浙江华海药业股份有限公司
HUAHAI ZHEJIANG HUAHAI PHARMACEUTICAL CO.,LTD.

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METAPHARMACEUTICAL

N DE LOTE: 0040825

05/08/2025

Certificate of Analysis

Product Name	Paroxetine hydrochloride hemihydrate		
Batch No.	5669-25-014	**Batch Size**	115.430kg
Batch Type	Commercial	**Report Date**	2025-06-11
Retest Date	2031-02-09	**Storage Condition**	Preserved in a well closed container.
Manufacture Date	2025-02-10	**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
Identification	B. It gives reaction of chlorides.	Conforms
Identification	The principal peak in the chromatogram obtained with the test solution is similar in retention time to the principal peak in the chromatogram obtained with paroxetine standard solution in the test for enantiomeric purity.	Conforms
Identification	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)	99.5%
Isomers(HPLC) Enantiomeric purity	≤0.1%	N.D
Isomers(HPLC) Impurity E	≤0.10%	N.D
Isomers(HPLC) Sum of isomer impurities	≤0.1%	N.D
ImpurityG	≤1ppm	N.D
Related substances Impurity A	≤0.1%	<LOQ
Related substances Any unspecified impurity	≤0.10%	<LOQ
Related substances Total impurities	≤0.5%	0.06%
Residual solvent(GC) Acetone	≤1000ppm	313ppm
Residual solvent(GC) Toluene	≤890ppm	1ppm
Conclusion	Complies with R1-CEP 2006-192-Rev 01	

Signature: WANGXIANG (QC manager) Issued Date: 2025-06-11

Signature: ZHANGCHAOCHAO (QA manager) Issued Date: 2025-06-11

Notes:COA was generated by LIMS with electronic signatures.

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Remarks: N/A

Signature: WANGXIANG (QC manager) Issued Date: 2025-06-11

Signature: ZHANGCHAOCHAO (QA manager) Issued Date: 2025-06-11

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