

TEST RESULTS

Date / Period of Performance of test 03/07/2024 to 19/07/2024.

Reference to protocol :- I.P-2022.

Description :- Clear colourless solution filled in amber colour glass ampoules.

Identification (A) (by TLC) :- Complies.

(B,C) :- Complies.

		LIMIT	
		Lower	Upper
pH	:- 6.52	6.0	8.2

Nominal Volume :- 10ml.

Extractable volume :- 10.5ml NLT 10ml.

Particulate matter :- Complies.

Sterility :- Complies with the test for Sterility.

Bacterial endotoxins :- Less than 0.17EU/mg of Calcium Gluconate - 0.17EU/mg of Calcium Gluconate.

Assay :-

Contents of	Obtained	Claim	LIMIT		Method
			Lower	Upper	
Calcium Gluconate eq. to Calcium	:- 0.918%w/v	10%w/v of calcium gluconate is eq.to 8.5% to 9.4% of calcium	0.85%w/v	0.94%w/v	IP.

NOTE:- SAMPLE CONSUMED IN TESTING.

Report: In Opinion of the undersigned, The sample referred to above is of Standard Quality as defined in the Act and the rules made there under for the reason given: Complies as per IP. with respect above test only.

