Potassium Phosphate, Monobasic, Crystal, NF Multi-Compendial



Material No.: 3248-01

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 (KH <sub>2</sub> PO <sub>4</sub> ) (dried basis)	98.0 - 100.5 %	
NF - Arsenic (As)	≤ 3 ppm	
NF - Endotoxin Concentration (2.5 EU/g max.)	Passes Test	
NF - Fluoride (F)	≤ 0.001 %	
NF - Identification	Passes Test	
NF - Insoluble Substances	≤ 0.2 %	
NF - Lead (Pb)	≤ 2 ppm	
NF - Loss on Drying at 105°C	≤ 1.0 %	
EP/BP - Assay (KH <sub>2</sub> PO <sub>4</sub> ) (dried basis)	98.0 - 100.5 %	
EP/BP - Appearance of Solution	Passes Test	
EP/BP - Chloride (Cl)	≤ 200 ppm	
EP/BP - Identification A	Passes Test	
EP/BP - Identification B	Passes Test	
EP/BP - Identification C	Passes Test	
EP/BP - Iron (Fe)	≤ 10 ppm	
EP/BP - Loss on Drying at 125 - 130°C	≤ 2.0 %	
EP/BP - Reducing Substances	Passes Test	
EP/BP - pH	4.2 - 4.5	
EP/BP - Sulfate (SO <sub>4</sub> )	≤ 300 ppm	
EP/BP - Arsenic (As)	≤ 2 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: Paris Mfg Ctr & DC

