



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/25/451
Generic Name	Injection of Calcium Gluconate & Calcium Lactobionate		
Mother Batch No.	A25GR003	Reference	IHS
Child Batch No.	A25GR003A	Batch size	27722 Ampoules
Mfg. Date	10/2025	Exp. Date	09/2027
Specification No. (STS No.)	QC/LA/FG/STS/084	Standard Test Procedure No.	QC/LA/FG/STP/084
Sampled Quantity	55 Ampoules	Sampling Date	06/10/2025
Released Date	28/10/2025		

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	10.04 ml
4.	Extractable Volume	Not less than 10.0 ml	10.04 ml
5.	pH (At 25°C±2 °C)	5.0 to 7.0	6.51
6.	Particulate matter:		
	For Visible Particles	Should comply the test of sterility	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	280.0 particles/container 12.0 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 %)	9.29mg (103.22%)

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	Saurav Kumar	Sunil Kumar	Aditya Singh
Designation	Chemist QC	Sr.Officer QC	Asst.Manager QC
Signature			
Date	28/10/25	28/10/25	28/10/25

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

Approved
Name: Aditya Singh
Designation: Asst. Manager QC
Qualification: Bsc
Enrollment No. 11-009545
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