

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Sodium Dihydrogen Phosphate Dihydrate USP (Item No. 41023700)	Spec. No. : SP-AK30-S026
Reference(s) : USP 40 p.6201-6202 [Monobasic Sodium Phosphate, Dihydrate USP]	Rev. No. : 01
Other Requirements : -	Page : 1/2

USP40

Description	: Colorless crystals or white, crystalline powder. Is odorless and is slightly deliquescent.
Solubility	: Freely soluble in water; practically insoluble in alcohol.
Identification	: A. It responds to the test for Sodium. B. It responds to the test for Phosphate.
Insoluble substances	: Not more than 20 mg (0.2%).
Chloride and Sulfate, Chloride	: Not more than 0.014%.
Chloride and Sulfate, Sulfate	: Not more than 0.15%.
Aluminium, Calcium, and Related elements	: The sample solution does not become turbid when rendered slightly alkaline to litmus paper with 6 N ammonium hydroxide. [Sample solution : Equivalent to 1.0 g of $\text{NaH}_2\text{PO}_4 \cdot \text{H}_2\text{O}$ in 10 mL of purified water.]
Arsenic <Method I>	: Not more than 8 ppm.
Heavy metals	: Not more than 20 ppm.
pH	: 4.1 to 4.5.
Water	: 18.0% to 26.5%.
Assay	: It contains not less than 98.0% and not more than 103.0% of Monobasic Sodium Phosphate (NaH_2PO_4), calculated on the anhydrous basis.

Prepared by : J. Ropadech, 18/08/17 Head of Raw Material Standard Section 2	Reviewed by : Yawayaw, 18/08/17 Director of Raw Material Standard Division	VARIPIN, 21/08/17 Director of Regulatory Compliance and Documentation Division	Approved by : Vichin Runggrongroj, 21/08/17 Director of Quality Assurance Department (Chiny)	Eff. Date 27/08/17
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Product Information

Approved source (s)	Refer to current version of Approved Supplier List of Dihydrogen Phosphate Dihydrate USP (Item No. 41023700).
Sampling plan	P plan : For Identification. $\sqrt{N} + 1$ plan : For Other Tests.
Testing procedure	Tests to be performed as per current version of WI-AK30-S026.
Storage condition	Store at a condition stated on the label from the manufacturer. Preserve in well-closed containers.
Retest period	2 years after first testing date.

History of changes

Rev. No.	Description	Effective Date
01	จัดทำข้อกำหนด โดยอ้างอิงตาม USP40 [Monobasic Sodium Phosphate, Dihydrate USP]	27/08/17

Prepared by : J. Ropphoedek / 18/08/17 Head of Raw Material Standard Section 2	Reviewed by : Yanaporn / 18/08/17 Director of Raw Material Standard Division	Approved by : Vichin Ruengvongchai / 21/08/17 Director of Quality Assurance Department (Achary)	Eff. Date 27/08/17
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