WRS
C28-8

(10)

GODAVARI DRUGS LIMITED

CERTIFICATE OF ANALYSIS

Product	: CIPROFLOXACIN HYDROCHLORIDE BP	Customer Name	: TRIVENI FORMULATIONS LTD.
Batch No.	: CIP52401185	Date of Manufacture	: Aug 2015
Quantity	: 1.0g	Date of Expiry	: Jul 2020
A.R.No.	: FP/060608/15	Date of Analysis	: 10.12.2015
Reference	: BP	Use before	: 09.12.2016
Storage	: Preserve in tight, light resistant containers, Store at 25°C, excursions permitted between 15°C and 30°C		

QUALITY CONTROL LABORATORY RECEIVED 12 MAY 2016 GODAVARI DRUGS LTD. NAIDUPET

WORKING STANDARD

Sl. No.	TEST	RESULT	SPECIFICATION
01.	Description	A pale yellow crystalline powder.	A pale yellow crystalline powder.
02.	Solubility	Complies	Soluble in water, slightly soluble in acetic acid and in methanol, very slightly soluble in ethanol, practically insoluble in acetone, in acetonitrile, in ethyl acetate. in hexane, andin dichloromethane.
03.	Identification by a. IR absorption spectrum	Matches with working standard	The infrared absorption spectrum exhibits maxima only at the same wavelengths as that of similar preparation of Ciprofloxacin Hydrochloride Working standard.
	b. TLC	Matches with working standard	The intensity of Rf value of the principle band obtained from the test solution corresponds to that obtained from the working standard solution.
	c. Test for Chlorides	Positive	A solution of it responds to the test for chloride.
04.	pH (1 g in 40 mL of water)	3.78	Between 3.0 and 4.5
05.	Water	5.6% w/w	Between 4.7% and 6.7% w/w
06.	Sulphated Ash	0.04% w/w	Not more than 0.1% w/w
07.	Sulphates	Less than 400ppm	Not more than 400ppm
08.	Heavy metals	Less than 20ppm	Not more than 20ppm
09.	Fluoroquinolonic Acid	Complies	Any secondary spot in the chromatogram obtained with the test solution corresponding to the spot of Fluoroquinolonic acid should not be more intense than the spot in the chromatogram obtained with the reference solution.

Remarks : The product CONFORMS as per BP specifications.

Complied by: Date: 10-12-15

Checked by: Date: 10.12.15

Head, Quality Control: Date: 10.12.2015

TRIVENI FORMULATIONS LTD.