

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Disodium Hydrogen Phosphate Extra Pure USP (Item No. 41031760) **Spec. No. :** SP-AK30-S66/1
(Dibasic Sodium Phosphate (dried))

Reference(s) : USP 39 p. 5884-5885 **Rev. No. :** 02

Other Requirements : ----- **Page :** 1/2

USP 38

Test Items	Specification
Description	White powder, odorless.
Solubility	Freely soluble in water, 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.
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.
Heavy metals	Not more than 20 ppm.
Assay	98.0% to 100.5% of Na_2HPO_4 , calculated on the dried basis.

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by : Sunanree, 04/05/16 Head of Raw Material Standard Section 1	Reviewed by : Nalapa, 04/05/16 Director of Raw Material Standard Division	Approved by : Vichin Ruengwongroj, 17/05/16 Director of Regulatory Compliance and Documentation Division	Eff. Date 24/05/16
---	--	--	-----------------------

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Disodium Hydrogen Phosphate Extra Pure USP (Item No. 41031760) (Dibasic Sodium Phosphate (dried))	Spec. No. : SP-AK30-S66/1
Reference(s) : USP 39 p. 5884-5885	Rev. No. : 02
Other Requirements : -----	Page : 2/2

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	P plan : for Identification. $\sqrt{N} + 1$: for other tests.
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	Up spec เป็น USP 39 โดยเนื้อหาของ USP 34 และ USP 39 เหมือนกัน	24/05/16

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by : Sunanee, 04/05/16 Head of Raw Material Standard Section 1	Reviewed by : Nakapa, 04/05/16 Director of Raw Material Standard Division	Approved by : Vichin Ruengongroj, 17/05/16 Director of Regulatory Compliance and Documentation Division	Eff. Date 24/05/16
--	--	---	-----------------------