



Specification

Ciprofloxacin Hydrochloride Monohydrate EP

Catalog Number: CH1005
CAS Number: 86393-32-0
Molecular Formula: $C_{17}H_{18}FN_3O_3 \cdot HCl \cdot H_2O$
Molecular Weight: 385.82
Storage: 15°C – 30°C
Retest Period: Three years from the date of manufacture

| Test | Specification |
|---|---|
| Appearance | Off-white to pale yellow powder, slightly hygroscopic |
| Assay | 98.0 – 102.0% |
| Identification A. FTIR B. Test for Chlorides | To match spectra of reference standard Solution responds to test for chlorides |
| Solubility | Clear, not more intensely colored than GY5 |
| pH | 3.5 – 4.5 |
| Moisture | ≤ 6.7% |
| Sulfated Ash | ≤ 0.1% |
| Impurity A | ≤ 0.2% |
| Related Substances Impurity B Impurity C Impurity D Impurity E Impurity F Single Impurity Total Impurities | ≤ 0.2% ≤ 0.2% ≤ 0.2% ≤ 0.3% ≤ 0.1% ≤ 0.1% ≤ 0.5% |
| Heavy Metals | ≤ 20ppm |
| Residual Solvents Ethanol | ≤ 5,000ppm |
| All batches will be in compliance with EP8. | |

Approved:

Date: November 24, 2016

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