Lote: 007/115

RECORDATI
INDUSTRIA CHIMICA E FARMACEUTICA S.p.A.
VIA M. CIVITALI, 1 - 20148 MILANO. ITALIA
TEL. (39) 0248787.1
MANUFACTORING SITE: CAMPOVERDE
VIA MEDIANA CISTERNA, 4
04011 CAMPOVERDE DI APRILIA (LT), ITALY
Tel.(39) 0692900010 - FAX.(39) 0692902016

Certificate of Analysis

Date
27.10.2015
Purchase Order No. / Date
2015 6595 / 21.10.2015
Delivery Note No.
5535000068 000010
Export No. / Date
5515000060 000010 / 23.10.2015
Customer's Code No.
618600

N. of Packages: 1 DRUM/S

SERTRALINE HYDROCHLORIDE POL. 1
EUR.PH.8 ED. USP 38
Code N.: 08015600
Lot N.: 15100541 **Quantity Delivered:** 5 KG
Manufacturing Date: 25.07.2015 **Retesting Date:** 23.07.2020

Analysis N.: 30000274415 **Date** 03.08.2015
Analytical Procedure: 148SR1-15

Solubility:
Very soluble in dimethylsulfoxide and chloroform; soluble in dilute methanolic and ethanolic HCl; slightly soluble in water; insoluble in dilute NaOH.

ANALYTICAL TESTS	RESULTS	SPECIFICATIONS MIN	MAX
Description	Complies	White or almost white crystalline powder	
IR Spectrum identification	Complies	Complies with the reference	
Chlorides identification	Positive	Positive	
Diff.scanning cal.(DSC)	Complies	Complies	
Loss on drying	0.03 %		0.50 %
Water content (K.F.)	0.02 %		0.50 %
Sulphated ash	0.03 %		0.10 %
Heavy metals	< 10 ppm		10 ppm

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ANALYTICAL TESTS	RESULTS	SPECIFICATIONS MIN	MAX	
Specific optical rotation	40.1 °	38.8	41.2	°
HPLC EP Imp A (trans-sertraline)	< 0.05 %		0.10	%
HPLC EP Imp B (dehalg-sertraline)	< 0.05 %		0.10	%
HPLC EP Imp C (4-monochloro)	< 0.05 %		0.20	%
HPLC EP Imp D (3-monochloro)	< 0.05 %		0.10	%
HPLC EP Imp E (mandelic ac.)	< 0.05 %		0.20	%
HPLC EP Imp F (Tetralon)	< 0.05 %		0.20	%
HPLC Each max.unidentified	< 0.05 %		0.10	%
HPLC Total impurities	< 0.05 %		1.00	%
HPLC assay (on dried basis)	99.5 %	99.0	101.0	%
HPLC Enantiomeric Purity "Eur.Ph.	0.05 %		1.50	%
Org.res.solv.Ethanol	22 ppm		100	ppm

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ANALYTICAL TESTS	RESULTS	SPECIFICATIONS MIN	MAX	
Org.res.solv.Ethyl acetate	146 ppm		750	ppm
Org.res.solv.Toluene	4 ppm		100	ppm
Particle size D(10%)	22 µm			µm
Particle size D(50%)	78 µm			µm
Particle size D(90%)	163 µm			µm
Particle size D(37%)	62 µm		100	µm
Particle size D(95 %)	192 µm		425	µm
Bulk density Loose	0.69 gr/ml			gr/ml
Bulk density Tapped	0.77 gr/ml			gr/ml

This batch has been manufactured, packaged and tested in accordance with EU GMP Guideline Volume 4 Part II (ICHQ7).

QUALITY CONTROL MANAGER
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