Issued on 15/02/2013

HETERO DRUGS LIMITED QUALITY ASSURANCE QA RELEASED 15/02/2013

Hetero Drugs Limited

S.No.s, 213, 214 & 255, Bonthapally Village, Jinnaram Mandal, Medak District, Andhra Pradesh, INDIA.
Phone: +91-8458-275314/275777, Fax: +91-8458-275271

CERTIFICATE OF ANALYSIS

Product	: Sertraline hydrochloride (Form-II)	Reference STP No.	: SRI-007-02
Batch No.	: SR0060113	Reference	: Ph.Eur.
Date of Manufacture	: January - 2013	Batch Quantity	: 439.53 Kg
Analytical Report No.	: SR009/13	Date of Analysis	: 15/02/2013
		Retest date	: December- 2017
		Status	: Re-certified

S.No.	Test	Specifications	Results	Reference
1	Appearance	White or almost white, crystalline powder	A white crystalline powder	Visual Inspection
* 2	Solubility	Sparingly soluble in methanol and in Dimethylformamide.	Complies	Visual Inspection
3	Polymorphism by XRD	XRD: The X-ray diffractogram of the test sample should match with that of Sertraline hydrochloride (Form-II) working standard.	Matches with the standard diffractogram	Ph.Eur. < 2.9.33 >
4	Identification by	a) Specific optical rotation on anhydrous basis: Should be between (+) 38.8° to (+) 43.0°	(+) 39.2°	Ph.Eur. < 2.2.7 >
		b) IR: The Infra Red absorption spectrum of the finely ground sample in KCl dispersion compressed into a disc should exhibit maxima only at the same wave numbers as that of a similar preparation of Sertraline Hydrochloride (Form-II) Working standard.	Matches with the standard spectrum	Ph.Eur. < 2.2.24 >
		* c) HPLC: The retention time of the principal peak obtained in assay preparation-1 should match with that of the standard preparation-1 in Assay on anhydrous basis by HPLC.	Matches with the standard	Ph.Eur. < 2.2.29 >
		d) Chlorides: Should comply the test for chlorides.	Complies	Ph.Eur. < 2.3.1 >
		* e) DSC: The thermogram of the test sample should matches with that of Sertraline Hydrochloride (Form-II) working standard.	Matches with the standard thermogram	Ph.Eur. < 2.2.34 >
* 5	Chloride content on anhydrous basis	Should be between 10.1% and 10.6% w/w	10.3 % w/w	Ph.Eur. < 2.2.20 > In-House
* 6	Water content	Not more than 0.50 % w/w	0.12 % w/w	Ph.Eur. < 2.5.12 > In-House
7	Sulphated ash	Not more than 0.10% w/w	0.08 % w/w	Ph.Eur. < 2.4.14 >
8	Heavy metals	Not more than 0.001%w/w.	Less than 0.001%w/w	Ph.Eur. < 2.4.8 >
9	Enantiomeric purity by HPLC	(1R,4R)-4-(3,4-dichlorophenyl)-N-methyl-1,2,3,4-tetrahydrophthalen-1-amine (Sertraline enantiomer) (Impurity-G): Not more than 1.5%	0.10 % (LOQ=0.01%)	Ph.Eur. < 2.2.29 >
10	Impurity-E by HPLC	(2R)-hydroxyphenylacetic acid ((R)-mandelic acid) (Impurity-E): Not more than 0.2%	Below LOQ (LOQ=0.01%)	Ph.Eur. < 2.2.29 >
11	Related substances by GC	(1RS,4SR)-4-(3,4-dichlorophenyl)-N-methyl-1,2,3,4-tetrahydro naphthalen-1-amine (Impurity-A): Not more than 0.2%	0.07 % (LOQ=0.0492%)	Ph.Eur. < 2.2.28 >
		(1RS,4RS)-N-methyl-4-phenyl-1,2,3,4-tetrahydronaphthalen-1-amine (Impurity-B): Not more than 0.2%	Below LOQ (LOQ=0.0156%)	

Compiled by: Date: 15/02/2013

Checked by: Date: 15/02/2013

Authorised signatory: Date: 15/02/2013

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S.No.	Test	Specifications	Results	Reference
	Related substances by GC	Sum of (1RS,4RS)-4-(4-chloro phenyl)-N-methyl-1,2,3,4-tetrahydronaphtahlen-1-amine and (1RS,4RS)-4-(3-chlorophenyl)-N-methyl-1,2,3,4-tetrahydronaphthalen-1-amine (Sum of Impurities - C and D): Not more than 0.8%	0.02%	Ph.Eur. < 2.2.28 >
		(4R)-4-(3,4-dichlorophenyl)-3,4-dihydronaphthalen-1(2H)-one (Impurity-F): Not more than 0.2%	Not detected	
		unspecified impurities: Not more than 0.10%	0.06%	
		Total impurities Not more than 1.5%	0.15%	
12	Assay on anhydrous by HPLC	Should be between 98.0% w/w and 102.0 % w/w	99.9 % w/w	Ph.Eur. < 2.2.29 >
* 13	Residual solvents by GC**	Methanol : Not more than 500 ppm	Below LOQ (LOQ=30ppm)	Ph.Eur. < 2.2.28 > In-House
		Diisopropyl Ether : Not more than 50 ppm	Below LOQ (LOQ=25ppm)	
		Ethyl acetate : Not more than 500 ppm	Below LOQ (LOQ=25ppm)	
		n-Butyl alcohol : Not more than 1000 ppm	385 ppm (LOQ=25ppm)	

** No potential for the class-1 solvents as specified by ICH to be present in Sertraline hydrochloride (Form-II), as they are not used in the manufacturing process. The material if tested for these solvents, will comply with the established standards.

* In-house specifications

The product **conforms** to the above specifications

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