



QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

Product		Ciprofloxacin Hydrochloride EP		Page 1 of 1	
CAS No.		86393-32-0		Date of Mfg.	February 2014
Batch No.		CE/140201		Expiry Date	January 2018
Batch Quantity		225.10 Kg.		Date of Analysis	08/02/2014
A.R. No.		E-22/14B0003		Date of Release	26/02/2014
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	3.60	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	Not Detected. 0.02% 0.01% 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)	5.92%	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)	99.61%	Not Less Than 98.0% and Not More Than 102.0%		
12.	EDTA Content	109 ppm	Not More Than 200 ppm.		
In-House Test					
13.	Residual Solvents • Methanol • n-Butanol • Toluene	185 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