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
ISP – Assay (K2HPO4) (dried basis)	98.0 - 100.5 %	99.6
SP – Arsenic (As)	<= 3 ppm	< 3
JSP – Carbonate (CO₃)	Passes Test	РТ
SP – Chloride (Cl)	<= 0.03 %	< 0.03
ISP – Endotoxin Concentration (2.5 EU/g max.)	Passes Test	РТ
ISP – Fluoride (F)	<= 0.001 %	< 0.001
ISP – Identification A (USP)	Passes Test	РТ
ISP – Identification B (USP)	Passes Test	РТ
ISP – Insoluble Substances	<= 0.2 %	< 0.1
JSP – Iron (Fe)	<= 0.003 %	< 0.003
ISP – Loss on Drying	<= 1.0 %	< 0.1
ISP – Mono- or Tri- Basic Salt	Passes Test	РТ
JSP – pH (1 in 20)	8.5 - 9.6	9.2
ISP – Sodium (Na)	Passes Test	РТ
JSP – Sulfate (SO4)	<= 0.1 %	< 0.1
P/BP - Appearance of Solution	Passes Test	РТ
P/BP – Assay (K2HPO4) (dried basis)	98.0 - 101.0 %	99.7
P/BP – Arsenic (As)	<= 2 ppm	< 2
P/BP – Chloride (Cl)	<= 200 ppm	< 200
P/BP - Identification A	Passes Test	РТ
P/BP - Identification B	Passes Test	РТ
P/BP - Identification C	Passes Test	РТ
P/BP – Iron (Fe)	<= 10 ppm	< 10

For questions on this Certificate of Analysis please contact Technical Services at 855.282.6867 or +1.610.386.1700 Avantor Performance Materials, LLC 100 Matsonford Rd, Suite 200, Radnor, PA 19087. U.S.A. Phone: 610.386.1700

Test	Specification	Result
P/BP – Loss on Drying	<= 2.0 %	0.1
P/BP – Monopotassium phosphate	<= 0.025	< 0.025
P/BP – Reducing Substances	Passes Test	PT
P/BP – Sodium (Na)	<= 0.1 %	< 0.1
P/BP – Sulfate (SO4)	<= 0.1 %	< 0.1
Color (APHA), For Information Only		10
luminum (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

James Techie

Jamie Ethier Vice President Global Quality

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