


THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Coated Ascorbic Acid, Type EC (Item No. 41011640)	Spec. No. : SP-AK30- A21/4
Reference(s) : GPO Specification	Rev. No. : 03
Other Requirements : -----	Page : 1/2

GPO Specification

Test Items	Specification
Description	White to slightly yellowish powder, odorless.
Identification - Infrared absorption	Conforms to IR standard spectrum.
Loss on drying	Not more than 0.1%.
Specific rotation	Between +48.5° and +50.5°, on dried basis at 20 °C.
Assay	Not less than 97.5% of ascorbic acid, calculated on dried basis.

Prepared by : (Acting) Thunyanthorn / 16/04/21 Head of Raw Material Standard Section 1	Reviewed by : (Acting) Suvannavee / 16/04/21 Director of Raw Material Standard Division	 / 14/04/21 Director of Drug Registration and Pharmacovigilance Division	Approved by : (Acting) Tarnwan / 20/04/21 Director of Quality Assurance Department	Eff. Date 15/05/21
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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Coated Ascorbic Acid, Type EC (Item No. 41011640).
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-A21/4.
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	31/10/11
02	เนื้อหาเหมือนเดิม เนื่องจากเอกสารฉบับเก่ามีอายุมากกว่า 3 ปีจำเป็นต้องทบทวนและทบทวนแล้วยังคงใช้ได้	25/02/16
03	เนื้อหาเหมือนเดิม เนื่องจากเอกสารฉบับเก่ามีอายุมากกว่า 3 ปีจำเป็นต้องทบทวนและทบทวนแล้วยังคงใช้ได้	15/05/21

Prepared by : Thanyatorn (Acting) Head of Raw Material Standard Section 1 16/04/21	Reviewed by : Sunanee (Acting) Director of Raw Material Standard Division 16/04/21	Approved by : (Acting) Director of Quality Assurance Department 20/04/21	Eff. Date 15/05/21
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