

# THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

## RAW MATERIAL SPECIFICATION

<b>Title :</b> Ascorbic Acid USP [Fine Powder] (Item No. 41020180)	<b>Spec. No :</b> SP-AK30-A21/3
<b>Reference(s) :</b> USP 37 p. 1836-1837	<b>Rev. No :</b> 03
<b>Other Requirements :</b> GPO Specification	<b>Page :</b> 1/2

<b>USP 37</b>	Melting point	: Melts at about 190°C.
	Solubility	: Freely soluble in water; sparingly soluble in alcohol; insoluble in chloroform, in ether, and in benzene.
	Identification	: A. Infrared Absorption <197K> B. 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 0.002%.
	Optical Rotation, Specific Rotation	: Between +20.5° and +21.5°.
	Assay	: It contains not less than 99.0% and not more than 100.5% of $C_6H_8O_6$ .

<b>GPO Specification</b>	Description	: White crystalline powder; odorless.
	Fineness	
	- Pass through sieve no.100	: Not less than 98% by weight.

Prepared by : J. Noppadech, 17/07/14 Head of Raw Material Standard Section 2	Reviewed by : C. Suwanaporn, 17/07/14 Director of Raw Material Standard Division	Approved by : C. R. 17/07/14 Director of Regulatory Compliance and Documentation Division	Eff. Date 19/08/14
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### Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Ascorbic Acid USP [Fine Powder] (Item No. 41020180).
Sampling plan	$1 + \sqrt{N}$ plan.
Testing procedure	Tests to be performed as per current version of WI-AK30-COL048.
Storage condition	Store at a condition stated on the label from the manufacturer or store in tight, light-resistant containers.
Retest period	1 year after first testing date.

Prepared by :	Reviewed by :	Approved by :	Eff. Date
J. Noppadechy, 17/07/14	C. Suwanwattana, 17/07/14	....., 17/07/14	19/08/14
Head of Raw Material	Director of Raw Material	Director of Quality Assurance	
Standard Section 2	Standard Division	Department	
	Director of Regulatory Compliance and Documentation Division		