lot: 0230320

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CERTIFICATE OF ANALYSIS

Product name	Paroxetine hydrochloride hemihydrate		
Batch No.	5320-19-026	Batch Size	112.42kg
Batch Type	Commercial	Report Date	2020-02-26
Retest Date	2025-08	Storage Condition	Preserved in a well closed container.
Manufacture Date	2019-09-19	Manufacture Site	Xunqiao,Linhai,Zhejiang,317024,China.
Reference	R1-CEP 2006-192-Rev 01		

Test	Specification	Results
Appearance	White or almost white crystalline powder	Almost white crystalline powder
Identification	A.The infrared absorption spectrum is concordant with the reference spectrum of CRS	Conforms
	B. It gives reaction of chlorides.	Conforms
	C.The retention time of principal peak in test solution corresponds to that of paroxetine in test for impurity D.	Conforms
	D.It complies with the test for water.	Conforms
Water	2.2~2.7%	2.4%
Sulfated ash	≤0.1%	<0.1%
Assay	98.5-101.5% (anhydrous substance)	99.9%
Isomers (HPLC)	Impurity D ≤0.1%	<LOD(LOD=0.02%)
	Impurity E ≤0.10%	N.D
	Sum of isomer impurities ≤0.1%	<LOD
ImpurityG	≤1ppm	<LOD(LOD=0.3ppm)
Related substances	Impurity A ≤0.1%	<LOQ(LOQ=0.05%)
	Any unspecified impurity≤0.10%	<LOQ(LOQ=0.05%)
	Total impurities ≤0.5%	<LOQ
Residual solvent (GC)	Acetone ≤1000ppm	341ppm
	Toluene ≤890ppm	3ppm
Conclusion	Complies with R1-CEP 2006-192-Rev 01	

Signature : zhuxing (QC manager) Issued Date: 2020.02.26

Signature : Wujinglan (QA manager) Issued Date: 2020.02.28