



COPY No. 3

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Ascorbic acid USP (สำหรับผลิตยาฉีด) (Item No. 41033960)	Spec. No. : SP-AK30-A20
Reference(s) : USP 36 p.2531	Rev. No. : 02
Other Requirements : GPO specification	Page : 1/2

USP 36

Test Parameters	Specifications
Description	White or slightly yellow powder, odorless.
Solubility	Freely soluble in water, sparingly soluble in alcohol; insoluble in chloroform, in ether and in benzene.
Identification	
A. Infrared absorption (197K)	Conforms to standard spectrum.
B. Chemical Test	A 20-mg/ml solution reduces alkaline cupric tartrate TS slowly at room temperature but more readily upon heating.
Residue on ignition	Not more than 0.1%.
Heavy metals	Not more than 20 ppm.
Specific rotation	Between +20.5° and +21.5°.
Assay	99.0 – 100.5% of C ₆ H ₈ O ₆ .

GPO Spec

Test Parameters	Specifications
Bacterial endotoxins	Not more than 1.2 USP Endotoxin units per mg.

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by : Sintanee, 07/03/17 Head of Raw Material Standard Section 1	Reviewed by : Yuwaporn, 08/03/17 Director of Raw Material Standard Division	Vichin Punpongroj, 12/03/17 Director of Regulatory Compliance and Documentation Division	Approved by : [Signature], 08/06/17 Director of Quality Assurance Department	Exp. Date 20/06/17
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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Ascorbic acid USP (สำหรับผลิตยาฉีด) (Item No. 41033960)
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-A20.
Storage condition	Preserve in tight, light-resistant containers.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
01	ประกาศใช้ครั้งแรก เป็น USP 36	16/06/14
02	เนื่องจากเอกสารมีอายุครบ 3 ปีจึงต้องทบทวน โดยยังคงเนื้อหา USP 36	20/06/17

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by : Sungmee, Otholif Head of Raw Material Standard Section I	Reviewed by : Yuwapon, 08/03/17 Director of Raw Material Standard Division	Vijitnin Rungvitharaj, 22/03/17 Director of Regulatory Compliance and Documentation Division	Approved by : B. Cle, 22/06/17 Director of Quality Assurance Department	Eff. Date 20/06/17
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