



COPY No. 2

## THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

## RAW MATERIAL SPECIFICATION

Title : Ascorbic Acid 97% for Direct Compression (Item No. 41011636)

Spec. No : SP-AK30- A21/1

Reference(s) : Manufacturer's Specification

Rev. No : 03

Other Requirements : -----

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GPO Specification

Test Items	Specification
Description	White, fine granular powder, odorless.
Identification	
A. Infrared absorption	Conforms to IR standard spectrum.
B. Chemical Test	A grey precipitate is produced.
Loss on drying	Not more than 0.2%.
Heavy metals	The limit is 0.002%.
Assay	96.0%- 98.0% of ascorbic acid, calculated on dried basis.
Fineness	Pass sieve No. 20 : Not less than 95%.
	Pass sieve No. 100 : Not more than 20%

เอกสารไม่ควบคุม  
ใช้ในการจัดซื้อ

Prepared by : G. NAWANEE, 23/11/20 Head of Raw Material Standard Section 1	Reviewed by : T. WIRANEE, 24/11/20 Director of Raw Material Standard Division	Approved by : Y. WIRANEE, 24/11/20 Director of Drug Registration and Pharmacovigilance Division	Eff. Date 15/01/21
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### Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Ascorbic Acid 97% for Direct Compression (Item No. 41011636).
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-A21/1.
Storage condition	Stored in tightly closed container and avoid the moisture and light.
Retest period	1 year after first testing date.

### History of changes

Rev. No.	Description	Effective date
01	อ้างอิง Manufacturer 's specification	30/09/11
02	เอกสารมีอายุมากกว่า 3 ปี จำเป็นต้องทบทวน และคงเนื้อหาเดิม	25/02/16
03	เอกสารมีอายุมากกว่า 3 ปี จำเป็นต้องทบทวน และคงเนื้อหาเดิม	15/01/21

**เอกสารไม่ควบคุม**  
**ใช้ในการจัดซื้อ**

Prepared by : <i>Suvannee, 23/11/20</i> Head of Raw Material Standard Section 1	Reviewed by : <i>Tammarat, 24/11/20</i> Director of Raw Material Standard Division	Approved by : <i>Chanyaporn, 24/11/20</i> Director of Drug Registration and Pharmacovigilance Division	Eff. Date 15/01/21
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