



Specification

1.04871.0000 Potassium dihydrogen phosphate cryst., EMPROVE® ESSENTIAL Ph Eur, BP, ChP, JPC, NF, E 340

| Spec. Values | | |
|---|-----------------------------------|---|
| Assay (alkalimetric, calculated on dried substance) | 99.0 - 100.5 | % |
| Assay (alkalimetric; dried substance) | 99.0 - 100.5 | % |
| Identity | passes test | |
| Appearance of solution | passes test | |
| Insoluble substances | ≤ 0.2 | % |
| pH-value (1 %; water) | 4.2 - 4.8 | |
| pH-value (2 %; water) | 4.2 - 4.6 | |
| pH-value (5 %; water) | 4.2 - 4.5 | |
| Carbonate | passes test | |
| Condensed phosphate | passes test | |
| Chloride (Cl) | ≤ 0.001 | % |
| Fluoride (F) | ≤ 0.0010 | % |
| Sulfate (SO ₄) | ≤ 0.003 | % |
| Al (Aluminium) | ≤ 0.0005 | % |
| As (Arsenic) | ≤ 0.0001 | % |
| Cd (Cadmium) | ≤ 0.0001 | % |
| Fe (Iron) | ≤ 0.0010 | % |
| Hg (Mercury) | ≤ 0.0001 | % |
| Na (Sodium) | ≤ 0.1 | % |
| Na (Sodium) | passes test | |
| Pb (Lead) | ≤ 0.0001 | % |
| Sb (Antimony) (*) | ≤ 0.0009 | % |
| Heavy metals (as Pb) | ≤ 0.0005 | % |
| Residual solvents (ICH Q3C) | excluded by manufacturing process | |
| Reducing substances | passes test | |
| Reducing substances (ChP) | passes test | |
| Loss on Drying (105 °C) | ≤ 0.2 | % |
| 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 (*).
Conforms to the purity criteria on food additives according to the current European Commission Regulation.
Corresponds to Ph Eur, BP, ChP, JPC, NF, E 340

The original manufacturer name and address will be disclosed subsequent to signing a confidentiality agreement.

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Kristin Starke
Responsible laboratory manager quality control

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