Potassium Phosphate, Dibasic, U.S.P. Multi-Compendial Endotoxin Tested



Material No.: 3250-01

Revision No.: 0

Product Specification

Meets E.P. Chemical Specifications, Meets B.P. Chemical Specifications, Meets U.S.P Requirements, GMP Manufactured Product

Test	Specification	
USP - Assay (K₂HPO₄) (dried basis)	98.0 - 100.5 %	
USP - Arsenic (As)	≤ 3 ppm	
USP - Carbonate (CO₃)	Passes Test	
USP - Chloride (CI)	≤ 0.03 %	
USP - Endotoxin Concentration (2.5 EU/g max.)	Passes Test	
USP - Fluoride (F)	≤ 0.001 %	
USP - Identification A (USP)	Passes Test	
USP - Identification B (USP)	Passes Test	
USP - Insoluble Substances	≤ 0.2 %	
USP - Iron (Fe)	≤ 0.003 %	
USP - Loss on Drying	≤ 1.0 %	
USP - Mono- or Tri- Basic Salt	Passes Test	
USP - pH (1 in 20)	8.5 - 9.6	
USP - Sodium (Na)	Passes Test	
USP - Sulfate (SO₄)	≤ 0.1 %	
EP/BP - Appearance of Solution	Passes Test	
EP/BP - Assay (K ₂ HPO ₄) (dried basis)	98.0 - 101.0 %	
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	≤ 2.0 %	
EP/BP - Monopotassium phosphate	≤ 0.025	
EP/BP - Reducing Substances	Passes Test	
EP/BP - Sodium (Na)	≤ 0.1 %	
EP/BP - Sulfate (SO ₄)	≤ 0.1 %	
Color (APHA), For Information Only		

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Test	Specification
Aluminum (Al), For Information Only	ppm

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.

Preserve in well closed container. Store at ambient temperature.

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

