

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 (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 (CI)	≤ 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 <b>%</b>	
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	

Potassium Phosphate, Monobasic, Crystal, NF Multi-Compendial



Material No.: 3248-09

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.
Storage Condition: Preserve in Tight Containers

Packaging Site: Phillipsburg Mfg Ctr & DC

