

Lot: 0041019

Hallochem Group

HALLOCHEM

Chongqing Waycome Pharmaceutical Co.,Ltd.

CERTIFICATE OF ANALYSIS

Product name	FLUOXETINE HCL	Batch No.	20190811
Manuf. Date	2019-08-11	Expiry Date	2022-08-10
Quantity	100Kgs	Test Standard	EP9

TEST	SPECIFICATIONS	RESULTS
Appearance	Off white or white crystalline powder	conform
Identification	a) IR conforms to Ref. standard b) Chlorides:It gives reaction of chloride	Conform conform
Assay	98.0% - 102.0%	99.30%
Optical rotation	-0.05° ~ +0.05 °	0 °
Impurity	Total impurity ≤0.5% 3-methylamino-1-phenylpropan-1-ol ≤0.25% N-methyl-3- phenylpropane-1-amine≤0.25% N-methyl-3-phenyl-3-[3-(trifluoromethyl)phenoxy]propan-1-amine ≤0.15% other single impurity ≤0.10%	0.153% 0.015% 0.01% 0.015% 0.051%
Residue on ignition	≤0.1%	0.03%
Water	≤0.5%	0.08%
Ph	4.5 ~ 6.5	5.47
Heavy metals	≤20ppm	<20ppm
Appearance of solution	Clear and colorless	conform
Acetonitrile	≤0.5%	Not detected

Conclusion: The product complies with the requirements of EP9 standard

Quality Manager:

朱永章

Rechecker:

易洪成

Analyst:

刘媛

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