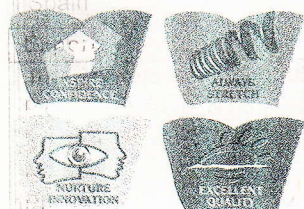


QUALITY CONTROL DEPARTMENT
CITALOPRAM HYDROCHLORIDE – Ph.Eur.
CERTIFICATE OF ANALYSIS

Commercial batch # : CHL/1307005		Dispatch Qty. : 52.00 Kg	
In-house Batch # : 2CHL2/13005		Batch Qty. : 60.30 Kg	
Mfg. Date : July– 2013		Retest. Date : June– 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	0.20%	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	0.05%	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	0.05%	Not more than 0.10%
	- Sum of the impurities	0.05%	Not more than 0.2%
9	Assay by Potentiometry (on dried basis)	99.9%	99.0% - 101.5%
10	Additional tests		
a)	Residual solvents		
	- Methanol	21 ppm	NMT 1000 ppm
	- Isopropyl alcohol	491 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	11 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 : <i>R 24/07/13</i> Date		CHECKED BY : <i>[Signature]</i> Date	APPROVED BY : <i>[Signature]</i> Date

A Jubilant Bhartia Company

OUR VALUES



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