



CALCIUM GLUCONATE (INJECTABLE)

Sr. No.	TESTS		SPECIFICATION		
			IP	USP	BP
1.	Description		White crystalline powder or granules	White, crystalline, odorless, tasteless granules or powder	White or almost white, crystalline or granular powder
2.	Solubility		Freely soluble in boiling water; sparingly soluble in water; insoluble in ethanol (95%)	Freely soluble in boiling water; sparingly (and slowly) soluble in water; insoluble in alcohol	Sparingly soluble in water, freely soluble in boiling water
3.	Assay (w/w)		98.5 %-102.0%	98.5 %-102.0%	99.0 %-101.0%
4.	Identification		As per IP	As per USP	As per BP
5.	Chloride		NMT 250 ppm	NMT 0.005%	MAX 50 ppm
6.	pH				6.4 to 8.3
7.	Heavy Metals		NMT 20 ppm	NMT 10 ppm	MAX 10 ppm
8.	Phosphates				MAX 100 ppm
9.	Sulphate		NMT 150 ppm	NMT 0.005%	MAX 50 ppm
10.	Arsenic		NMT 2 ppm	NMT 3 ppm	
11.	Iron			NMT 5 ppm	MAX 5 ppm
12.	Loss On Drying			NMT 1.0%	
13.	Appearance of Solution		As per IP		As per BP
14.	Acidity & Alkalinity		As per IP		
15.	Limit of Magnesium & Alkali Metals			NMT 0.4%	MAX 0.4%
16.	Limit of Phosphate			NMT 0.01%	
17.	Limit of Oxalate			NMT 0.01%	MAX 100 ppm
18.	Reducing Substance			NMT 1.0%	
19.	Organic impurity & boric acid		----	----	As per BP
20.	Sucrose & reducing sugar		As per IP		As per BP
21.	Microbial Contamination	TAMC			10 ² CFU/g
22.	Bacterial endotoxins				Less than 167 IU/g