WANBURY

Certificate of Analysis

Product	: Sertraline Hydrochloride Form-I Ph.Eur	Batch No	: SN02531118
Mfg. Date	: Nov,2018	Retest Date	: Oct, 2023
Dispatch Quantity	: 25 Kg	No. of containers	: 01
Customer Name	: COLUMBUS TRANSIT S.A. SPAIN		

S. No	Test	Result	Specification
01	Appearance	White crystalline powder	White or almost white crystalline powder.
	Solubility	Complies	Slightly soluble in water, Slightly soluble in anhydrous ethanol, slightly soluble in acetone and in isopropanol.
02	Identification		
	A) Specific optical rotation (anhydrous substance)	+40.6°	+38.8° to +43.0° (Measured at 25°C)
	B) By IR	Concordant	The IR spectrum concordant with spectra obtained with Sertraline Hydrochloride Form-I working standard.
	C) Reaction of (a) of chlorides	Complies	The solution gives reaction of chloride.
03	Enantiomeric purity by HPLC Impurity G	0.44 %	Not more than 1.5 %
04	Impurity E (by HPLC)	Below Detectable Limit	Not more than 0.2 %
05	Related substances (by GC)		
	Impurity A	0.09 %	Not more than 0.2 %
	Impurity B	Below Detectable Limit	Not more than 0.2 %
	Impurity F	Below Detectable Limit	Not more than 0.2 %
	Sum of impurities C and D	Below Quantification Limit	Not more than 0.8 %
	Unspecified impurity	0.02 %	Not more than 0.10 %
	Total impurities	0.18 %	Not more than 1.5 %
06	Heavy metals	Less than 20 ppm	Not more than 20 ppm
07	Water content	0.04 %	Not more than 0.5 %
08	Sulfated Ash	0.04 %	Not more than 0.2 %
09	Assay on anhydrous basis (By HPLC)	99.9 %	97.5 % to 102.0 %
Additional Tests:			
10	Residual Solvents		
	Ethyl acetate	49 ppm	Not more than 2000 ppm
	Isopropyl alcohol	Below Detectable Limit	Not more than 200 ppm
	Methanol	Below Detectable Limit	Not more than 500 ppm
11	Particle size by Malvern		
	d(0.10)	1.7 µm	Not more than 20 µm
	d(0.50)	20.0 µm	Not more than 60 µm
	d(0.90)	79.0 µm	Not more than 120 µm

Remarks: The product complies with Ph. Eur / R1CEP 2008-173-Rev.04/customer specification..

Prepared by:
Asst. Manager– QC
Date: 01/12/18

Reviewed by:
Dy. Manager-QC
Date: 01/12/18

Approved by:
Manager - QA
Date: 01/12/18

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Regd. Office : 10th Floor, B-Wing, BSEL, Tech Park, Sector-30A, Opp. vashi railway stn., Vashi Navi Mumbai-400703. (INDIA)
Tel. : 91-22-6794 2222, Fax : 91-22-6794 2111/333

WANBURY

Certificate of Analysis

Product	: Sertraline Hydrochloride Form-I Ph.Eur	Batch No	: SN02541118
Mfg. Date	: Nov,2018	Retest Date	: Oct, 2023
Dispatch Quantity	: 200 Kg	No. of containers	: 08
Customer Name	: COLUMBUS TRANSIT S.A. SPAIN		

S. No	Test	Result	Specification
01	Appearance	White crystalline powder	White or almost white crystalline powder.
	Solubility	Complies	Slightly soluble in water, Slightly soluble in anhydrous ethanol, slightly soluble in acetone and in isopropanol.
02	Identification		
	A) Specific optical rotation (anhydrous substance)	+41.4°	+38.8° to +43.0° (Measured at 25°C)
	B) By IR	Concordant	The IR spectrum concordant with spectra obtained with Sertraline Hydrochloride Form-I working standard.
	C) Reaction of (a) of chlorides	Complies	The solution gives reaction of chloride.
03	Enantiomeric purity by HPLC Impurity G	0.43 %	Not more than 1.5 %
04	Impurity E (by HPLC)	Below Detectable Limit	Not more than 0.2 %
05	Related substances (by GC)		
	Impurity A	0.10 %	Not more than 0.2 %
	Impurity B	Below Detectable Limit	Not more than 0.2 %
	Impurity F	Below Detectable Limit	Not more than 0.2 %
	Sum of impurities C and D	Below Quantification Limit	Not more than 0.8 %
	Unspecified impurity	0.02 %	Not more than 0.10 %
	Total impurities	0.20 %	Not more than 1.5 %
06	Heavy metals	Less than 20 ppm	Not more than 20 ppm
07	Water content	0.03 %	Not more than 0.5 %
08	Sulfated Ash	0.05 %	Not more than 0.2 %
09	Assay on anhydrous basis (By HPLC)	99.7 %	97.5 % to 102.0 %
Additional Tests:			
10	Residual Solvents		
	Ethyl acetate	49 ppm	Not more than 2000 ppm
	Isopropyl alcohol	Below Detectable Limit	Not more than 200 ppm
	Methanol	Below Detectable Limit	Not more than 500 ppm
11	Particle size by Malvern		
	d(0.10)	1.7 µm	Not more than 20 µm
	d(0.50)	22.2 µm	Not more than 60 µm
	d(0.90)	90.3 µm	Not more than 120 µm

Remarks: The product complies with Ph. Eur / R1CEP 2008-173-Rev.04/customer specification..

Prepared by:
Asst. Manager– QC
Date: 01/12/18

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Date: 01/12/18

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