



QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

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Product	Ciprofloxacin Hydrochloride EP		
CAS No.	86393-32-0	Date of Mfg.	September 2014
Batch No.	CEP/140909	Expiry Date	August 2019
Batch Quantity	455.14 Kg.	Date of Analysis	10/09/2014
A.R. No.	E-22/14P0080	Date of Release	17/09/2014
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	3.69	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	0.00% 0.02% 0.03% Not Detected. 0.03% 0.16%	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)	5.96%	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)	99.83%	Not Less Than 98.0% and Not More Than 102.0%
12.	EDTA Content	50 ppm	Not More Than 200 ppm.
In-House Test			
13.	Residual Solvents • Methanol • n-Butanol • Toluene	171 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			
Position	Officer Q.C. Prepared By	Executive Q.C. Checked By	Head Q.C. Approved by

Certificate Of Analysis Issued On : 17/09/2014

