



浙江华海药业股份有限公司

HUHHN ZHEJIANG HUHHN PHARMACEUTICAL CO., LTD.

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CERTIFICATE OF ANALYSIS

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Product name	Paroxetine hydrochloride, anhydrous		
Batch No.	5665-18-003	Batch Size	100.46Kg
Batch Type	Commercial	Report Date	2018-01-18
Retest Date	2020-11	Storage Condition	Store at a temperature not exceeding 25 °C and preserved in an airtight container
Manufacture Date	2017-12-24	Manufacture Site	Xunqiao, Linhai, Zhejiang, 317024, China.
Reference	R1-CEP 2006-002-Rev 01		
Test	Specification		Results
Appearance	White or almost white, crystalline powder, hygroscopic.		Almost white, crystalline powder, hygroscopic.
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°C	124°C
		No secondary peak is allowed between 130°C and 150°C	Conforms
	Specific optical rotation: -86° ~ -91°		-89°
Water	≤1.5%		0.3%
Heavy metals	≤20ppm		<20ppm
Sulfated ash	≤0.1%		<0.1%
Residual solvents	Acetone ≤3.5%		2.166%
	Toluene ≤0.089%		<0.001%
	Isopropanol ≤0.5%		N.D(LOD=0.00134%)
Isomers	Impurity D ≤0.1%		<LOD(LOD=0.01%)
	Impurity D+Impurity E ≤0.1%		<LOD
Impurity G	≤1ppm		N.D(LOD=0.3ppm)
Assay(HPLC)	97.5%~102.0% (anhydrous and solvents-free substance)		100.5%
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%		<LOQ(LOQ=0.03%)
	Impurity A ≤0.1%		<LOQ(LOQ=0.03%)
	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%		<LOQ(LOQ=0.03%)
	Total impurities ≤0.5%		<LOQ
Conclusion	Complies with R1-CEP 2006-002-Rev 01		

Signature: Ke feng (QC manager)

Issued Date: 2018.01.18

Signature: Zhengyong (QA manager)

Issued Date: 2018.01.20



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Retest Date	2020-11	Storage Condition	Store at a temperature not exceeding 25℃ and preserved in an airtight container
Manufacture Date	2017-12-24	Manufacture Site	Xunqiao,Linhai,Zhejiang,317024,China.
Reference	Customer Specification		
Test	Specifications	Results	
PSD	D50≤50μm	12μm	
	D90≤100μm	43μm	
Conclusion	Complies with Customer Specification		

Signature: Kefeng (QC manager)

Issued Date: 2018.01.18

Signature: Zhang Majun (QA manager)

Issued Date: 2018.01.20