(1)

COPY No. 2

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Amitriptyline Hydrochloride USP (Item No. 41010090)	**Spec. No.** : SP-AK30-A26
Reference(s) : USP 39 p. 2494-2496	**Rev. No.** : 05
Other Requirements : GPO specification	**Page** : 1/3

USP 39

Test Items	Specification	
Description	White or practically white, odorless or practically odorless, crystalline powder.	
Solubility	Freely soluble in water, in alcohol, in chloroform and in methanol; insoluble in ether.	
Identification A. Infrared Absorption (197K) B. HPLC C. Chloride Test	The IR absorption spectrum of sample exhibits the same spectrum as Reference Standard. The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay. -Add one drop of diluted nitric acid and 0.5 ml of silver nitrate TS to a solution of 20 mg of sample in 2 ml of water ; a white curdy precipitate is formed. Centrifuge the mixture without delay and decant the supernatant layer. Wash the precipitate with three 1-ml portions of nitric acid solution (1 in 100), and discard the washings. Add ammonia TS dropwise to this precipitate. It dissolves readily.	
pH	Between 5.0 and 6.0, in a solution (1 in 100).	
Loss on drying	Not more than 0.5%.	
Residue on ignition	Not more than 0.1%.	
Heavy metals	Not more than 10 ppm, Method II.	
Organic impurities	Amitriptyline related compound A	: Not more than 0.05%.
	Amitriptyline related compound B	: Not more than 0.15%.
	Nortriptyline	: Not more than 0.15%.
	Cyclobenzaprine	: Not more than 0.15%.
	Any individual unspecified impurity	: Not more than 0.10%.
	Total impurities	: Not more than 1.0%.
Assay	98.0% to 102.0% of amitriptyline hydrochloride ($C_{20}H_{23}N.HCl$), calculated on the dried basis.	

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by :	Reviewed by :		Approved by :	Eff. Date
Suwannee /04/07/17	Yuwaree /17/07/17	/18/07/17	/19/07/17	27/07/17
Head of Raw Material Standard Section 1	Director of Raw Material Standard Division	Director of Regulatory Compliance and Documentation Division	Director of Quality Assurance Department (Acting)	

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GPO Specification

Test Items	Specification
Particle size - Laser diffraction, Malvern d (0.9)	70-180 µm.

Method Parameters for Particle Size Analysis Malvern Mastersizer 2000

No.	Parameter	Specification
1	Condition	Dry Dispersion (Air pressure 2.5-3.5 bar).
2	Absorption	0.1 (For slightly colored powders).
3	Particle Refractive Index (RI)	1.520 (For organic compounds).
4	Weighted Residual	< 2%.
5	Obscuration	1% - 3%.
6	Analysis Model	General purpose.
7	Particle Shape	Irregular-particles have angular shapes (default).
8	Measurement Integration Time	≥ 3000 ms/ sample and measure 20 times/ sample.
9	Measurement Background Time	≥ 10 seconds.
10	Result Units	Volume.

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Product Information

Approved source (s)	Refer to current version of Approved Vendor List of Amitriptyline Hydrochloride USP (Item No. 41010090).
Sampling plan	P plan : for Identification. $\sqrt{N} + 1$: for other tests.
Testing procedure	Tests to be performed as per current version of WI-AK30-A26.
Storage condition	Preserve in well-closed containers.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective date
04	Update spec. เป็น USP 34	20/03/15
05	อ้างอิง CR No. AN80-60061 Update spec. เป็น USP 39 โดยเนื้อหาของ USP 34 และ USP 39 เหมือนกัน เพื่อใช้สำหรับตำรับยา E-bidding และให้สอดคล้องกับ FP spec. โดยต้องอ้างอิงไม่ต่ำกว่า USP 35	27/07/17

เอกสารใช้ภายนอก
ใช้ในการจัดซื้อ

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