



QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

Product		Ciprofloxacin Hydrochloride EP		Page 1 of 1	
CAS No.		86393-32-0		Date of Mfg.	
Batch No.		CEP-MZ/140102		January 2014	
Batch Quantity		161.50 Kg.		Expiry Date	
A.R. No.		E-22/14PP0002		June 2018	
Date of Analysis		03/01/2014		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 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 GYs.
5.	pH	3.61	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	0.02% 0.03% 0.02% Not Detected. 0.04% 0.13%	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.	Not More Than 20 ppm.
9.	Water (By KF)	5.87%	Maximum 6.7 %, determined on 0.2g
10.	Sulphated Ash	0.06%	Maximum 0.1%, determined on 1 gm
11.	Assay (by HPLC) (on anhydrous basis)	99.66%	Not Less Than 98.0% and Not More Than 102.0%
12.	EDTA Content	80 ppm	Not More Than 200 ppm.
In-House Test			
13.	Residual Solvents • Methanol • n-Butanol • Toluene	197 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	 14/04/2014	 14/04/2014	 14/04/2014
Position	Officer Q.C. Prepared By	Executive Q.C. Checked By	Head Q.C. Approved by

Certificate Of Analysis Issued On: 14/04/2014