2024/04/25

Distributed by FUJIFILM Wako Pure Chemical Corporation

Manufactured by FUJIFILM Wako Pure Chemical Corporation

Code No.19-1885

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)

revised on 2023/04/20