

R-673, T.T.C., MIDC, Rabale, Thane Belapur Road, Navi Mumbai, Maharashtra - 400701

Product : FGOIN0025 Gentamicin Sulfate Ophthalmic Ointment USP 0.3 %		AR No : AD17002F	
Generic Name :	Gentamicin Sulfate Ophthalmic Ointment USP 0.3 %	Completion Date :	10/01/2018
Analysis Date :	26/12/2017	Mfg. Date :	Dec,2017
Batch No. :	AD17002	Exp. Date :	Nov,2019
Batch Size :	420.000 Kg	Sampled Date :	26/12/2017
Sample Type :	Finished Product	Sample Qty. :	75 Nos
Spec. No. :	QA/FPS/143/08-07	Sampled By :	Khedkar Ganesh
Packsize :	3.5g Batch: Packing Batch Size:203.000 Kg		
License No. :	KD-180		
SO.No. & Date :	NA		

SR. No.	Test	Specification	Observation
1	Description	White soft ointment, free from foreign matters	White soft ointment, free from foreign matters.
2	Identification by Thin layer Chromatography	The intensities and R F values of the three principal spots of the sample solution correspond to those of the Standard solution	The intensities and R F values of the three principal spots of the sample solution correspond to those of the Standard solution.

Analysed By RL

Date \_\_\_\_\_

10/01/2018

Approved By \_\_\_\_\_

Date \_\_\_\_\_

1010112018

**Galentic Pharma (India) Pvt Ltd (Rabale)**

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**CERTIFICATE OF ANALYSIS**

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SO.No. & Date :	NA		
3	Minimum fill	Stage 1: 1. The average net content of the 10 containers is NLT the labeled amount, and the net content of any single container is NLT 90% of the labeled amount where the labeled amount is 60 g or 60 mL or less or NLT 95% of the labeled amount where the labeled amount is more than 60 g or 60 mL. If these criteria are not met, and the net content of NMT 1 container is less than 90% of the labeled amount where the labeled amount is 60 g or 60 mL or less, or 95% of the labeled amount where the labeled amount is more than 60 g or 60 mL, proceed to Stage 2. Stage 2: 1. Determine the content of 20 additional containers. 2. The average content of the 30 containers is NLT the labeled amount, and the net content of NMT 1 of the 30 containers is less than 90% of the labeled amount where the labeled amount is 60 g or 60 mL or less, or less than 95% of the labeled amount where the labeled amount is more than 60 g or 60 mL.	106.00 % (3.71 g)
4	pH (At 25°C)	3.5 to 6.5	4.2
5	Particle size	Not more than 20 Particles > 25 micron Not more than 2 Particle > 50 micron None Particle > 90 micron	None Particles > 25 micron None Particles > 50 micron None Particles > 90 micron.

Analysed By



Date

10/01/2018

Approved By



Date

10/01/2018


**Galentic Pharma (India) Pvt Ltd (Rabale)**


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SO.No. & Date :	NA		
6	Viscosity (at 25°C)	200- 700 cp	473 cp
7	Assay	90.0 % L.A. to 135.0 % L.A.	104.70 %
8	Leakage Test	No significant leakage occurs during or at the completion of the test from 10 tubes	No leakage occurs during and at the completion of the test from 10 tubes.
9	Sterility	The product should be sterile	The product is sterile
10	Uniformity in Containers	None of the three results are outside of the product assay range. (Note: If the test does not comply then refer the other stages of test those mention in method of analysis.)	None of the three results are outside of the product assay range.

Conclusion : The product **Complies** as per United State Pharmacopoeia and Finish product specification no. QA/FPS/143/08-07.

Analysed By   
Date 10/01/2018

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