RENOVA LIFESCIENCES PRIVATE LIMITED

Survey No: 54/1, Plot No: 35 / 36 / 37, R. K. Industrial Park Phase - I, Opp. Bharat Benz Showroom, Off. Rajkot Ahmedabad N. H. 8-B, "Rampara - 360 023. Dist: Rajkot. Gujarat - India.



MFG. AT: 136, 137, G.I.D.C ESTATE, WADHWAN CITY, GUJARAT L/C Number: 21-146223 DTD: 190603
Applicant Ref. No.: 204/19

Q.C. DEPARTMENT CERTIFICATE OF ANALYSIS

Name of Finish Product :- CHLORAMPHENICOL OPHTHALMIC SOLUTION 10 ML			
Generic Name :- Chloramphenicol Ophthalmic Solution 0.5% w/v			
Product Code :- RIFEDUCO04		A. R. No. :- FRLPAR90006	
Batch No. :- RI352		Batch Size :- 305 litre	Receipt Date :- 14/05/2019
Mfg. Dt. :- 05/2019		Sample Qty.:- 30 x 10 ml	Analysis Date :- 15/05/2019
Exp. Dt. :- 04/2021		Page No. :- 1 of 1	Release Date :- 30/05/2019
SR. NO	TEST	RESULT	SPECIFICATION
1	Description	Clear colorless solution free from any type of visible particles	Clear colorless solution free from any type of visible particles
2	Identification 1) Chloramphenicol	Complies	The retention time of the major peak in the chromatogram of the Sample Preparation corresponds to that of the due to Chloramphenicol in the chromatogram of the Standard Preparation as obtained in the Assay
3	pH	7.31	7.0 to 7.5
4	Uniformity of Volume	10.15 ml	10.0 to 10.4 ml
5	Capping	Satisfactory	Should be Satisfactory
6	Sterility	Growth or turbidity was not present in the original clear media	Growth or turbidity should not present in the original clear media
7	Assay Chloramphenicol	115.72 % i.e. 0.5786% w/v	90.0 % to 130.0 % as per the label amt i.e. 0.45% to 0.65 %w/v as per LC

REMARKS: - The Product Complies / Does not comply as per USP Specification.

Q. C. CHEMIST

Q. A. OFFICER

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