



Nixi Laboratories Pvt. Ltd.,
Village Mouza Ogli, Sadhaura Road, Kala-Amb, District Sirmour -173030,
Himachal Pradesh (INDIA).

CERTIFICATE OF ANALYSIS FINISHED PRODUCTS

Product Name	GLUTACAN 2000	AR. No.	NL/LYP/FG/26/083
Generic Name	Glutathione For Injection 2000 mg		
Mother Batch No.	L26JN001	Reference	IHS
Child Batch No.	L26JN001A	Batch Size	4000 Vials
Mfg. Date	01/2026	Exp. Date	12/2027
Specification No. (STS No)	QC/LYP/FG/STS/004-03	Standard Test Procedure No.	QC/LYP/FG/STP/004
Sample Quantity	60 Vials	Sampling Date	23/01/2026
Release Date	06/02/2026		

Sr.No.	TEST	SPECIFICATION	OBSERVATION
1.	Description	White colour lyophilized cake filled in 20 ml clear / amber colour glass vial, plugged with grey colour rubber stopper and sealed with flip off aluminum seal	White colour lyophilized cake filled in 20 ml clear colour glass vial, plugged with grey colour rubber stopper and sealed with flip off aluminum seal
2.	Identification (A) Determine By Liquid Chromatography (HPLC)	The retention time of the major peak in the chromatogram of the test solution should correspond to that in the chromatogram of the standard solution as obtained in the assay.	Complies
3.	Clarity of solution	a) The solid dissolves completely, leaving no visible residue as undissolved matter. b) The constituted injection is not significantly less clear than an equal volume of the diluent or of water for injections contained in a similar container and examined in the same manner.	Complies Complies
4.	Uniformity OF Dosage Units	Acceptance Value ≤ 15	10.67
6.	pH (At 25°C \pm 2°C)	1.5 to 4.0	2.76

	ANALYSED BY	CHECKED BY	APPROVED BY
Name	Tarun Kumar	Ganesh Jaiswal	Aditya Singh
Designation	Officer QC	Sr. Executive QC	Asst. Manager QC
Signature			
Date	06/02/26	06/02/26	06/02/26



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8.	Particulate matter		
	For Visible Particles:	Should be free from visible particles	Complies
	For sub visible particles: (i) Equal to or greater than 10µm. (ii) Equal to or greater than 25µm.	NMT 6000 particles/container NMT 600 particles/container	388.0 particles/container 3.0 particles/container
9.	Sterility	Should comply the test sterility	Complies
10.	Bacterial Endotoxins	NMT 0.58 EU/mg of glutathione	Complies
11.	Related Substances (By HPLC)		
	(i) Any Impurity (ii) Total Impurities	Not more than 2.0% Not more than 3.0%	1.39 % 1.92 %
12.	Assay: Each Lyophilized Vial Contains: Glutathione USP 2000 mg	1800.00 mg to 2200.00 mg (90.0% to 110.0%)	1962.79 mg (98.14 %)

RESULT: The above sample ~~COMPLIES / DOES NOT COMPLY~~ as per Specification No- QC/LYP/FG/STS/004-03.

Conclusion: In the opinion of the under signed the sample referred above is of ~~STANDARD QUALITY / IS NOT STANDARD QUALITY~~ as defined in the Drugs & Cosmetics Act, 1940 and the rules made hereunder further.

	ANALYSED BY	CHECKED BY	APPROVED BY
Name	Tarun Kumar	Ganesh Jaiswal	Aditya Singh
Designation	Officer QC	Sr. Executive QC	Asst. Manager QC
Signature			
Date	06/02/26	06/02/26	

Format No.: F/QC/013/03-04

Approved By
Name: Aditya Singh
Designation: Asst. Manager QC
Qualification:
Enrollment No. II-03345
Avadh University Ayazgaya