

## SPECIFICATION

## Citric Acid Hydrate

## Japanese Pharmacopoeia

REQUIREMENT	SPECIFICATION
* Description (JP) Identification (JP) Purity (JP) (1) Clarity and color of solution (JP) (2) Sulfates (JP) (3) Oxalic acid (as oxalic anhydride) (JP) (4) Readily carbonizable substances (JP) Water (JP) Residue on ignition (JP) Assay (as C <sub>6</sub> H <sub>8</sub> O <sub>7</sub> ) (JP) Identification (USP-NF) Assay (as C <sub>6</sub> H <sub>8</sub> O <sub>7</sub> ) (USP-NF) Impurities (USP-NF) (1) Residue on ignition (USP-NF) (2) Sulfate (USP-NF) (3) Limit of oxalic acid (USP-NF) Specific tests (USP-NF) (1) Bacterial endotoxins test (USP-NF) (2) Clarity of solution (USP-NF) (3) Color of solution (USP-NF) (4) Readily carbonizable substances (USP-NF) (5) Water determination (USP-NF)	Colorless crystals or white shot or crystalline powder to pass test - to pass test not more than 150ppm not more than 360ppm to pass test 7.5~9.0% not more than 0.1% 99.5~100.5% to pass test 99.5~100.5% - NMT 0.1% NMT 0.015% NMT 0.036% - less than 8EU/g ** to pass test to pass test to pass test
* Appearance (Ph.Eur.) Identification (Ph.Eur.) Appearance of solution (Ph.Eur.) Readily carbonisable substances (Ph.Eur.) Oxalic acid (as anhydrous oxalic acid) (Ph.Eur.) Sulfates (Ph.Eur.) Water (Ph.Eur.)	White or almost white, crystalline powder, colourless crystals or granules to pass test to pass test to pass test maximum 360ppm maximum 150ppm 7.5~9.0%

Sulfated ash (Ph.Eur.)	maximum 0.1%
Bacterial endotoxins (Ph.Eur.)	less than 0.5IU/mg
Assay (as C <sub>6</sub> H <sub>8</sub> O <sub>7</sub> ) (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)