



# Certificate of Analysis

1.37042.0000 tri-Sodium citrate dihydrate cryst. EMPROVE® EXPERT Ph Eur,BP,JP,  
USP,ACS  
Batch K54305442

|                                                                          | Spec. Values                      |        | Batch Values                      |        |
|--------------------------------------------------------------------------|-----------------------------------|--------|-----------------------------------|--------|
| Assay (Perchloric acid titration, calc. on anhydrous substance (Ph Eur)) | 99.0 - 101.0                      | %      | 100.0                             | %      |
| Assay (Perchloric acid titration, previously dried substance) (JP/USP)   | 99.0 - 100.5                      | %      | 99.7                              | %      |
| Identity (Na)                                                            | passes test                       |        | passes test                       |        |
| Identity (Citrate)                                                       | passes test                       |        | passes test                       |        |
| Identity (reaction upon ignition)                                        | passes test                       |        | passes test                       |        |
| Appearance                                                               | white crystals                    |        | passes test                       |        |
| Appearance of solution (100 g/l, CO <sub>2</sub> -free water)            | clear and colorless               |        | passes test                       |        |
| Acidity or alkalinity                                                    | passes test                       |        | passes test                       |        |
| pH (50 g/l CO <sub>2</sub> -free water)                                  | 7.5 - 8.5                         |        | 8.5                               |        |
| In water insoluble matter #                                              | ≤ 50                              | ppm    | ≤ 50                              | ppm    |
| Chloride (Cl)                                                            | ≤ 30                              | ppm    | ≤ 30                              | ppm    |
| Sulfate (SO <sub>4</sub> )                                               | ≤ 50                              | ppm    | ≤ 50                              | ppm    |
| Heavy metals (as Pb)                                                     | ≤ 5                               | ppm    | ≤ 5                               | ppm    |
| Al (Aluminium)                                                           | ≤ 5                               | ppm    | ≤ 5                               | ppm    |
| As (Arsenic)                                                             | ≤ 2                               | ppm    | ≤ 2                               | ppm    |
| NH <sub>4</sub> (Ammonium) #                                             | ≤ 30                              | ppm    | ≤ 30                              | ppm    |
| Ca (Calcium) #                                                           | ≤ 50                              | ppm    | 35                                | ppm    |
| Fe (Iron) #                                                              | ≤ 5                               | ppm    | < 5                               | ppm    |
| Oxalate (as C <sub>2</sub> H <sub>2</sub> O <sub>4</sub> )               | ≤ 300                             | ppm    | ≤ 300                             | ppm    |
| Tartrate (C <sub>4</sub> H <sub>4</sub> O <sub>6</sub> )                 | passes test                       |        | passes test                       |        |
| Residual solvents (ICH (Q3C))                                            | excluded by manufacturing process |        | excluded by manufacturing process |        |
| Readily carbonisable substance                                           | passes test                       |        | passes test                       |        |
| Water (according to Karl Fischer)                                        | 11.0 - 13.0                       | %      | 12.4                              | %      |
| Loss on drying (180 °C, 18 h)                                            | 10.0 - 13.0                       | %      | 12.3                              | %      |
| Total aerobic microbial count (TAMC)                                     | ≤ 100                             | CFU/g  | 1                                 | CFU/g  |
| Total combined yeasts/moulds count (TYMC)                                | ≤ 10                              | CFU/g  | < 1                               | CFU/g  |
| Bile-tolerant gram-negative bacteria (absent in 1 g)                     | passes test                       |        | passes test                       |        |
| Candida albicans (absent in 1 g)                                         | passes test                       |        | passes test                       |        |
| Escherichia coli (absent in 1 g)                                         | passes test                       |        | passes test                       |        |
| Pseudomonas aeruginosa (absent in 1 g)                                   | passes test                       |        | passes test                       |        |
| Salmonella (absent in 10 g)                                              | passes test                       |        | passes test                       |        |
| Staphylococcus aureus (absent in 1 g)                                    | passes test                       |        | passes test                       |        |
| Bacterial endotoxins                                                     | ≤ 2.5                             | I.U./g | < 1.6                             | I.U./g |

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## # Additional requirements by ACS

Elemental impurity specifications have been set considering ICH Q3D (Guideline for Elemental Impurities). Class 1-3 elements are not likely to be present above the ICH Q3D option 1 limit, unless specified and indicated (\*).

Corresponds to Ph. Eur., BP, JP, USP, ACS

Date of manufacture (DD.MM.YYYY) 02.02.2022

Date of examination (DD.MM.YYYY) 16.08.2022

Minimum shelf life (DD.MM.YYYY) 28.02.2025

Dr. Sebastian Lips

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Responsible laboratory manager quality control

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