JUBILANT LIFESCIENCES

QUALITY CONTROL DEPARTMENT

CITALOPRAM HYDROCHLORIDE – Ph.Eur.

CERTIFICATE OF ANALYSIS

Commercial batch # :	**CHL/1302002**	Dispatch Qty.	: 50.00 Kg
In-house Batch #	: 2CHL2/13002	Batch Qty.	: 64.30 Kg
Mfg. Date	: February– 2013	Retest. Date	: January– 2017
Specification #	: QCD/SP/FP/CHL/001-R_1	Method #	: QCD/MH/FP/CHL/001-R_1

Sl. #.	TESTS	OBSERVATIONS	STANDARD LIMIT
1	Characters		
	- Appearance	Almost white crystalline powder	White or almost white crystalline powder
	- Solubility	Meets the requirement	Very soluble in water, freely soluble in anhydrous ethanol.
2	Identification		
	- Optical rotation	Meets the requirement	Sample is to comply with the test
	- IR absorption spectrophotometry	Meets the requirement	The IR absorption spectrum of sample should be concordant with that of working standard
	- Test for Chloride	Positive	Should be positive
3	Appearance of solution	Meets the requirement	Should be clear and not more intensely colored than reference solution Y_6
4	Loss on drying at 105°C for 4 hrs	0.21%	Not more than 0.5%
5	Optical rotation (5% in methanol at 20°C)	0.02°	Between -0.10° and + 0.10°
6	Sulphated ash	0.04%	Not more than 0.1%
7	Heavy metals	Less than 20 ppm	Not more than 20ppm
8	Related substances by HPLC		
	Impurities at 230 nm		
	- Impurity - B	Not detected	Not more than 0.15%
	- Maximum unspecified impurity	Below disregard limit (0.05%)	Not more than 0.10%
	- Sum of the impurities	Not found	Not more than 0.2%
9	Assay by Potentiometry (on dried basis)	101.2%	99.0% - 101.5%
10	Additional tests		
a)	Residual solvents		
	- Methanol	18 ppm	NMT 1000 ppm
	- Isopropyl alcohol	652 ppm	NMT 3000 ppm
	- Toluene	Below detection limit (0.6 ppm)	NMT 100 ppm
	- Methylene dichloride	Below detection limit (7.5 ppm)	NMT 300 ppm
	- Tetrahydrofuran	Below detection limit (0.48 ppm)	NMT 300 ppm
	- Cyclohexane	6 ppm	NMT 1000 ppm

Remark: The product complies with above specification+ Customer's specification (CSO/459-R_2/13)
Storage condition: Store in airtight containers below 25°C
Note: The values given in the parenthesis are for limit of detection of HPLC and residual solvents

PREPARED BY : Date : 11/03/13	CHECKED BY : Date : 11/03/13	APPROVED BY : Date : 11/03/13

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