Aarti Drugs Limited

QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS

Product	**Ciprofloxacin Hydrochloride EP**		
CAS No.	**86393-32-0**	**Date of Mfg.**	**September 2014**
Batch No.	**CEP/140919**	**Expiry Date**	**August 2019**
Batch Quantity	**451.00 Kg.**	**Date of Analysis**	**28/09/2014**
A.R. No.	**E-22/14P0095**	**Date of Release**	**06/10/2014**

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 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	3.72	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 • Impurity C • Impurity D • Impurity E • Unspecified Impurity • Total Impurities	 0.01% 0.02% 0.02% Not Detected. 0.03% 0.11%	 Not More Than 0.2% Not More Than 0.2% Not More Than 0.2% Not More Than 0.3% Not More Than 0.10% Not More Than 0.5%
8.	Heavy Metals	Less Than 20 ppm.	Maximum 20 ppm.
9.	Water (By KF)	6.31%	Maximum 6.7 %, determined on 0.2g
10.	Sulphated Ash	0.05%	Maximum 0.1%, determined on 1 gm
11.	Assay (by HPLC) (on anhydrous basis)	100.45%	Not Less Than 98.0% and Not More Than 102.0%
12.	EDTA Content	76 ppm	Not More Than 200 ppm.
	In-House Test		
13.	Taped Density	0.49gm/ml.	For Information.
14.	Residual Solvents • Methanol • n-Butanol • Toluene	 242 ppm. Not Detected. Not Detected.	 Not More Than 3000 ppm. Not More Than 5000 ppm. 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**

Signature	07/10/2014	07/10/2014	07/10/2014
Position	**Officer Q.C.** **Prepared By**	**Executive Q.C.** **Checked By**	**Head Q.C.** **Approved by**

Certificate Of Analysis Issued On : 07/10/2014

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