2024/04/26

Distributed by FUJIFILM Wako Pure Chemical Corporation

Manufactured by FUJIFILM Wako Pure Chemical Corporation

Code No.04-3438

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 Na2HPO4) (JP)	not less than 98.0%
*	Bacterial endotoxins	less than 0.2EU/g
	Identification (USP-NF)	to pass test
	Assay (as Na2HPO4) (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)

revised on 2023/04/20