

SPECIFICATION

Sodium Dihydrogen Phosphate Dihydrate

Japanese Pharmaceutical Excipients

REQUIREMENT	SPECIFICATION
* Description (JPE) Identification (JPE) pH (JPE) Purity (JPE) (1) Clarity and color of solution (JPE) (2) Chloride (JPE) (3) Sulfates (JPE) (4) Heavy metals (JPE) (5) Arsenic (JPE) Loss on drying (JPE) Assay (as NaH ₂ PO ₄) (after drying) (JPE)	Colorless or white, crystals or crystalline powder to pass test 4.1~4.7 - to pass test not more than 0.005% not more than 0.019% not more than 10ppm not more than 2ppm 22.0~25.0% not less than 98.0%
* Bacterial endotoxins Identification (USP-NF) Assay (as NaH ₂ PO ₄) (USP-NF) Impurities (USP-NF) (1) Insoluble substances (USP-NF) (2) Chloride (USP-NF) (3) Sulfate (USP-NF) (4) Aluminum, Calcium, and Related elements (USP-NF) (5) Arsenic (USP-NF) Specific tests (USP-NF) (1) pH (USP-NF) (2) Water determination (USP-NF)	less than 2.0EU/g to pass test 98.0~103.0% - NMT 0.2% NMT 0.014% NMT 0.15% to pass test NMT 8ppm - 4.1~4.5 18.0~26.5%
* Appearance (Ph.Eur.) Identification (Ph.Eur.) Appearance of solution (Ph.Eur.) pH (Ph.Eur.) Reducing substances (Ph.Eur.) Chlorides (Ph.Eur.)	White or almost white powder or colourless crystals to pass test to pass test 4.2~4.5 to pass test maximum 200ppm

Sulfates (Ph.Eur.)	maximum 300ppm
Iron (Ph.Eur.)	maximum 10ppm
Loss on drying (Ph.Eur.)	21.5~24.0%
Assay (as NaH ₂ PO ₄) (Ph.Eur.)	98.0~100.5%

Japanese Pharmaceutical Excipients (Sodium Dihydrogen Phosphate Dihydrate)(*Additional test performed by Wako)United States Pharmacopeia - National Formulary(Monobasic Sodium Phosphate)European Pharmacopoeia(Sodium Dihydrogen Phosphate Dihydrate)(*Additional test performed by Wako)