GPO COPY No. 3

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title : Fluoxetine Hydrochloride USP (Item No. 41031975)		**Spec. No**	: SP-AK30-F23
Reference(s) : USP 37 p.3035-3036		**Rev. No**	: 02
Other Requirements : GPO Specification		**Page**	: 1/3

USP 37

	Description	: White to off-white, crystalline powder.
	Solubility	: Freely soluble in alcohol and in methanol; sparingly soluble in water and in dichloromethane; practically insoluble in ether.
	Identification	: A. Infrared absorption B. It responds to the tests for Chloride <191>.
	Water	: Not more than 0.5%.
	Heavy metals, Method II	: Not more than 0.003%.
	Related compounds	
	— fluoxetine related compound A	: not more than 0.15%,
	— α-[2-(methylamino)ethyl]-benzenemethanol	: not more than 0.25%,
	— fluoxetine related compound B	: not more than 0.25%,
	— any other individual impurity	: not more than 0.1%,
	— the sum of all impurities	: not more than 0.5%.
	Assay	: It contains not less than 98.0% and not more than 102.0% of $C_{17}H_{18}F_3NO \cdot HCl$, calculated on the anhydrous basis.

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by :	Reviewed by :		Approved by :	Eff. Date
J. Noppadechy 30/04/15	Nalaya 30/04/15	30/04/15	Prapanadee C. 30/04/15	10/05/15
Head of Raw Material Standard Section 2	Director of Raw Material Standard Division	Director of Regulatory Compliance and Documentation Division	Director of Quality Assurance Department	

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GPO Specification	Tapping volume	: 5.0-g portion occupies not more than 14.0 mL when tapped down mechanically for 20 drops at 3-mm height and nominal rate of 250 drops/min.
	Fineness	
	— Pass though sieve no.30	: For information
	Tapped Density	: For information

Prepared by :	Reviewed by :		Approved by :	Eff. Date
J. Noppadech 30/04/15	Walaya 30/04/15	30/04/15	Prapanadda 30/04/15	10/05/15
Head of Raw Material Standard Section 2	Director of Raw Material Standard Division	Director of Regulatory Compliance and Documentation Division	Director of Quality Assurance Department	

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Product Information

Approved source (s)	Refer to current version of Approved Supplier List of Fluoxetine Hydrochloride USP (Item No. 41031975).
Sampling plan	$1 + \sqrt{N}$ plan.
Testing procedure	Tests to be performed as per current version of WI-AK30-F23.
Storage condition	Store at a condition stated on the label from the manufacturer or store in tight container(s).
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Reviewed by	Effective Date
01	ประกาศใช้ครั้งแรก (USP 34)	ผอก. มาตรฐานวัตถุดิบ	29/09/11
02	Update ข้อกำหนดตาม USP 37	ผอก. มาตรฐานวัตถุดิบ	10/05/15

เอกสารไม่ควบคุม
ใช้ในการจัดซื้อ

Prepared by :	Reviewed by :		Approved by :	Eff. Date
J. Noppadech 30/04/15	Walapa 30/04/15	30/04/15	Prapanadee (Acting) 30/04/15	10/05/15
Head of Raw Material Standard Section 2	Director of Raw Material Standard Division	Director of Regulatory Compliance and Documentation Division	Director of Quality Assurance Department	