

Certificate Of Analysis

Product	CALCIUM GLUCONATE for Injection	
Batch No.	3202209016	Mfg.Date: SEP.13,2022
Quantity :	8000kg	Exp.Date:SEP.12,2024
Specification	USP/BP/EP	Report Date:SEP.14,2022
Tests	Specifications	Results
Characters	A White, crystalline or granular powder	Meets the requirements
Loss on drying	≤ 1.0 %	0.50%
Identification	Meets the requirements	Meets the requirements
Appearance of solution	Meets the requirements	Meets the requirements
Solubility	Sparingly soluble in water, freely soluble in boiling water.	Meets the requirements
Heavy metals	≤ 10 ppm	< 10 ppm
PH	6.4~8.3	6.8
Organic impurities and boric acid	Meets the requirements	Meets the requirements
Oxalate	≤ 100 ppm	< 50 ppm
Chloride	≤ 50 ppm	< 50 ppm
Sulphates	≤ 50 ppm	< 50 ppm
Arsenic	≤ 3 ppm	< 2 ppm
Iron	≤ 5 ppm	< 5 ppm
Phosphates	≤ 100 ppm	< 100 ppm
Magnesium and alkali metals	≤ 0.4 %	0.28%
Sucrose and regenerative sugar	Meets the requirements	Meets the requirements
Organic volatile impurities	Meets the requirements	Meets the requirements
Bacterial endotoxins	≤ 167 I.U./g	< 120 I.U./g
TAMC	≤ 100CFU/g	20CFU/g
Assay	99.0~101.0 %	99.70%
Conclusion	Complies with the requirements of USP/BP/EP Ed	