GPO COPY No. 2

THE GOVERNMENT PHARMACEUTICAL ORGANIZATION

RAW MATERIAL SPECIFICATION

Title: Fluoxetine Hydrochloride USP (Item No. 41031975)	**Spec. No.** : SP-AK30-F23
Reference(s): USP 41 page 1809 - 1810	**Rev. No.** : 03
Other Requirements: GPO Specification	**Page** : 1/3

USP 41

Test Parameters	Requirement	
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.	
Organic impurities	Aminomethyl-1-phenylpropanol	: Not more than 0.25%.
	Fluoxetine related compound B	: Not more than 0.25%.
	Fluoxetine related compound A	: Not more than 0.15%.
	4-Trifluoromethylphenol	: Not more than 0.1%.
	Any individual unspecified impurity	: Not more than 0.1%.
	Total impurities	: Not more than 0.5%.
Water	Not more than 0.5%.	
Assay	98.0% - 102.0% of Fluoxetine hydrochloride ($C_{17}H_{18}F_3NO \cdot HCl$), calculated on the anhydrous basis.	

Prepared by:	Reviewed by:		Approved by:	Eff. Date
J. Kloppadech, 29/01/20	Tawee Lubvorn, 29/01/20	, 30/01/20	Vichien Rungrongroj, 30/01/20	15/03/20
Head of Raw Material Standard Section 2	Director of Raw Material Standard Division	Director of Drug Registration and Pharmacovigilance Division	Director of Quality Assurance Department Acting	

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GPO Specification

Test Parameters	Requirement
Heavy metals	Not more than 30 ppm.
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 through sieve number 30]	For information.
Tapped density	For information.

Prepared by:	Reviewed by:		Approved by:	Eff. Date
J. Boppadech 29/01/20	29/01/20	30/01/20	30/01/20	15/03/20
Head of Raw Material Standard Section 2	Director of Raw Material Standard Division	Director of Drug Registration and Pharmacovigilance Division	Director of Quality Assurance Department (Acting)	

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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	For Identification : 100%. For Other Tests : 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. Preserve in tight containers.
Retest period	1 year after first testing date.

History of changes

Rev. No.	Description	Effective Date
00	ประกาศใช้ครั้งแรก USP 27	25/06/04
01	Update ข้อกำหนดตาม USP 34	29/09/11
02	Update ข้อกำหนดตาม USP 37	10/05/15
03	Update ข้อกำหนดตาม USP 41 และ GPO Specification	15/03/20

Prepared by:	Reviewed by:		Approved by:	Eff. Date
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