



THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title: Sodium Dihydrogen Phosphate, Dihydrate USP (Item No. 41033540) (Monobasic Sodium Phosphate, Dihydrate USP)	Spec. No. : SP-AK30-S69
Reference(s) : USP 43 p. 4088	Rev. No. : 05
Other Requirements : GPO specification	Page : 1/2

USP 43

Test Items	Specification
Description	Colorless crystals or white, crystalline powder, odorless.
Solubility	Freely soluble in water, practically insoluble in alcohol.
Identification A. Sodium Test B. Phosphate Test	A dense white precipitate is formed. With silver nitrate TS, neutral solutions of orthophosphates yield a yellow precipitate that is soluble in 2 N nitric acid and in 6 N ammonium hydroxide.
pH	4.1-4.5.
Water	18.0% - 26.5% , for dihydrate form.
Insoluble substances	Not more than 20 mg (0.2%).
Chloride	Not more than 0.014%.
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.
Arsenic	Not more than 8 ppm, Method I.
Assay	98.0% to 103.0% of NaH_2PO_4 , calculated on the anhydrous basis.

GPO specification

Test Items	Specification
Heavy metals	Not more than 20 ppm.

Prepared by : (Acting) Thunyastorn / 29/11/21 Head of Raw Material Standard Section 1	Reviewed by : Suvannnee / 29/11/21 Director of Raw Material Standard Division	Approved by : (Acting) Jannet / 30/11/21 Director of Regulatory Strategy Division	Eff. Date 14/02/22
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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Sodium Dihydrogen Phosphate, Dihydrate (Item No. 41033540)
Sampling plan	1. N Plan ($\sqrt{N} + 1$) : for other tests. 2. 100% Identification.
Testing procedure	Tests to be performed as per current version of WI-AK30-S69.
Storage condition	Preserve in well closed containers.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
03	อ้างอิง spec. เป็น USP 37	30/01/15
04	Update spec. เป็น USP 40 โดยเนื้อหาของ USP 37 และ USP 40 เหมือนกัน เนื่องจากเอกสารมีอายุครบ 3 ปี จึงต้องทบทวน	15/03/18
05	Update spec. เป็น USP 43 โดยเนื้อหาของ USP 40 และ USP 43 เหมือนกัน เนื่องจากเอกสารมีอายุครบ 3 ปี จึงต้องทบทวน	14/02/22

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