



**JUBILANT**  
**LIFE SCIENCES**

QUALITY CONTROL DEPARTMENT  
CITALOPRAM HYDROCHLORIDE – Ph.Eur.  
CERTIFICATE OF ANALYSIS

Commercial batch # : <b>CHL/1212006</b>		Dispatch Qty. : 50.00 Kg	
In-house Batch # : 2CHL2/12006		Batch Qty. : 63.20 Kg	
Mfg. Date : December– 2012		Retest. Date : November– 2016	
Specification # : QCD/SP/FP/CHL/001-R <sub>1</sub>		Method # : QCD/MH/FP/CHL/001-R <sub>1</sub>	

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 <sub>6</sub>
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)	-0.01°	Between -0.10° and + 0.10°
6	Sulphated ash	0.03%	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 - Maximum unspecified impurity - Sum of the impurities	Not detected 0.06% 0.06%	Not more than 0.15% Not more than 0.10% Not more than 0.2%
9	Assay by Potentiometry (on dried basis)	100.9%	99.0% - 101.5%
10	Additional tests a) Residual solvents - Methanol - Isopropyl alcohol - Toluene - Methylene dichloride - Tetrahydrofuran - Cyclohexane	Below quantification limit(16 ppm) 957ppm Below detection limit (0.6 ppm) Below detection limit (7.5 ppm) Below detection limit (0.48 ppm) 12 ppm	NMT 1000 ppm NMT 3000 ppm NMT 100 ppm NMT 300 ppm NMT 300 ppm NMT 1000 ppm

**Remark:** The product complies with above specification+ Customer's specification (CSO/459-R<sub>1</sub>/11)  
**Storage condition:** Store in airtight containers below 25°C  
**Note:** The values given in the parenthesis are for limit of detection and quantification of HPLC and residual solvents

PREPARED BY : <i>P. 06/12/12</i>	CHECKED BY : <i>P. 06/12/12</i>	APPROVED BY : <i>[Signature]</i>
Date : <i>06/12/12</i>	Date : <i>06/12/12</i>	Date : <i>06/12/12</i>

A Jubilant Bhartia Company

OUR VALUES



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