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
08.09.2014
Purchase Order No. / Date

Delivery Note No.

Export No. / Date

Customer's Code No.

N. of Packages: DRUM/S

SERTRALINE HYDROCHLORIDE POL. 1
EUR.PH.8 ED.
Code N.: 08015600
Lot N.: 14100379 **Quantity Delivered:** KG
Manufacturing Date: 15.05.2014 **Retesting Date:** 14.05.2019

Analysis N.: 30000257271 **Date** 26.05.2014
Analytical Procedure: 148SR1-14

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	0.04 %		0.50 %
Water content (K.F.)	0.02 %		0.50 %
Sulphated ash	0.02 %		0.10 %
Heavy metals	< 10 ppm		10 ppm

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Delivery Note No.
5424001546 000010

N. of Packages: DRUM/S

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ANALYTICAL TESTS	RESULTS	SPECIFICATIONS MIN	MAX
Specific optical rotation	39.1 °	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)	0.06 %		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	0.06 %		1.00 %
HPLC assay (on dried basis)	99.9 %	99.0	101.0 %
HPLC Enantiomeric Purity "Eur.Ph.	0.02 %		1.50 %
Org.res.solv.Ethanol	< 4 ppm		100 ppm

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ANALYTICAL TESTS	RESULTS	SPECIFICATIONS MIN	MAX	
Org.res.solv.Ethyl acetate	110 ppm		750	ppm
Org.res.solv.Toluene	< 1 ppm		100	ppm
Particle size D(10%)	41 µm			µm
Particle size D(50%)	109 µm			µm
Particle size D(90%)	221 µm			µm
Particle size D(37%)	88 µm		100	µm
Particle size D(95 %)	258 µm		425	µm
Bulk density Loose	0.72 gr/ml			gr/ml
Bulk density Tapped	0.82 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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