

lot 0110119

Hallochem Group

HALLOCHEM

Chongqing Waycome Pharmaceutical Co.,Ltd.

CERTIFICATE OF ANALYSIS

|              |                |               |            |
|--------------|----------------|---------------|------------|
| Product name | FLUOXETINE HCL | Batch No.     | 20181203   |
| Manuf. Date  | 2018-12-10     | Expiry Date   | 2021-12-09 |
| Quantity     | 10Kgs          | Test Standard | EP9        |

| TEST                   | SPECIFICATIONS                                                                                                                                                                                                       | RESULTS                                   |
|------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|
| Appearance             | Off white or white crystalline powder                                                                                                                                                                                | conform                                   |
| Identification         | a) IR conforms to Ref. standard<br>b) Chlorides:It gives reaction of chloride                                                                                                                                        | Conform<br>conform                        |
| Assay                  | 98.0% - 102.0%                                                                                                                                                                                                       | 99.90%                                    |
| Optical rotation       | -0.05° ~ +0.05 °                                                                                                                                                                                                     | 0 °                                       |
| Impurity               | Total impurity ≤0.5%<br>3-methylamino-1-phenylpropan-1-ol ≤0.25%<br>N-methyl-3-phenylpropane-1-amine ≤0.25%<br>N-methyl-3-phenyl-3-[3-(trifluoromethyl)phenoxy]propan-1-amine ≤0.15%<br>other single impurity ≤0.10% | 0.08%<br>0.00%<br>0.04%<br>0.02%<br>0.01% |
| Residue on ignition    | ≤0.1%                                                                                                                                                                                                                | 0.02%                                     |
| Water                  | ≤0.5%                                                                                                                                                                                                                | 0.11%                                     |
| Ph                     | 4.5 ~ 6.5                                                                                                                                                                                                            | 6.32                                      |
| 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:

Rechecker:

Analyst:

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