



## **PRODUCT SPECIFICATION**

Product : **Calcium Gluconate for Injection**

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Appearance	:	White crystalline powder or white crystals
Solubility	:	Sparingly soluble in water, freely soluble in boiling water
Identification TLC test	:	Identical with Calcium Gluconate CRS
Ca <sup>2+</sup> Reaction(b)	:	Meet the requirement
Appearance solution	:	Colority: ≤ Ref. sol. B7 Opacity: ≤ Ref. sus. II
Loss on drying	:	≤ 1.0 %
pH	:	6.4 ~ 8.3
Organic impurities and Boric acid	:	Meets the requirements
Oxalate	:	≤ 100 ppm
Sucrose and reducing sugars	:	Meets the requirements
Chlorides	:	≤ 50 ppm
Phosphates	:	≤ 100 ppm
Sulphates	:	≤ 50 ppm
Iron	:	≤ 5 ppm
Magnesium and alkali metals	:	≤ 0.4 %
Heavy metals	:	≤ 10 ppm
Bacterial endotoxins	:	167 I.U./g
Microbial contamination TAMC	:	≤ 100 CFU/g
Assay (calc. on C <sub>12</sub> H <sub>22</sub> CaO <sub>14</sub> · H <sub>2</sub> O)	:	99.0- 101.0 %
MSDS	:	available upon request

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