

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 |

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| 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)