



CORPORATE OFFICE : C-1101 / 1102, Lotus Corporate Park, Graham Firth Steel Compound, Jay Coach Junction, Western Express Highway, Goregaon (East), Mumbai - 400 063.
Tel.: +91-22-62748000 | Email: mail@cironpharma.com | www.cironpharma.com
(UNIT1) N-118, N-119, N-113, M.I.D.C., Tarapur, Boisar, Dist. Palghar - 401 506. Maharashtra, INDIA.
(UNIT 2) 35-37, 43-45, CFC-B, Dewan Udyog Nagar, Aliyali, Palghar, Dist. Palghar - 401 404. Maharashtra, INDIA.



CIN U24246MH1090PTC0056735

CERTIFICATE OF ANALYSIS FINISHED PRODUCT			
Generic Name	GENTAMICIN EYE DROPS BP		
Brand Name (if applicable)	GENTAMICIN COL FCO	Sampled Qty.	60 x 5 ml
Reference Specification No.	C1/FP/QA/SPEC/E/ED/0172/ 005/B/OO/07/05	Sampling Date	09/06/2019
Batch Size	110.0 Ltrs.	Analytical Report No.	19/CFIB/317
Batch No.	9EB11211	Analysis Started Date	09/06/2019
Mfg. Date	06/2019	Analysis Completed Date	23/06/2019
Exp. Date	05/2021	Reported Date	23/06/2019

SR. No.	Tests	Specifications	Results
1.	Description	A clear, colourless to pale yellow solution.	A clear, colourless solution.
2.	Identification	A) By TLC : The three principal spots in the chromatogram obtained with solution (1) correspond to the three principal spots in the chromatogram obtained with solution (2).	The three principal spots in the chromatogram obtained with solution (1) correspond to the three principal spots in the chromatogram obtained with solution (2).
		B) By HPLC : In the test for Composition of gentamicin sulphate, the retention times of the four principal peaks in the chromatogram obtained with solution (1) correspond to those of the four principal peaks in the chromatogram obtained with solution (2).	In the test for Composition of gentamicin sulphate, the retention times of the four principal peaks in the chromatogram obtained with solution (1) correspond to those of the four principal peaks in the chromatogram obtained with solution (2).
3.	pH	6.5 to 7.5	7.09
4.	Average Filled Volume	Not less than 5.0 ml	5.0 ml
5.	Leakage Test	No leakage should be observed	No leakage observed
6.	Particulate Matter	≥10µm : Not more than 50 per ml ≥25 µm : Not more than 5 per ml	10.7 per ml 0.8 per ml
7.	Sterility Test	Solution should sterile	Sterile
8.	Composition of Gentamicin	C ₁ = 25.0 to 50.0%; C _{1a} = 10.0 to 35.0%; C ₂ plus C _{2a} = 25.0 to 55.0%.	30.29% 31.92% 37.8%

	Prepared By	Reviewed By	Approved By	Authorized By
Sign & Date	 23/06/2019	 23/06/2019	 23/06/2019	 23.06.2019
Name	Gouri Ghule	Susai Harpalkar	S. K. Kulkarni	Anand Dutt
Designation	QC-officer	QC Executive	Manager QC	Manager QA

Format No.: C1QC/F/337-00, Ref. SOP No.: C1QC/266-00



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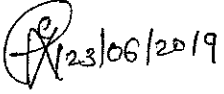
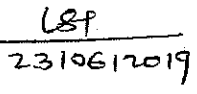
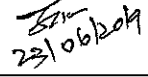
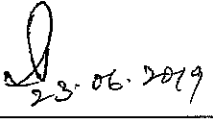
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9.	Assay Each ml contains Gentamicin sulphate BP eq. to Gentamicin 0.3% w/v	The upper fiducial limit of error is not less than 90.0% and the lower fiducial limit of error is not more than 120.0% of the stated content.	107.8%
	Phenyl mercuric nitrate BP 0.002%w/v	80.0% to 120.0% of the labeled amount	99.7%

Remarks	: The above sample Complies/ Dees Not Comply as per BP specification.
Storage Condition	: Store in cool, dry place protect from light & moisture at temperature below 25°C.
Manufactured At	: N -119, MIDC, Tarapur, Boisar, Dist. Palghar – 401 506, Maharashtra India

	Prepared By	Reviewed By	Approved By	Authorized By
Sign & Date	 23/06/2019	 23/06/2019	 23/06/2019	 23.06.2019
Name	Gourishankar	S. K. Harpalkar	S. K. Harpalkar	Alan Dutt
Designation	QC OFFICER	QC EXECUTIVE	MANAGER QC	MANAGER QC