



COPY No. 2

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title: Sodium Dihydrogen Phosphate, Dihydrate USP (Item No. 41033540) **Spec. No.** : SP-AK30-S69
(Monobasic Sodium Phosphate, Dihydrate USP)

Reference(s) : USP 40 p.6201 - 6202

Rev. No. : 04

Other Requirements : GPO specification

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USP 40

Test Items	Specification
Description	Colorless crystals or white, crystalline powder, odorless.
Solubility	Freely soluble in water, practically insoluble in alcohol.
Identification	
A. Sodium Test	A dense white precipitate is formed.
B. Phosphate Test	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.

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by : Gunawanee, 21/02/18 Head of Raw Material Standard Section 1	Reviewed by : S. Tantithanont, 21/02/18 Director of Raw Material Standard Division	Approved by : Varin Rungtongkeo, 22/02/18 Director of Regulatory Compliance and Documentation Division	Eff. Date 15/03/18
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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	P plan : for Identification. $\sqrt{N} + 1$: for other tests.
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

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by : Suwannee, 21/02/18 Head of Raw Material Standard Section 1	Reviewed by : B. Tamthithanarat, 21/02/18 Director of Raw Material Standard Division	VARIPIN, 22/02/18 Director of Regulatory Compliance and Documentation Division	Approved by : Wichit Rungwongroj, 22/02/18 Director of Quality Assurance Department (Acting)	Eff. Date 15/03/18
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