Nixi Laboratories Pvt. Ltd.

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

CERTIFICATE OF ANALYSIS FINISHED PRODUCTS

Product Name	CALCIGLU	**AR. No.**	NL/LA/FG/26/486
Generic Name	Injection of Calcium Gluconate & Calcium Lactobionate		
Mother Batch No.	A26GR002	**Reference**	IHS
Child Batch No.	A26GR002	**Batch size**	39603 Ampoules
Mfg. Date	06/2026	**Exp. Date**	05/2028
Specification No. (STS No.)	QC/LA/FG/STS/084	**Standard Test Procedure No.**	QC/LA/FG/STP/084
Sampled Quantity	65 Ampoules	**Sampling Date**	18/09/2026
Released Date	04/10/2026		

Sr.No.	TEST	SPECIFICATION	OBSERVATION
1.	**Description**	Clear, colourless liquid, free from foreign particles, filled in 10 ml amber / clear colour glass ampoule.	Clear, colourless liquid, free from foreign particles, filled in 10 ml clear colour glass ampoule.
2.	**Identification:** **By Chemical**	Blue Colour is produced.	Complies
3.	**Average filled volume**	Not less than 10.0 ml	10.02 ml
4.	**Extractable Volume**	Not less than 10.0 ml	10.02 ml
5.	**pH (At 25°C±2 °C)**	5.0 to 7.0	6.58
6.	**Particulate matter:**		
	For Visible Particles	Should be free from visible particles	Complies
	For sub visible Particles: (i) Equal to greater than 10µm. (ii) Equal to greater than 25µm.	NMT 6000 particles/container NMT 600 particles/container	825.0 particles/container 25.0 particles/container
7.	**Sterility**	Should comply the test of sterility	Complies
8.	**Bacterial Endotoxins**	Not more than 0.17EU/mg	Complies
9.	**Assay:** Each ml Contains: Calcium Gluconate IP 50 mg Calcium lactobionate USP 87.5 mg eq. To elemental Calcium 9 mg	8.1 mg to 9.9 mg (90.00 % to 110.00 %)	8.97mg (99.67%)
10.	**Diethylene glycol and Ethylene glycol (By GC)**	Not more than 0.1%	Not Detected

Result: The above sample **COMPLIES/~~DOES NOT COMPLY~~** as per Specification No- QC/LA/FG/STP/084.**Conclusion:** In the opinion of the under signed the sample referred above is of **STANDARD QUALITY / IS ~~NOT STANDARD QUALITY~~.**

	ANALYSED BY	CHECKED BY	APPROVED BY
Name	**Ganesh Jaiswal**	**Meenakshi Panday**	**Aditya Singh**
Designation	**Sr.Executive QC**	**Sr.Executive QC**	**Manager QC**
Signature			Approved By Name : Aditya Singh Designation : Manager QC Qualification : Bsc Enrollment No. U-000545 Avadh University Ayodhya
Date	04/10/26	04/10/26	

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