



COPY No. 2

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Antimony Potassium Tartrate USP (Item No. 41020140)	Spec. No : SP-AK30-A14
Reference(s) : USP 36 p.2515 -2516	Rev. No : 03
Other Requirements : -	Page : 1/2

USP36

Description	: Colorless, odorless, transparent crystals, or white powder.
Solubility	: Freely soluble in boiling water; soluble in water and in glycerin; insoluble in alcohol.
Completeness of solution	: The sample solution is not less clear than an equal volume of purified water contained in a similar vessel and examined similarly.
Identification	: A. This residue has an alkaline reaction, and when a small fragment of it is held in a nonluminous flame, the flame is tinted violet. B. In a solution (1 in 20), acidified with hydrochloric acid, hydrogen sulfide TS produces an orange-red precipitate, which is soluble in ammonium sulfide TS and in 1 N sodium hydroxide. C. It responds to the test for Tartrate.
Acidity or alkalinity	: Not more than 2.0 mL is required.
Loss on drying	: Not more than 2.7%.
Arsenic	: Not more than 0.015%.
Lead	: Not more than 0.002%.
Assay	: It contains not less than 99.0% and not more than 103.0% of Antimony Potassium Tartrate $[C_8H_4K_2O_{12}Sb_2 \cdot 3H_2O]$.

Prepared by : <u>J. Wopadech on losing</u> Head of Raw Material Standard Section 2	Reviewed by : <u>[Signature]</u> 11/05/17 Director of Raw Material Standard Division	Approved by : <u>[Signature]</u> 16/05/17 Director of Quality Assurance Department (Acting)	Eff. Date 20/06/17
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Product Information

Approved source (s)	Refer to current version of Approved Supplier List of Antimony Potassium Tartrate USP (Item No. 41020140).
Sampling plan	P plan : For Identification. $\sqrt{N} + 1$ plan : For Other Tests.
Testing procedure	Tests to be performed as per current version of WI-AK30-A14.
Storage condition	Store at a condition stated on the label from the manufacturer. Preserve in well-closed containers.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective Date
02	ทบทวนเอกสารให้ทันสมัย โดยอ้างอิงตาม USP31 และ GPO Specification	19/01/09
03	Update โดยอ้างอิงตาม USP36	20/06/17

Prepared by : J. Neppasdech, 09/05/17 Head of Raw Material Standard Section 2	Reviewed by : [Signature], 11/05/17 Director of Raw Material Standard Division	Approved by : [Signature], 15/05/17 Director of Regulatory Compliance and Documentation Division	Eff. Date 20/06/17
		Vithum Rungwongroj, 16/05/17 Director of Quality Assurance Department (Acting)	