COPY No. 9

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Atropine Sulfate USP (Item No. 41030420)	**Spec. No.** : SP-AK30-A003
Reference(s) : USP 41 p. 405 - 406	**Rev. No.** : 07
Other Requirements : -	**Page** : 1/2

USP 41

Test Parameters	Specifications	
Description	White, crystalline powder, odorless.	
Solubility	Very soluble in water; freely soluble in alcohol and even more so in boiling alcohol; freely soluble in glycerin.	
Identification A. Infrared absorption <197K>	Conforms to FT-IR standard spectrum.	
B. Sulfate	1. With barium chloride TS, solutions of sulfates yield a white precipitate that is insoluble in hydrochloric acid and in nitric acid. 2. With lead acetate TS, neutral solutions of sulfates yield a white precipitate that is soluble in ammonium acetate TS. 3. Hydrochloric acid produces no precipitate when added to solutions of sulfates (distinction from thiosulfates).	
C. HPLC	The retention time of the major peak in the Sample solution corresponds to that of the System suitability solution, as obtained in the Assay.	
Optical rotation	Between -0.50° and +0.05°.	
Water	Not more than 4.0%.	
Residue on ignition	Not more than 0.2%.	
Organic impurities	Tropic acid	: Not more than 0.2%.
	7-Hydroxyhyoscyamine	: Not more than 0.2%.
	Scopolamine	: Not more than 0.2%.
	6-Hydroxyhyoscyamine	: Not more than 0.2%.
	Hyoscyamine related compound A	: Not more than 0.3%.
	Littorine	: Not more than 0.2%.
	Apoatropine	: Not more than 0.2%.
	Any individual, unspecified impurity	: Not more than 0.1%.
	Total impurities	: Not more than 0.5%.
Assay	98.0 – 102.0% of Atropine sulfate $(C_{17}H_{23}NO_3)_2 \cdot H_2SO_4$, calculated on the anhydrous basis.	

Prepared by :	Reviewed by :		Approved by :	Eff. Date
Suwannee ,19/07/19	,26/07/19	,26/07/19	,30/07/19	30/10/19
Head of Raw Material Standard Section I	Director of Raw Material Standard Division	Director of Regulatory Compliance and Documentation Division	Director of Quality Assurance Department Acting	

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

COPY No. 3

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Atropine Sulfate USP (Item No. 41030420)	**Spec. No.** : SP-AK30-A003
Reference(s) : USP 41 p. 405 - 406	**Rev. No.** : 07
Other Requirements : -	**Page** : 2/2

Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Atropine Sulfate USP (Item No. 41030420).
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-A003.
Storage condition	Preserve in tight, light-resistant containers.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
05	อ้างอิง spec. เป็น USP 34	15/02/12
06	Update spec. เป็น USP 38 อ้างอิง CR No. AN80-59082	24/05/16
07	Update spec. เป็น USP 41 ตามประกาศกระทรวงสาธารณสุข เรื่องระบุตำรา พ.ศ. 2561 โดยให้ใช้ตำรายาฉบับ USP 39/BP 2016 ขึ้นไป นอกจากนี้เนื่องจากเอกสารมีอายุครบ 3 ปี จึงต้องทบทวน โดยเนื้อหาของ USP 38 และ USP 41 เหมือนกัน	30/10/19

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by :	Reviewed by :		Approved by :	Eff. Date
Head of Raw Material Standard Section I	Director of Raw Material Standard Division	Director of Regulatory Compliance and Documentation Division	Director of Quality Assurance Department	30/10/19