

## SPECIFICATION

## Sodium Citrate Hydrate

## Japanese Pharmacopoeia

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