COPY No. 2

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Disodium Hydrogen Phosphate Extra Pure USP (Item No. 41031760) (Dibasic Sodium Phosphate (dried form))	**Spec. No.** : SP-AK30-S66/1
Reference(s) : USP 43 p. 4087 - 4088	**Rev. No.** : 03
Other Requirements : GPO specification	**Page** : 1/2

USP 43

Test Items	Specification
Description	White powder, odorless.
Solubility	Freely soluble in water, 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.
Loss on drying	Not more than 5.0%, for the dried form.
Insoluble substances	Not more than 20 mg (0.4%).
Chloride	Not more than 0.06%.
Sulfate	Not more than 0.2%.
Arsenic	Not more than 16 ppm, Method I.
Assay	98.0% to 100.5% of Na_2HPO_4, calculated on the dried basis.

GPO specification

Test Items	Specification
Heavy metals	Not more than 20 ppm.

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by :	Reviewed by :		Approved by :	Eff. Date
Suwannee , 12/10/20	Tawee Unbroont , 12/10/20	, 14/10/20	Yuwaporn , 14/10/20	30/11/20
Head of Raw Material Standard Section 1	Director of Raw Material Standard Division	Director of Drug Registration and Pharmacovigilance Division	Director of Quality Assurance Department (Acting)	

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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Disodium Hydrogen Phosphate Extra Pure USP (Dibasic Sodium Phosphate (dried)) (Item No. 41031760).
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-S66/1.
Storage condition	Preserved in tight container. Label it to indicate whether it is dried or is the monohydrate, the dihydrate, the heptahydrate or the dodecahydrate.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
01	ประกาศใช้ครั้งแรก อ้างอิง USP 34	17/10/11
02	Update spec. เป็น USP 39 โดยเนื้อหาของ USP 34 และ USP 39 เหมือนกัน	24/05/16
03	เอกสารมีอายุครบ 3 ปี จึงต้องทบทวน โดย update spec. เป็น USP 43 โดยเนื้อหาของ USP 39 และ USP 43 เหมือนกัน	30/11/20

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by :	Reviewed by :		Approved by :	Eff. Date
Sunannee , 12/10/20	Tarmie Uniservant , 12/10/20	, 14/10/20	Yuwaporn , 14/10/20	30/11/20
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