

Code No.07-0515

SPECIFICATION

Glucono- δ -Lactone

Japanese Pharmaceutical Excipients

REQUIREMENT	SPECIFICATION
* Description Identification Purity (1) Clarity and color of solution (2) Chloride (3) Sulfate (4) Heavy metals (5) Arsenic (6) Sucrose and reducing sugars Loss on drying Residue on ignition Assay (after drying) ** Bacterial endotoxins	White crystals or crystalline powder to pass test - to pass test not more than 0.035% not more than 0.024% not more than 20ppm not more than 4ppm to pass test not more than 1.0% not more than 0.10% not less than 99.0% less than 2.0EU/g

Japanese Pharmaceutical Excipients(*:Reference item)(**:.Additional test performed by Wako)