Potassium Phosphate, Monobasic, Crystal, NF
Multi-Compendial

Material No.: 3248-09
Revision No.: 0

## Product Specification

Meets N.F. Requirements, Meets E.P. Chemical Specifications, Meets B.P. Chemical Specifications, GMP Manufactured Product

| Test | Specification |
| :---: | :---: |
| NF - Assay ( $\mathrm{KH}_{2} \mathrm{PO}_{4}$ ) (dried basis) | 98.0-100.5 \% |
| NF - Arsenic (As) | $\leq 3 \mathrm{ppm}$ |
| NF - Endotoxin Concentration (2.5 EU/g max.) | Passes Test |
| NF - Fluoride (F) | $\leq 0.001$ \% |
| NF - Identification | Passes Test |
| NF - Insoluble Substances | $\leq 0.2$ \% |
| NF - Lead (Pb) | $\leq 2 \mathrm{ppm}$ |
| NF - Loss on Drying at $105^{\circ} \mathrm{C}$ | $\leq 1.0$ \% |
| EP/BP - Assay ( $\mathrm{KH}_{2} \mathrm{PO}_{4}$ ) (dried basis) | 98.0-100.5 \% |
| EP/BP - Appearance of Solution | Passes Test |
| EP/BP - Chloride (Cl) | $\leq 200$ ppm |
| EP/BP - Identification A | Passes Test |
| EP/BP - Identification B | Passes Test |
| EP/BP - Identification C | Passes Test |
| EP/BP - Iron (Fe) | $\leq 10 \mathrm{ppm}$ |
| EP/BP - Loss on Drying at 125-130 ${ }^{\circ} \mathrm{C}$ | $\leq 2.0$ \% |
| EP/BP - Reducing Substances | Passes Test |
| EP/BP - pH | 4.2-4.5 |
| EP/BP - Sulfate ( $\mathrm{SO}_{4}$ ) | $\leq 300 \mathrm{ppm}$ |
| EP/BP - Arsenic (As) | $\leq 2 \mathrm{ppm}$ |

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Test
Specification

GMP Manufactured Product
Bulk Pharmaceutical Chemical
CAUTION: For Manufacturing, processing or repackaging
No Class 1,2,3 or other solvents are used or produced in the manufacturing or purification of the product.
Elemental Impurities (USP 232, EP 5.20) - Information on elemental impurities for this product is available on the associated
Product Regulatory Data Sheet and elemental impurity profile report.
Packaging Site: Phillipsburg Mfg Ctr \& DC

Jamie Ethier
Vice President Global Quality

