SHIJIAZHUANG LONZEAL PHARMACEUTICALS CO., LTD.
NO. 16, WEST RING ROAD, SHENZE, SHIJIAZHUANG,
HEBEI PROVINCE, CHINA, 052560

CERTIFICATE OF ANALYSIS

COMMERCIAL NAME: PAROXETINE HYDROCHLORIDE
CHEMICAL NAME: (3S,4R)-3-[(1,3-BENZODIOXOL-5-YLOXY)METHYL]-4-(4-FLUOROPHENYL)PIPERIDINE HYDROCHLORIDE HEMIHYDRATE
CAS No. : 110429-35-1
CHEMICAL FORMULA: $C_{19}H_{21}ClFNO_3, 1/2H_2O$

Batch No.	Date of Manufacture	Retest Date	Date of Analysis	Package	Quantity
2030026031	Feb-21-2020	Feb-20-2023	Feb-27-2020	5Kg/Drum	5Kg
ASSAY ITEMS	**SPECIFICATION**			**TEST RESULTS**	
Appearance	White to off-white crystalline powder			Complies	
Solubility	Soluble in methanol, slightly soluble in ethanol and dichloromethane, slightly soluble in acetone and water, almost insoluble in 0.1mol / L hydrochloric acid			Complies	
Specific Optical Rotation	-88°～ -91°（10mg/ml methanol solution）			Complies	
Uv Identification	Absorption spectrum of the filtrate.it exhibits maxima 235 nm,265 nm, 271nm and 295 nm.The ratio of the absorbance at 235nm to the absorbance at 295nm should be 0.92-0.96			Complies	
IR Identification	The IR absorption spectrum of sample is concordant with the the reference spectrum			Complies	
HPLC Identification	The retention time of the Paroxetine Hydrochloride peak in the chromatogram of the test solution corresponds to that in the chromatogram of the standard solution, as obtained in the test of Assay.			Complies	
Fluoride Identification	Identification of fluoride in aqueous solution of the test sample			Complies	
Chloride Identification	It gives reaction of chlorides.			Complies	
Acidity	Between 5.5 and 6.5			5.6	
Water	Between 2.2% and 2.7%			2.4%	
Residue on Ignition	Not more than 0.1%			0.03%	
Heavy Metals	Not more than ten parts per million			Complies	
Enantiomeric Purity (Limit of Related Compound C)	Not more than 0.1%			Not detected	
Limit of	Not more than 0.0001%			Not detected	

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1-Methyl-4-(p-Fluorophenyl)-1,2,3,6-Tetrahydropyridine		
Organic Impurities	Paroxetine Related Compound B is not more than 0.1%	0.043%
	Paroxetine Related Compound F is not more than 0.1%	0.046%
	Any individual impurity is not more than 0.10%	0.066%
	Total impurities are not more than 0.5%	0.27%
Residual Solvents	Ethanol is not more than 0.1%	Not detected
	Acetone is not more than 0.2%	0.0028%
	Isopropanol is not more than 0.2%	0.0044%
	Dichloromethane is not more than 0.06%	Not detected
	Toluene is not more than 0.089%	Not detected
	Total residual solvents is not more than 0.5%	0.007%
Assay	98.5%~102.0% (anhydrous and solvent-free basis)	99.9%
Conclusion	Batch No. 2030026031 Paroxetine Hydrochloride complies with USP Specification.	

REPORT BY: 2020.03.16 CHECK BY: 2020.03.16 QA ADMIN: 2020.03.16