aurolab

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Tel : 91 452 309 6100 Fax: 91 452 244 6200
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CERTIFICATE OF ANALYSIS

PRODUCT INFORMATION

Product Name : Aurosol - 10ml	Sample received : 30No's
Generic Name : Hypromellose Eye Drops BP 0.7% w/v – 10ml	Date of Sampling :10/10/2016
Batch No : 6J495	Date of Completion : 24/10/2016
Manufacturing Date : OCT -2016	Date of Release : 24/10/2016
Expiry Date : SEP -2018	Report No : ARF -16/495

ANALYSIS

S. No.	Test Name	Test Result	Acceptance Criteria	Reference to the test method
	PHYSICAL ANALYSIS			
1.	Description	**Clear, colorless viscous solution**	Clear, colorless viscous solution	In-House
2.	Label Checking	**Clear &legible**	Clear & Legible	In-House
3.	Uniformity of volume (ml)	**10.3 ml**	NLT 10ml	In-House
4.	Specific gravity at 25° C	**1.011**	1.005 – 1.012 at 25° C	In-House
5.	Refractive index at 25° C	**1.3372**	1.335 – 1.348 at 25° C	In-House
6.	Viscosity at 25° C (cPs)	**51.4 cPs**	40cPs – 70cPs at 25° C	In-House
	CHEMICAL ANALYSIS			
7.	Identification a. with heating b. with acetic acid and tannic acid	***a.* The solution is clear on cooling** **b. A yellowish white flocculent precipitate is produced. which is Dissolved in 6M ammonia Solution.**	a. The solution becomes clear on cooling b. A yellowish white flocculent precipitate should be produced. The precipitate should be dissolved in 6M ammonia	BP BP

Analyzed By: (QC Chemist) Date : 24/10/2016	Checked By: (QC Manager) Date : 24/10/2016	Approved By: (QA Manager) Date : 24/10/2016

PHARMACEUTICAL DIVISION

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S. No.	Test Name	Test Result	Acceptance Criteria	Reference to the test method
8.	pH	8.33	8.2 – 8.6	BP
9.	Assay of a. Hydroxy propyl methyl cellulose (%) b. Chloride (ppm)	0.718% 4450ppm	0.595% - 0.805% 4000 – 4900ppm	In-House
10.	Assay of Benzalkonium chloride (%)	0.0109 %	0.0090% - 0.0120%	In-House
	MICROBIOLOGICAL ANALYSIS			
11	Sterility	No growth	No growth .It has to be sterile.	USP, IP, Ph.Eur.,

This is to certify that the Batch mentioned above complies with BP specification.

Analyzed By: (QC Chemist) Date : 24/10/2016	Checked By: (QC Manager) Date : 24/10/2016	Approved By: (QA Manager) Date : 24/10/2016