SPECIFICATION

Citric Acid Hydrate

Japanese Pharmacopoeia

	REQUIREMENT	SPECIFICATION
*	Description (JP)	Colorless crystals or white shot or crystalline
	Identification (JP)	powder to pass test
	Purity (JP)	-
(1)	Clarity and color of solution (JP)	to pass test
(2)	Sulfates (JP)	not more than 150ppm
(3)	Oxalic acid (as oxalic anhydride) (JP)	not more than 360ppm
(4)	Heavy metals (JP)	not more than 10ppm
(5)	Readily carbonizable substances (JP)	to pass test
	Water (JP)	7.5~9.0%
	Residue on ignition (JP)	not more than 0.1%
	Assay (as C6H8O7) (JP)	99.5~100.5%
	Identification (USP-NF)	to pass test
	Assay (as C6H8O7) (USP-NF)	99.5~100.5%
	Impurities (USP-NF)	-
(1)	Residue on ignition (USP-NF)	NMT 0.1%
(2)	Sulfate (USP-NF)	NMT 0.015%
(3)	Limit of oxalic acid (USP-NF)	NMT 0.036%
	Specific tests (USP-NF)	-
(1)	Bacterial endotoxins test (USP-NF)	less than 8EU/g **
(2)	Clarity of solution (USP-NF)	to pass test
(3)	Color of solution (USP-NF)	to pass test
(4)	Readily carbonizable substances (USP-NF)	to pass test
(5)	Water determination (USP-NF)	7.5~9.0%
*	Appearance (Ph.Eur.)	White or almost white, crystalline powder,
	Identification (Ph.Eur.)	colourless crystals or granules to pass test
	Appearance of solution (Ph.Eur.)	to pass test
	Readily carbonisable substances (Ph.Eur.)	to pass test
	Oxalic acid (as anhydrous oxalic acid) (Ph.Eur.)	maximum 360ppm
	Sulfates (Ph.Eur.)	maximum 150ppm

Water (Ph.Eur.)	7.5~9.0%
Sulfated ash (Ph.Eur.)	maximum 0.1%
Bacterial endotoxins (Ph.Eur.)	less than 0.5IU/mg
Assay (as C6H8O7) (Ph.Eur.)	99.5~100.5%

Japanese Pharmacopoeia(Citric Acid Hydrate)(*:Additional test performed by Wako)United States Pharmacopeia - National Formulary(Citric Acid Monohydrate)(**:The specification is originally set by Wako)European Pharmacopoeia(Citric Acid Monohydrate)(*:Additional test performed by Wako)

(2 / 2) revised on 2023/04/26