

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title: Antimony Potassium Tartrate USP (Item No. 41020140)	Spec. No. : SP-AK30-A14
Reference(s): USP 42 page 345 - 346	Rev. No. : 04
Other Requirements: -	Page : 1/2

USP 42

Test Parameter	Requirement
Description	Colorless, odorless, transparent crystals, or white powder.
Solubility	Freely soluble in boiling water; soluble in water and in glycerin; insoluble in alcohol.
Identification	A. It chars, emits an odor resembling that of burning sugar, and leaves a blackened residue. 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. It yields 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.
Assay	99.0% - 103.0% of Antimony potassium tartrate $[C_8H_4K_2O_{12}Sb_2 \cdot 3H_2O]$.
Arsenic	Not more than 0.015%.
Lead	Not more than 20 ppm.
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.
Loss on drying	Not more than 2.7%.
Acidity or alkalinity	Not more than 2.0 mL of 0.010 N hydrochloric acid or 0.010 N sodium hydroxide.

Prepared by: <i>S. Ropadech</i> / 31/01/20 Head of Raw Material Standard Section 2	Reviewed by: <i>Tamra Limwong</i> / 31/01/20 Director of Raw Material Standard Division	Approved by: <i>Wichin Ruengprongroj</i> / 03/02/20 Director of Quality Assurance Department (Active)	Eff. Date 15/02/20
---	--	--	-----------------------

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title: Antimony Potassium Tartrate USP (Item No. 41020140)	Spec. No. : SP-AK30-A14
Reference(s): USP 42 page 345 - 346	Rev. No. : 04
Other Requirements: -	Page : 2/2

Product Information

Approved source(s)	Refer to current version of Approved Supplier List of Antimony Potassium Tartrate USP (Item No. 41020140).
Sampling plan	For Identification : 100%. For Other Tests : n plan.
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	พบทวนเอกสารให้ทันสมัย โดยอ้างอิงตาม USP 31 และ GPO Specification	19/01/09
03	Update โดยอ้างอิงตาม USP 36	20/06/17
04	Update ข้อกำหนดตาม USP 42	15/02/20

Prepared by: J. Koppadech / 31/01/20 Head of Raw Material Standard Section 2	Reviewed by: <div style="display: flex; justify-content: space-between;"> <div> <i>Tumma</i> Limkumthong / 31/01/20 Director of Raw Material Standard Division </div> <div> <i>[Signature]</i> 31/01/20 Director of Drug Registration and Pharmacovigilance Division </div> </div>	Approved by: <div style="display: flex; justify-content: space-between;"> <div> <i>Vichum</i> Ruengroj / 03/02/20 Director of Quality Assurance Department (Acting) </div> </div>	Eff. Date 15/02/20
---	---	---	-----------------------