



COPY No. 2

## THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

## RAW MATERIAL SPECIFICATION

<b>Title :</b> Ascorbic Acid 97% for Direct Compression (Item No. 41011636)	<b>Spec. No :</b> SP-AK30- A21/1
<b>Reference(s) :</b> Manufacturer's Specification	<b>Rev. No :</b> 02
<b>Other Requirements :</b> -----	<b>Page :</b> 1/2

GPO Specification

Test Items	Specification
Description	White, fine granular powder, odorless.
Identification	
A. Infrared absorption spectrophotometry	Examine the substances prepared as disc. Compare the spectrum with reference the spectrum of <i>Ascorbic acid 97% DC WS</i> . It should be concordant with <i>standard</i> .
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 : Sumanee, 05/01/16 Head of Raw Material Standard Section 1	Reviewed by : Ratapa, 05/01/16 Director of Raw Material Standard Division	Approved by : R (binh), 6/1/16 Director of Regulatory Compliance and Documentation Division	Eff. Date 25/02/16
----------------------------------------------------------------------------------	------------------------------------------------------------------------------------	------------------------------------------------------------------------------------------------------	-----------------------



## THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

## RAW MATERIAL SPECIFICATION

<b>Title :</b> Ascorbic Acid 97% for Direct Compression (Item No. 41011636)	<b>Spec. No</b> : SP-AK30- A21/1
<b>Reference(s) :</b> Manufacturer's Specification	<b>Rev. No</b> : 02
<b>Other Requirements :</b> -----	<b>Page</b> : 2/2

## 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	P plan : for Identification. $\sqrt{N} + 1$ : for other tests.
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	เนื้อหาเหมือนเดิม เนื่องจากเอกสารฉบับเก่ามีอายุมากกว่า 3 ปีจำเป็นต้องทบทวนและยังคงใช้ได้	25/02/16

เอกสารไม่ควบคุม  
ใช้ในการจัดซื้อ

Prepared by : Surannee, 05/01/16 Head of Raw Material Standard Section 1	Reviewed by : Walapa, 05/01/16 Director of Raw Material Standard Division	Approved by : B. Uthairat, 6/1/16 Director of Regulatory Compliance and Documentation Division	Eff. Date 25/02/16
-----------------------------------------------------------------------------------	------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------	-----------------------