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QUALITY DIVISION
CERTIFICATE OF ANALYSIS

NAME OF THE PRODUCT : PAROXETINE HYDROCHLORIDE HEMIHYDRATE USP			
BATCH SIZE : 150.70 Kgs	BATCH No. : 4023PK3RII		
MFG. DATE : Nov. 2014	A. R. No. : IBD - 145993		
EXP. DATE : Oct. 2019	DATE : 17/02/2015		

TESTS	SPECIFICATIONS	RESULTS
APPEARANCE	White or off-white solid.	White solid
SOLUBILITY	Slightly soluble in water, soluble in methanol and in alcohol.	Conforms
IDENTIFICATION	A. Infrared Absorption spectrum of sample and standard are concordant.	Conforms
	B. Conforms by test for Chloride.	Conforms
WATER	Hemihydrate form : Between 2.2% w/w and 2.8% w/w	2.43% w/w
RESIDUE ON IGNITION	NMT 0.1% w/w	0.04% w/w
HEAVY METALS	NMT 0.002% w/w	< 0.002% w/w
LIMIT OF RELATED COMPOUND C and RELATED COMPOUND D	Related Compound C : NMT 0.10%	< 0.05%
LIMIT OF 1-METHYL-4-(P-FLUOROPHENYL)-1,2,3,6-TETRAHYDROPYRIDINE	Related Compound D : NMT 0.10%	Not Detected
CHROMATOGRAPHIC PURITY (By HPLC)	NMT 0.0001%	Not Detected
	TEST 2:	
	Paroxetine Related Compound B : NMT 0.50%	< 0.06%
	Paroxetine Related Compound F : NMT 0.20%	< 0.05%
	Paroxetine Related Compound G : NMT 0.20%	Not Detected
	Any single unknown impurity : NMT 0.10%	Not Detected
	Total impurities : NMT 1.0%	< 0.06%
RESIDUAL SOLVENTS	Methanol : NMT 3000 ppm	BDL
	Methylene Chloride : NMT 600 ppm	Not Detected
	Toluene : NMT 890 ppm	58 ppm
	Acetone : NMT 5000 ppm	1281 ppm
	Isopropyl Alcohol : NMT 5000 ppm	< 350 ppm
	Dimethyl sulphoxide : NMT 5000 ppm	Not Detected
ASSAY (By HPLC)	98.5% - 102.0% of $C_{19}H_{20}FNO_3 \cdot HCl$, calculated on the anhydrous and solvent free basis.	99.5% (oab)

REMARKS : The above sample **CONFORMS** as per USP Specifications.

*Note: BDL - Below Detection Limit

DEEPIKA SHARMA
ANALYST
DATE : 10/04/2015

NAVEEN BHAWSAR
MANAGER QUALITY CONTROL
DATE OF PRINT : 10/04/2015