled amount	Limits % of labeled amount
Glutathione (Sterile)		600 mg	652.93 mg	108.82%	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.

Analysis by	Checked by	Approved By
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