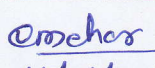
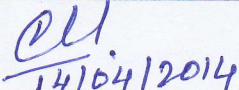
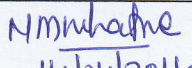


QUALITY CONTROL DEPARTMENT CERTIFICATE OF ANALYSIS

Product		Ciprofloxacin Hydrochloride EP		Page 1 of 1
CAS No.		86393-32-0	Date of Mfg.	July 2013
Batch No.		CEP/1307143	Expiry Date	June 2018
Batch Quantity		460.00 Kg.	Date of Analysis	07/08/2013
A.R. No.		E-22/13P0210	Date of Release	24/08/2013

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 _s .
5.	pH	3.62	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	0.02%	Not More Than 0.2%
	• Impurity C	0.02%	Not More Than 0.2%
	• Impurity D	0.02%	Not More Than 0.2%
	• Impurity E	Not Detected.	Not More Than 0.3%
	• Unspecified Impurity	0.04%	Not More Than 0.10%
	• Total Impurities	0.13%	Not More Than 0.5%
8.	Heavy Metals	Less Than 20 ppm.	Not More Than 20 ppm.
9.	Water (By KF)	5.44%	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)	99.77%	Not Less Than 98.0% and Not More Than 102.0%
12.	EDTA Content	82 ppm.	Not More Than 200 ppm.
	In-House Test		
13.	Residual Solvents		
	• Methanol	277 ppm.	Not More Than 3000 ppm.
	• n-Butanol	Not Detected.	Not More Than 5000 ppm.
	• Toluene	Not Detected.	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