

Vill – Sachana, Tal – Viramgam, Dist. – Ahmedabad – 382150, Gujarat. Phone : 02715-248001-5 Fax : 248007

CERTIFICATE OF ANALYSIS

PRODUCT : CIPROFLOXACIN INTRAVENOUS INFUSION BP.(0.2 % W / V) 100ML	
Batch No. : 2L01912	Insp Lot NO.: 040000582000
Mfg. Date : DEC-2020	Exp. Date : NOV-2023
Batch Size : 9000.00 LTR.	Qty. sampled : 18 NOS.
Testing Date: 27/12/2020	Completion Date : 11/01/2021

Sr. No.	Tests	Observation	Specification
01	Packaging	Printed cardboard box containing a bottle of low density polyethylene granulated, with labeled and labeled, with clamping system with cap, within a bag sealed Polyethylene film, labeled with 100 ml injectable solution with patient brochure.	
02	Physical Aspect	Colorless to pale yellow solution.	A Colorless to pale yellow solution.
03	Colour of Solution	Complies	The intravenous infusion is not more intensely colored than reference solution GY6.
04	Acidity (pH)	4.08 Complies	Between 3.9 to 4.5
05	Identification	Complies	Should Comply
06	Extractable Volume	104.0 ml Complies	Not less than nominal volume.
07	Particulate Contamination	260 prc/ct 13 prc/ct Complies	Counts Per Container ≥10 micron- Max 6000 ≥25 micron- Max 600
08	Related Substances	Complies	Should Comply
09	Bacterial Endotoxins	Complies	Not more than 0.5 IU/ml
10	Assay Ciprofloxacin	0.2027 % w/v	0.190 % w/v to 0.210 % w/v
		101.3 % of labeled	95.0 to 105.0 % of labeled
		Complies	
	Assay Sodium Chloride	909.36 mg/100ml	855 mg to 945 mg/100ml
		101.04 % of labeled	95.0 to 105.0 % of labeled
11	Sterility	Complies	
		Complies	Should Comply

Report: The product complies with the prescribed standards of the quality as per specification.

ANALYST : N 21/01/2021
NAME : Nikita

QA MANAGER : [Signature] 21/01/2021
NAME : [Signature]