PACKING LIST

Exporter
HETERO DRUGS LIMITED
7-2-A2,HETERO CORPORATE
INDUSTRIAL ESTATES, SANATH NAGAR,
HYDERABAD-500018
INDIA

Invoice No. & Date.
1000003832 DT:21.09.2013

Buyer's Order No. & date
2013.102 DT:10.09.2013

Other Reference(s)

Consignee
M/s.COLUMBUS TRANSIT, S.A
AV.DRASSANES, 6-8 PLANTA 14
08001 BARCELONA, SPAIN.
K.ATTN.Mr. FERRAN VALLS OCHOA
NOTIFY: METAPHARMACEUTICAL IND.S.L.
C/ JOSEP PLA, N 163, ESC.B,PISO 2,LOCAL 5,
08020 BARCELONA - SPAIN.

Buyer's (if other than consignee)
META PHARMACEUTICAL IND. S.L
JOSEP PLA 163 ESC.B, PISO 20,LOCAL 5
BARCELONA
Spain-08020

Country of origin of goods	Country of final Destination
INDIA	Spain

Pre-carriage by	Place of receipt by pre-carriage
Vessel/Flight No.	Port of loading HYDERABAD / INDIA
Port of discharge BARCELONA / SPAIN	Place of Final Destination BARCELONA / SPAIN

Marks & Nos./	No.&Kind of pakgs	Description of Goods	Quantity	Remarks
METAPHARMACEUTICAL IND. S.L, BARCELONA, SPAIN.	EIGHT HDPE DRUMS [7X40+1X12 KGS] DRUM NO. 9577/2013 TO 9584/2013	SERTRALINE HCL	292.000 KG NET 328.500 KG GROSS	

BATCH NO(S): SR0410813

GROSS WT. : 328.500 KGS.
TARE WT. : 36.500 KGS.
NET WT. : 292.000 KGS.

Signature & Date
For HETERO DRUGS LIMITED

Authorised Signatory

21/09/2013

HETERO DRUGS LIMITED QA RELEASED 21/09/2013 QUALITY ASSURANCE

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.	: SR0410813	Reference	: Ph.Eur.
Date of Manufacture	: August - 2013	Batch Quantity	: 441.25 Kg
Analytical Report No.	: SR057/13	Date of Analysis	: 02/09/2013
		Retest date	: July - 2018
		Status	: Initial certification

S.No.	Test	Specifications	Results	Reference
1	Appearance	White or almost white, crystalline powder	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°	(+) 39.9°	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	0.17 % w/w	Ph.Eur. < 2.5.12 > In-House
7	Sulphated ash	Not more than 0.10% w/w	0.07 % 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%	0.03% (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%	0.04% (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: 02/09/2013

Checked by: Date: 02/09/2013

Authorised signatory: Date: 02/09/2013