

CAREWIN PHARMACEUTICALS (GUJ.) PVT. LTD.

Moraiya

QUALITY CONTROL DEPARTMENT

THE DRUGS & COSMETIC ACT 1940 & THE RULES THERE UNDER FROM 39/RULE 150-E/F

FINISHED PRODUCT CERTIFICATE OF ANALYSIS


PRODUCT NAME : INJ. OF CALCIUM GLUCONO- GALACTO -GLUCONATE.....10ML (CALCIGLU)		AR.NO. : F/448/24
PACKING : 10 ML		DATE OF REPORT : 24/10/2024
GENERIC NAME : CALCIUM GLUCONO GALACTO GLUCONATE ANHYDROUS		ADVICE SHEET NO : 448
BATCH NO. : 404		DATE OF RECEIPT : 10/10/2024
BATCH SIZE : 450.0 LITS		MFG DATE : 10/2024
SAMPLE SIZE : 50 AMPS + 10 AMPS		EXP DATE : 09/2026
TEST AS PER : SPECIFICATION		MFG LIC NO : G/984
MANUFACTURED ON BEHALF OF M/S. SELF		FILLED QTY : 44100 AMPS

Sr. No.	TEST	RESULT	SPECIFICATION
1)	Description	A Clear and colourless liquid.	Clear and colourless solution.
2)	Particulate matter	Passes the test	Liquid should be clear and free from any visible foreign particles.
3)	Extractable Volume	10.2 ml	NLT 10.0 ml.
4)	pH	7.05	6.0 to 8.2
5)	Identification	Complies the test	Complies the test
6)	Assay:- Calcium Glucono-Galacto Gluconate	Each ml contains 137.8 mg	i.e.% 100.21 % 90.0% To 110.0%
7)	Sterility	Passes the Test Vide A.R. No. ST/460/24 Dt.: 24/10/2024	No sign of Growth of bacterial or Fungi during 14 days.
8)	B.E.T. Test	Passes the test vide A. R. No. BT/624/24 Dt.: 10/10/2024	Complies the test

CONCLUSION: - The Product is Complies With Standard Quality Measures As per I.H.S. – SPECIFICATION.

DATE: 24/10/2024

Analyst


Q.C. In charge

