Aarti Drugs Limited

# QUALITY CONTROL DEPARTMENT
# CERTIFICATE OF ANALYSIS

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|---|---|---|---|
| **Product** | **Ciprofloxacin Hydrochloride EP** | | **Page 1 of 1** |
| **CAS No.** | **86393-32-0** | **Date of Mfg.** | **January 2013** |
| **Batch No.** | **CE/130101** | **Expiry Date** | **July 2017** |
| **Batch Quantity** | **320.00 Kg.** | **Date of Analysis** | **12/01/2013** |
| **A.R. No.** | **E-22/13B0001** | **Date of Release** | **17/01/2013** |

| SR. NO. | TESTS | OBSERVATIONS | SPECIFICATIONS |
|---|---|---|---|
| 1. | Appearance | Pale yellow crystalline, slightly hygroscopic powder. | Pale yellow, crystalline, slightly hygroscopic powder. |
| 2. | Solubility | Complies. | Soluble in Water, Slightly soluble in Methanol, Very slightly soluble in anhydrous Ethanol, Practically insoluble in Acetone, in Ethyl acetate and in Methylene chloride. |
| 3. | Identification<br>A) By IR | Confirm. | The Infrared absorption spectrum of test sample being examined must be concordant with the IR spectrum obtained from Ciprofloxacin Hydrochloride WS. |
| | B) Reaction For Chloride | Complies. | It gives the reaction of chlorides. |
| 4. | Appearance of Solution | Complies. | The solution is clear and not more intensely coloured than reference solution $GY_5$. |
| 5. | pH | 3.90 | Between 3.5 to 4.5 |
| 6. | Impurity A (By TLC) | Less Than 0.2% | Not More Than 0.2% |
| 7. | Related Substances | | |
| | • Impurity B | 0.03% | Not More Than 0.2% |
| | • Impurity C | 0.03% | Not More Than 0.2% |
| | • Impurity D | 0.01% | Not More Than 0.2% |
| | • Impurity E | 0.01% | Not More Than 0.3% |
| | • Any Other Impurity | 0.05% | Not More Than 0.10% |
| | • Total Impurities | 0.17% | Not More Than 0.5% |
| 8. | Heavy Metals | Less Than 20 ppm. | Maximum 20 ppm. |
| 9. | Water (By KF) | 5.66% | Maximum 6.7 %, determined on 0.2g |
| 10. | Sulphated Ash | 0.05% | Maximum 0.1%, determined on 1 gm |
| 11. | Assay (by HPLC)<br>(on anhydrous basis) | 99.80% | Not Less Than 98.0% and Not More Than 102.0% |
| 12. | EDTA Content | 99 ppm. | Not More Than 200 ppm. |
| | In-House Test | | |
| 13. | Residual Solvents | | |
| | • Methanol | 66 ppm. | Not More Than 3000 ppm. |
| | • n-Butanol | Not Detected. | Not More Than 5000 ppm. |
| | • Toluene | Not Detected. | Not More Than 890 ppm. |

**Opinion :** The above product **Complies** as per EP & In-house Specification with the prescribed standard of quality with respect to above test as per specification No.**FPS/CIPR/015-A Rev. 02**

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|---|---|---|---|
| **Signature** | 12/06/2014 | 12/06/2014 | 12/06/2014 |
| **Position** | **Officer Q.C.<br>Prepared By** | **Executive Q.C.<br>Checked By** | **Head Q.C.<br>Approved by** |

**Certificate Of Analysis Issued On : 12/06/2014**

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