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



Material No.: 3250-01 Batch No.: 0000273517

Manufactured Date: 2020/04/04

Retest Date: 2025/04/03 Release Date: 2020/12/22

Revision No: 1

Certificate of Analysis

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

Test	Specification	Result
USP - Assay (K ₂ HPO ₄) (dried basis)	98.0 - 100.5 %	99.6
USP – Arsenic (As)	<= 3 ppm	< 3
USP - Carbonate (CO₃)	Passes Test	PT
USP – Chloride (Cl)	<= 0.03 %	< 0.03
USP – Endotoxin Concentration (2.5 EU/g max.)	Passes Test	PT
USP – Fluoride (F)	<= 0.001 %	< 0.001
USP - Identification A (USP)	Passes Test	PT
USP – Identification B (USP)	Passes Test	PT
USP – Insoluble Substances	<= 0.2 %	< 0.1
USP – Iron (Fe)	<= 0.003 %	< 0.003
USP – Loss on Drying	<= 1.0 %	< 0.1
USP – Mono– or Tri– Basic Salt	Passes Test	PT
USP - pH (1 in 20)	8.5 - 9.6	9.2
USP – Sodium (Na)	Passes Test	PT
USP – Sulfate (SO ₄)	<= 0.1 %	< 0.1
EP/BP - Appearance of Solution	Passes Test	PT
EP/BP - Assay (K ₂ HPO ₄) (dried basis)	98.0 - 101.0 %	99.7
EP/BP – Arsenic (As)	<= 2 ppm	< 2
EP/BP - Chloride (Cl)	<= 200 ppm	< 200
EP/BP - Identification A	Passes Test	PT
EP/BP - Identification B	Passes Test	PT
EP/BP - Identification C	Passes Test	PT
EP/BP - Iron (Fe)	<= 10 ppm	< 10

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Test	Specification	Result
EP/BP – Loss on Drying	<= 2.0 %	0.1
EP/BP - Monopotassium phosphate	<= 0.025	< 0.025
EP/BP – Reducing Substances	Passes Test	PT
EP/BP – Sodium (Na)	<= 0.1 %	< 0.1
EP/BP – Sulfate (SO ₄)	<= 0.1 %	< 0.1
Color (APHA), For Information Only		10
Aluminum (Al), For Information Only	ppm	0.4

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.

Country of Origin: US

Packaging Site: Paris Mfg Ctr & DC

Manufacturer: PBG

Manufacturer source batch: 0000256367

