

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 <sub>6</sub> H <sub>8</sub> O <sub>7</sub> として) (JP)         | 99.5~100.5%   |
| Identification (USP-NF)   | to pass test  |
| Assay (as C <sub>6</sub> H <sub>8</sub> O <sub>7</sub> ) (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,<br>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 <sub>6</sub> H <sub>8</sub> O <sub>7</sub> ) (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)