

## SPECIFICATION

## Dibasic Sodium Phosphate Hydrate

## Japanese Pharmacopoeia

REQUIREMENT	SPECIFICATION
* Description (JP)	Colorless or white crystals
Identification (JP)	to pass test
pH (JP)	9.0~9.4
Purity (JP)	-
(1) Clarity and color of solution (JP)	to pass test
(2) Chloride (JP)	not more than 0.014%
(3) Sulfates (JP)	not more than 0.038%
(4) Carbonate (JP)	to pass test
(5) Heavy metals (JP)	not more than 10ppm
(6) Arsenic (JP)	not more than 2ppm
Loss on drying (JP)	57.0~61.0%
Assay (as Na <sub>2</sub> HPO <sub>4</sub> ) (JP)	not less than 98.0%
* Bacterial endotoxins	less than 0.2EU/g
Identification (USP-NF)	to pass test
Assay (as Na <sub>2</sub> HPO <sub>4</sub> ) (dried basis) (USP-NF)	98.0~100.5%
Impurities (USP-NF)	-
(1) Insoluble substances (USP-NF)	NMT 0.4%
(2) Chloride (USP-NF)	NMT 0.06%
(3) Sulfate (USP-NF)	NMT 0.2%
(4) Arsenic (USP-NF)	NMT 16ppm
Specific tests (USP-NF)	-
(1) Loss on drying (USP-NF)	55.0~64.0%
* Appearance (Ph.Eur.)	Colourless, transparent crystals
Identification (Ph.Eur.)	to pass test
Appearance of solution (Ph.Eur.)	to pass test
Reducing substances (Ph.Eur.)	to pass test
Monosodium phosphate (Ph.Eur.)	maximum 2.5%
Chlorides (Ph.Eur.)	maximum 200ppm
Sulfates (Ph.Eur.)	maximum 500ppm

Iron (Ph.Eur.)	maximum 20ppm
Loss on drying (Ph.Eur.)	57.0~61.0%
Assay (Ph.Eur.)	98.5~102.5%

Japanese Pharmacopoeia (Dibasic Sodium Phosphate Hydrate)(\*Additional test performed by Wako)United States Pharmacopeia - National Formulary(Dibasic Sodium Phosphate)European Pharmacopoeia(Disodium Phosphate Dodecahydrate)(\*Additional test performed by Wako)