

## SPECIFICATION

## Sodium Dihydrogen Phosphate Dihydrate

## Japanese Pharmaceutical Excipients

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

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

Japanese Pharmaceuical 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)