



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

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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)	The IR absorption spectrum of sample exhibits the same spectrum as Reference Standard.
B. HPLC	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.
C. Chloride Test	-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.

เอกสารไม่ควรถูก
ใช้ในการตัดสินใจ

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

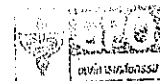
Test Items	Specification
Particle size - Laser diffraction, Malvern d (0.9)	70-180 μ m.

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	\geq 3000 ms/ sample and measure 20 times/ sample.
9	Measurement Background Time	\geq 10 seconds.
10	Result Units	Volume.

เอกสารนี้ควบคุม
ใช้ในการจัดซื้อ

Prepared by : Sunannee, 04/07/17 Head of Raw Material Standard Section 1	Reviewed by : Yuwapan, 17/07/17 Director of Raw Material Standard Division	Approved by : Vichum Rungtongroj, 19/07/17 Director of Quality Assurance Department (Acting)	Eff. Date 27/07/17
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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

เอกสารนี้เป็นเอกสาร
ใช้ในการจัดซื้อ

Prepared by : Sunanee 04/07/17 Head of Raw Material Standard Section 1	Reviewed by : Yuxipom 17/07/17 Director of Raw Material Standard Division	Approved by : Vichan 19/07/17 Director of Quality Assurance Department (Pharm.)	Eff. Date 27/07/17
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