



# Specification

1.37039.0000 Potassium dihydrogen phosphate cryst. EMPROVE® EXPERT Ph Eur,BP, ChP,JPC,NF

| 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 (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 <sub>4</sub> )                          | ≤ 0.003                           | %      |
| Al (Aluminium)                                      | ≤ 0.0005                          | %      |
| As (Arsenic)  | ≤ 0.0001                          | %      |
| Fe (Iron)   | ≤ 0.0010                          | %      |
| Na (Sodium)   | ≤ 0.1                             | %      |
| Na (Sodium)   | passes test                       |        |
| Na (Sodium) (ChP)                                   | ≤ 0.1                             | %      |
| Pb (Lead)   | ≤ 0.0004                          | %      |
| 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                             | %      |
| Endotoxins  | ≤ 2.5                             | I.U./g |
| Total aerobic microbial count                       | ≤ 100                             | CFU/g  |
| Total yeast and mould count                         | ≤ 100                             | CFU/g  |
| DNases (Exo- and endonucleases) (not detectable)    | passes test                       |        |
| RNases (not detectable)                             | passes test                       |        |
| Proteases (not detectable)                          | passes test                       |        |

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, ChP, JPC, NF

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Kristin Starke

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Responsible laboratory manager quality control

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