2021/09/26

Distributed by FUJIFILM Wako Pure Chemical Corporation

Manufactured by FUJIFILM Wako Pure Chemical Corporation

Code No.19-1849

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 NaH2PO4) (after drying) (JPE)	not less than 98.0%
*	Bacterial endotoxins	less than 2.0EU/g
	Identification (USP-NF)	to pass test
	Assay (as NaH2PO4) (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 NaH2PO4) (Ph.Eur.)	98.0～100.5%

(1/3)Japanese Pharmaceutical Excipients (Sodium Dihydrogen Phosphate Dihydrate)(*:Additional test performed by Wako)
(2/3)United States Pharmacopeia - National Formulary)(Monobasic Sodium Phosphate)(3/3)European Pharmacopoeia(Sodium Dihydrogen Phosphate Dihydrate)(*:Additional test performed by Wako)

revised on 2021/03/19