

Certificate of Analysis/

Product Name	Paroxetine hydrochloride hemihydrate		
Batch Number	3923010203	Quantity	160.550Kg
Mfg Site	No.5	Packing Specification	5Kg/tin
Mfg Date	2023.01.07	Retest Date	2027.01.06
Certificate No.	3923010203	Report Date	2023.01.17
Storage condition	Light protection, Well-closed container, controlled room temperature		
Contents	Specification:EP10.0	Results of analysis	
Appearance	White or almost white crystalline powder	Almost white crystalline powder	
Identification	(1) Water (by KF)	Conform	
	(2) Reaction of chlorides	Conform	
	(3) Comparing with the spectrum obtained with CRS	Conform	
	(4) The retention time of the main peak of the test solution should be consistent with the retention time of the main peak of the reference solution	Conform	
Impurity D	≤0.2%	Not detected	
Impurity G	≤0.0001%	Not detected	
Related substances	(1) Impurity A: not more than 0.3%	<0.05%	
	(2) Unspecified impurities: For each impurity, not more than 0.10 %	0.06%	
	(3) Total impurities: not more than 0.5%	0.1%	
Heavy metals	≤0.002%	<0.002%	
Water	2.2%~2.7%	2.5%	
Residue on ignition	≤0.1%	0.04%	
Assay(anhydrous substance)	97.5%~102.0%	99.4%	
Residual solvents	(1) Methanol: Not more than 0.3%	0.02%	
	(2) Acetone: Not more than 0.5%	0.02%	
	(3) Isopropanol: Not more than 0.5%	0.06%	
	(4) Dichloromethane: Not more than 0.06%	Not detected	
	(5) Toluene: Not more than 0.089%	0.002%	
Conclusion: Conforming to EP10.0.			