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

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CERTIFICATE OF ANALYSIS

Product name	Paroxetine hydrochloride anhydrous		
Batch no.	5306-16-035	Batch Size	100.56Kg
Batch Type	Commercial	Report Date	2016-04-15
Retest Date	2019-02	Storage Condition	Store at a temperature not exceeding 25 ℃ and preserved in an airtight container
Manufacture Date	2016-03-30	Manufacture Site	Xunqiao,Linhai,Zhejiang,317024,China.
Reference	R1-CEP 2006-002-Rev 01		
Test Items	Specifications		Results
Appearance	White or almost white, crystalline powder, hygroscopic.		Almost white, crystalline powder, hygroscopic.
Solubility	Slightly soluble in water, freely soluble in methanol, sparingly soluble in anhydrous ethanol and in methylene chloride.		Conforms
Identification	The infrared absorption spectrum is concordant with that of the reference standard.		Conforms
	It gives reaction of chlorides.		Conforms
	Melting point (DSC)	Peak maximum：113～125℃	122℃
		No secondary peak is allowed between 130℃ and 150℃	Conforms
	Specific optical rotation：-86°～ - 91°		-89°
Water	≤1.5%		0.5%
Heavy metals	≤20ppm		<20ppm
Sulfated ash	≤0.1%		<0.1%
Residual solvents	Acetone ≤3.5%		1.814%
	Toluene ≤0.089%		<0.001%
	Isopropanol ≤0.5%		N.D(LOD=0.00134%)
Isomers	Impurity D ≤0.1%		N.D(LOD=0.01%)
	Impurity D+Impurity E ≤0.1%		N.D
Impurity G	≤1ppm		N.D(LOD=0.3ppm)
Assay(HPLC)	97.5%～102.0%（anhydrous and solvents-free substance)		99.2%
Impurity H	≤0.1%		N.D(LOD=0.02%)
Impurity I	≤0.1%		N.D(LOD=0.01%)
Related substances (HPLC)	N-Methyl paroxetine ≤0.10%		<0.05%
	Impurity A ≤0.1%		<0.05%
	Impurity C ≤0.1%		N.D(LOD=0.003%)
	Impurity E ≤0.10%		N.D(LOD=0.01%)
	Impurity F ≤0.1%		N.D(LOD=0.003%)
	Impurity J ≤0.1%		N.D(LOD=0.003%)
	Any unspecified impurity≤0.10%		<0.05%
	Total impurities ≤0.5%		<0.05%
Conclusion	Complies with R1-CEP 2006-002-Rev 01		

Signature : Lin Zhenghuai (QC manager) Issued Date: 2016.04.15

Signature : Zhou Mingji (QA manager) Issued Date: 2016.04.18

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Product name	Paroxetine hydrochloride anhydrous		
Batch no.	5306-16-035	Batch Size	100.56Kg
Batch Type	Commercial	Report Date	2017-10-30
Retest Date	2019-02	Storage Condition	Store at a temperature not exceeding 25℃ and preserved in an airtight container
Manufacture Date	2016-03-30	Manufacture Site	Xunqiao,Linhai,Zhejiang,317024,China.
Reference	Customer Specification		

Test	Specifications	Results
PSD	50%≤50μm	13μm
	90%≤100μm	49μm
Conclusion	Complies with Customer Specification	

Signature : Lin Zhenghuai (QC manager) Issued Date: 2017.10.31

Signature : Zhao Xiaohong (QA manager) Issued Date: 2017.11.02