

SPECIFICATION

Sodium Citrate Hydrate

Japanese Pharmacopoeia

REQUIREMENT	SPECIFICATION
* Description (JP) Identification (JP) pH (JP) Purity (JP) (1) Clarity and color of solution (JP) (2) Chloride (JP) (3) Sulfate (JP) (4) Heavy metals (JP) (5) Arsenic (JP) (6) Tartrate (JP) (7) Oxalate (JP) (8) Readily carbonizable substances (JP) Loss on drying (JP) Assay (after drying) (JP)	Colorless crystals, or a white, crystalline powder to pass test 7.5~8.5 - to pass test not more than 0.015% not more than 0.048% not more than 10ppm not more than 2ppm to pass test to pass test to pass test 10.0~13.0% 99.0~101.0%
* Bacterial endotoxins Identification (USP-NF) Assay (USP-NF) Impurities (USP-NF) (1) Tartrate (USP-NF) Specific tests (USP-NF) (1) Alkalinity (USP-NF) (2) Water determination (USP-NF)	less than 5.2EU/g to pass test 99.0~100.5% - to pass test - to pass test 10.0~13.0%
* Appearance (Ph.Eur.) Identification (Ph.Eur.) Appearance of solution (Ph.Eur.) Acidity or alkalinity (Ph.Eur.) Readily carbonisable substances (Ph.Eur.) Chlorides (Ph.Eur.) Oxalates (Ph.Eur.)	White or almost white, crystalline powder or white or almost white, granular crystals to pass test to pass test to pass test to pass test maximum 50ppm maximum 300ppm

Sulfates (Ph.Eur.)	maximum 150ppm
Water (Ph. Eur.)	11.0~13.0%
Assay (Ph.Eur.)	99.0~101.0%

The Japanese Pharmacopoeia (Sodium Citrate Hydrate)(* : Additional test performed by Wako) United States Pharmacopeia - National Formulary (Sodium Citrate) European Pharmacopoeia (Sodium Citrate Hydrate)(* : Additional test performed by Wako)