

SPECIFICATION

Monobasic Potassium Phosphate

Japanese Pharmaceutical Codex

REQUIREMENT	SPECIFICATION
* Description (JPC)	White crystals or crystalline powder
Identification (JPC)	to pass test
pH (JPC)	4.2~4.6
Purity (JPC)	-
(1) Clarity and color of solution (JPC)	to pass test
(2) Chloride (JPC)	not more than 0.009%
(3) Sulfate (JPC)	not more than 0.017%
(4) Carbonate (JPC)	to pass test
(5) Heavy metals (JPC)	not more than 10ppm
(6) Sodium (JPC)	to pass test
(7) Arsenic (JPC)	not more than 2ppm
(8) Condensed phosphate (JPC)	to pass test
Loss on drying (JPC)	not more than 0.5%
Assay (after drying) (JPC)	not less than 99.0%
Identification (USP-NF)	to pass test
Assay (dried basis) (USP-NF)	98.0~100.5%
Impurities (USP-NF)	-
(1) Arsenic (USP-NF)	NMT 3 μ g/g
(2) Lead (USP-NF)	NMT 5 μ g/g
(3) Limit of fluoride (USP-NF)	NMT 10 μ g/g
Specific tests (USP-NF)	-
(1) Insoluble substances (USP-NF)	NMT 0.2%
(2) Loss on drying (USP-NF)	NMT 1.0%
Identification (Ph.Eur.)	to pass test
Appearance of solution (Ph.Eur.)	to pass test
pH (Ph.Eur.)	4.2~4.5
Reducing substances (Ph.Eur.)	to pass test
Chlorides (Ph.Eur.)	maximum 200 ppm
Sulfates (Ph.Eur.)	maximum 300 ppm

Arsenic (Ph.Eur.)	maximum 2 ppm
Iron (Ph.Eur.)	maximum 10 ppm
Loss on drying (Ph.Eur.)	maximum 2.0%
Assay (dried substance) (Ph.Eur.)	98.0~100.5%

Japanese Pharmaceutical Codex 2002(Monobasic Potassium Phosphate)(*Additional test performed by Wako)United States Pharmacopeia - National Formulary(Monobasic Potassium Phosphate)European Pharmacopoeia(Potassium Dihydrogen Phosphate)