

Pace

Add Pace To Health

Pace Biotech

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

Title

:

Certificate of Analysis Finished Product

Product Name	GLUTACAN Injection	A.R. No.	NB/FP/24/068
Generic Name	Glutathione For Injection 600mg	Sampled qty.	45 Vials
Batch No.	N24051C	Sampled by	Aakashdeep
Batch Size	5000 Vials	Sampled on	31/05/2024
Mfg. Date	05/2024	Date of Testing	31/05/2024
Exp. Date	04/2026	Date of Release	17/06/2024

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 $\pm 10\%$	-1.11% & +1.79%
4.	Average weight	Informative.	652.1 mg
5.	Particulate Matter		
	(a.) Sub-Visible particle count		
	(1.) Particles $\geq 10\mu\text{m}$	NMT-6000/vial	679/vial
	(2.) Particles $\geq 25\mu\text{m}$	NMT-600/ vial	6/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	647.00 mg	107.83%	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
Quality Manager

