Aarti Drugs Limited

# QUALITY CONTROL DEPARTMENT
# CERTIFICATE OF ANALYSIS

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|---|---|---|---|
| **Product** | **Ciprofloxacin Hydrochloride EP** | |  |
| **CAS No.** | **86393-32-0** | **Date of Mfg.** | **January 2014** |
| **Batch No.** | **CEP-MZ/140103** | **Expiry Date** | **June 2018** |
| **Batch Quantity** | **220.00 Kg.** | **Date of Analysis** | **03/01/2014** |
| **A.R. No.** | **E-22/14PP0003** | **Date of Release** | **11/01/2014** |

| 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** | 3.67 | Between 3.5 to 4.5 |
| 6. | **Impurity A (By TLC)** | Less Than 0.2% | Not More Than 0.2% |
| 7. | **Related Substances**<br>• **Impurity B**<br>• **Impurity C**<br>• **Impurity D**<br>• **Impurity E**<br>• **Unspecified Impurity**<br>• **Total Impurities** | <br>0.03%<br>0.02%<br>0.02%<br>Not Detected.<br>0.04%<br>0.15% | <br>Not More Than 0.2%<br>Not More Than 0.2%<br>Not More Than 0.2%<br>Not More Than 0.3%<br>Not More Than 0.10%<br>Not More Than 0.5% |
| 8. | **Heavy Metals** | Less Than 20 ppm. | Not More Than 20 ppm. |
| 9. | **Water (By KF)** | 5.78% | 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)** | 99.76% | Not Less Than 98.0% and Not More Than 102.0% |
| 12. | **EDTA Content** | 81 ppm | Not More Than 200 ppm. |
| | **In-House Test** | | |
| 13. | **Residual Solvents**<br>• **Methanol**<br>• **n-Butanol**<br>• **Toluene** | <br>216 ppm.<br>Not Detected.<br>Not Detected. | <br>Not More Than 3000 ppm.<br>Not More Than 5000 ppm.<br>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** | 14/04/2014 | 14/04/2014 | 14/04/2014 |
| **Position** | **Officer Q.C.**<br>**Prepared By** | **Executive Q.C.**<br>**Checked By** | **Head Q.C.**<br>**Approved by** |

**Certificate Of Analysis Issued On: 14/04/2014**

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