

**WANBURY****Certificate of Analysis**

Product	: Sertraline Hydrochloride Form-II Ph. Eur	Batch No	: SK00030515
Mfg. Date	: May, 2015	Retest Date	: Apr, 2020
Quantity	: 100 Kg	No. of containers	: 04

S. No	Test	Result	Specification
01	Appearance	White crystalline powder	A White or almost white crystalline powder
02	Solubility	Complies	Slightly soluble in water, sparingly soluble or slightly soluble in anhydrous ethanol, slightly soluble in acetone and in Isopropanol.
03	Identification		
	A) Specific optical rotation (anhydrous substance)	+39.2°	+38.8° and +43.0° (Measured at 25°C)
	B) By IR	Concordant	The IR spectrum concordant with spectra obtained with Sertraline Hydrochloride Form-II working standard.
	C) Test for chlorides	Complies	The solution gives reaction of chloride
	D) Enantiomeric purity (by HPLC) Impurity G	Complies	The retention time of the major peak in chromatogram of the test preparation corresponds to that in the chromatogram of reference solution (a) of Sertraline peak as obtained in the Enantiomeric purity method.
04	Enantiomeric purity (by HPLC) Impurity G	1.00 %	Not more than 1.5 %
05	Impurity E (by HPLC)	0.003 %	Not more than 0.2 %
06	Related Substances by GC		
	Impurity – A	Not detected	Not more than 0.2 %
	Impurity – B	Not detected	Not more than 0.2 %
	Impurity – F	Not detected	Not more than 0.2 %
	Sum of impurities C and D	0.06 %	Not more than 0.8 %
	Unspecified impurity	0.05 %	Not more than 0.10 %
	Total impurities	0.16 %	Not more than 1.5 %
07	Heavy Metals	Less than 20 ppm	Not more than 20 ppm
08	Water content	0.05 %	Not more than 0.5 % w/w
09	Sulphated ash	0.05 %	Not more than 0.2 % w/w
10	Assay by HPLC	99.4 %	97.5% to 102.0% (anhydrous basis)
<b>Additional Tests:</b>			
11	Residual Solvents		
	Methanol	63 ppm	Not more than 500 ppm
	Isopropyl alcohol	Below detectable limit	Not more than 200 ppm
	Ethyl acetate	124 ppm	Not more than 2000 ppm
12	XRD	Complies	Should be match with Sertraline HCl Form-II Working Standard
13	Particle size by Malvern		
	D(0.1)	3.8 µm	For Information
	D(0.5)	34.7 µm	For Information
	D(0.9)	91.9 µm	For Information

Remarks: The product complies with Ph. Eur-8<sup>th</sup> Edition, R1-CEP 2008-173-Rev01 / In-house specifications.

Prepared By:

Executive – QC

Date: 21/05/15

Reviewed By:

Dy. Manager – QC

Date: 21/05/15

Approved By:

Dy. Manager – QA

Date: 21/05/15

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