

QUALITY CONTROL DEPARTMENT  
CITALOPRAM HYDROBROMIDE – Ph.Eur.

CERTIFICATE OF ANALYSIS




Commercial batch # : CTH/1406063	Dispatch Qty. : 80.00 Kg
In-house Batch # : 2CTH9/14061	Batch Qty. : 86.40 Kg
Mfg. Date : June- 2014	Exp. Date : May - 2019
Specification # : QCD/SP/FP/CTH/004-R <sub>4</sub>	Method # : QCD/MH/FP/CTH/004-R <sub>3</sub>

Sl. #.	TESTS	OBSERVATIONS	STANDARD LIMIT
1	Characters - Appearance - Solubility	Almost white powder Meets the requirement	White or almost white crystalline powder Sparingly soluble in water and in anhydrous ethanol.
2	Identification - Optical rotation - IR absorption spectrophotometry - Test for Bromide	Meets the requirement Meets the requirement Positive	Should be positive. The IR absorption spectrum of sample should be concordant with that of working standard Should be positive
3	Loss on drying at 105°C for 4 hrs	0.20%	Not more than 0.5%
4	Optical rotation (5% solution in methanol at 20°C)	-0.01°	Between -0.10° and + 0.10°
5	Sulphated ash	0.04%	Not more than 0.1%
6	Heavy metals	Less than 20 ppm	Not more than 20ppm
7	Related substances by HPLC Impurities at 230 nm - Impurity - B - Impurity - D - Maximum unspecified impurity - Sum of the impurities (Other than impurity-G) Impurities at 254 nm - Impurity -G	Not detected Below disregard limit (0.05%) Below disregard limit (0.05%) Below disregard limit (0.05%) Below quantification limit (0.0133%)	Not more than 0.15% Not more than 0.2% Not more than 0.10% Not more than 0.5% Not more than 0.15%
8	Assay by Potentiometry (on dried basis)	100.2%	99.0% - 101.5%
9	Additional tests a) Residual solvents - Methanol - Isopropyl Alcohol - Toluene	55 ppm 80 ppm Below detection limit( 0.5 ppm)	Not more than 500ppm Not more than 500ppm Not more than 100 ppm

**Remark :** The product complies with the above specification + Customer's specification (CSO/506-R<sub>1</sub>/12).

**Storage condition:** Store in airtight containers below 25°C

**Note:** The values given in the parenthesis are of Below detection limit and disregard limit of residual solvents and HPLC

PREPARED BY : 	CHECKED BY : 	APPROVED BY : 
Date : 28/06/14	Date : 28/06/14	Date : 28/06/14

A Jubilant Bhartia Company

OUR VALUES



**Jubilant Life Sciences Limited**

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CITALOPRAM HYDROBROMIDE – Ph.Eur.

CERTIFICATE OF ANALYSIS

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