

Code No. 03-2524

製品規格書

クエン酸水和物「製造専用」

日本薬局方

試験項目	規格値
* 性状 (JP)	無色の結晶又は白色の粒若しくは結晶性の粉末
確認試験 (JP)	試験適合
純度試験 (JP)	-
(1) 溶状 (JP)	試験適合
(2) 硫酸塩 (JP)	150ppm以下
(3) シュウ酸(シュウ酸無水物として) (JP)	360ppm以下
(4) 重金属 (JP)	10ppm以下
(5) 硫酸呈色物 (JP)	試験適合
水分 (JP)	7.5~9.0%
強熱残分 (JP)	0.1%以下
含量(C ₆ H ₈ O ₇ として) (JP)	99.5~100.5%
Identification (USP-NF)	to pass test
Assay (as C ₆ H ₈ O ₇) (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, colourless crystals or granules
Identification (Ph.Eur.)	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 C ₆ H ₈ O ₇) (Ph.Eur.)	99.5~100.5%

日本薬局方(Citric Acid Hydrate)(*：当社追加項目)United States Pharmacopeia - National Formulary(Citric Acid Monohydrate)**：当社設定規格値)European Pharmacopoeia(Citric Acid Monohydrate)(*：当社追加項目)