



Specification

1.06585.1000 di-Sodium hydrogen phosphate anhydrous EMPROVE® ESSENTIAL
Ph Eur, BP, USP, JPE, E 339

| | Spec. Values | |
|---|--------------------------------|---|
| Assay (calculated on dried substance according to Ph Eur) | 98.0 - 101.0 | % |
| Assay (calculated on dried substance according to USP) | 98.0 - 100.5 | % |
| Assay (acidimetric; dried substance) | 99.0 - 101.0 | % |
| Identity | passes test | |
| Appearance of solution | passes test | |
| In water insoluble matter (calculated on dried substance) | ≤ 0.20 | % |
| Sodium dihydrogen phosphate (NaH ₂ PO ₄) | ≤ 2.5 | % |
| pH-value (1 %, water) | 9.0 - 9.4 | |
| Carbonate | passes test | |
| Chloride (Cl) | ≤ 0.010 | % |
| Fluoride (F) | ≤ 0.001 | % |
| Sulfate (SO ₄) | ≤ 0.030 | % |
| Heavy metals (as Pb) | ≤ 0.0010 | % |
| As (Arsenic) | ≤ 0.0001 | % |
| Cd (Cadmium) | ≤ 0.0001 | % |
| Fe (Iron) | ≤ 0.002 | % |
| Hg (Mercury) | ≤ 0.0001 | % |
| Ni (Nickel)* | ≤ 0.0002 | % |
| Pb (Lead) | ≤ 0.0001 | % |
| Residual solvents (ICH Q3C) | excluded by production process | |
| Substances reducing potassium permanganate | passes test | |
| Loss on drying (130 °C) | ≤ 1.0 | % |

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, USP, JPE, E 339

Conforms to the purity criteria on food additives according to the current European Commission Regulation.

Kristin Haufschildt

Responsible laboratory manager quality control

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