

Lot: 0160916

Certificate of Analysis

Date
06.09.2016
Purchase Order No. / Date
2016 4910 / 20.07.2016
Delivery Note No.
5635000057 000010
Export No. / Date
5615000044 000010 / 20.07.2016
Customer's Code No.
618600

N. of Packages: 1 DRUM/S

SERTRALINE HYDROCHLORIDE POL. 1

EUR.PH.8 ED. USP 39

Code N.: 08015600

Lot N.: 16100483 Quantity Delivered: 25 KG

Manufacturing Date: 18.07.2016 Retesting Date: 17.07.2021

Analysis N.: 30000298317 Date 21.07.2016

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

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ANALYTICAL TESTS	RESULTS	SPECIFICATIONS	
		MIN	MAX
Specific optical rotation	41.0 °	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.)	< 0.01 %		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)	99.4 %	99.0	101.0 %
HPLC Enantiomeric Purity "Eur.Ph.	< 0.05 %		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	92 ppm	750	ppm
Org.res.solv.Toluene	< 1 ppm	100	ppm
Particle size D(10%)	25 µm	µm	
Particle size D(50%)	108 µm	µm	
Particle size D(90%)	240 µm	µm	
Particle size D(37%)	81 µm	100	µm
Particle size D(95 %)	275 µm	425	µm
Bulk density Loose	0.69 gr/ml	gr/ml	
Bulk density Tapped	0.83 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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