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CERTIFICATE OF ANALYSIS

PRODUCT INFORMATION

Product Name :Prednisolona Acetato Ophthalmic suspension USP 1.0% w/v -5ml	Sample received : 30No's
Generic Name : Prednisolona Acetato Ophthalmic suspension USP 1.0% w/v	Date of Sampling : 19/04/2018
Batch No : 8D270C	Date of Completion : 07/05/2018
Manufacturing Date : 2018 - 04	Date of Release : 07/05/2018
Expiry Date : 2020 - 03	Report No : ARF – 18/270C

ANALYSIS

S. No.	Test Name	Test Result	Acceptance Criteria	Reference to the test method
		PHYSICAL ANALYSIS		
1.	Description	**Sterile, White suspension**	Sterile, White suspension	In-House
2.	Label Checking	**Clear & legible**	Clear & legible	In-House
3.	Uniformity of volume (ml)	**5.8ml**	NLT 5.0ml	In-House
4.	Specific gravity at 25° C	**1.010**	1.000 – 1.025 at 25° C	In-House
		CHEMICAL ANALYSIS		
5.	Identification HPLC method	**The retention time of the Prednisolone acetate peak in the chromatogram of the assay preparation is identical with that of standard.**	The retention time of the Prednisolone acetate peak in the chromatogram of the assay preparation should be identical with that of standard.	USP
6.	pH	**5.65**	5.0 – 6.0	USP
7.	Assay of Prednisolone acetate (%)	**1.01%**	0.90% - 1.15%	USP
8.	Assay of Benzalkonium chloride (%)	**0.0103%**	0.0090% - 0.0120%	In-House
		MICROBIOLOGICAL ANALYSIS		
9.	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 USP specification

Analyzed By: P. Gayathri (QC Chemist) Date : 07/05/2018	Checked By: S. Pathy (QC Manager) Date : 07/05/2018	Approved By: Narayanaswamy (QA Manager) Date : 07/05/2018

AUROLAB MADURAI PHARMACEUTICAL DIVISION

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STERILITY TEST REPORT FORM

Batch & Sample Details **Report No : AS-P/ 308**

Name of the Division	: Pharmaceutical Division	**Name of the Product**	: Prednisolona acetate – 5 mL
Batch / ~~RM / Lot~~ No.	: 8D270C	**Sample Received on**	: 19/04/2018
No. of Samples	: 20 Nos	**Sample Tested on**	: 19/04/2018

Testing Conditions

Method of Inoculation	: Membrane filtration with Prior Treatment		
Incubation Temperature :	Soyabean Casein Digest Medium 20 – 25^0 C Fluid Thioglycollate Medium 30 – 35^0 C	**Incubation period**	: 18 Days

Result

Media Inoculated	Observation (in Days)														Result
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	
Soyabean Casein Digest Medium	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	No growth
Fluid Thioglycollate Medium	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	✔	No growth

Applicable only for suspension type of products

Media Inoculated	Observation (in Days)				Result
	15	16	17	18	
Soyabean Casein Digest Medium	✔	✔	✔	✔	No growth
Fluid Thioglycollate Medium	✔	✔	✔	✔	No growth

Note (If any):

Conclusion:

The above referenced batch/~~Lot~~ complies the sterility test

✔ - No Growth; ✕ - Growth

Complying Standards: *ISO 11737-2, USP <71>, European Pharmacopoeia (2.6.1), Indian Pharmacopeia (2.2.11)*

Reported by

Microbiologist

Reported on : 07/05/2018

Form Approval:

Issued by: A. A. Dandekar
(Microbiology Supervisor)
Date : 03/04/2014

Checked by: Soundarya K
(Microbiologist)
Date : 03/04/14

Approved by: Hanumanth
(Microbiologist)
Date : 03/04/2014

Form No: MB – 01 **MBP-08** **Issue-15** **Effective Date:** 05 APR 2014

Reason for change: To include ISO 11737-Part 2 reference

Connecting Documents: MBP – 08 ☒ Checked No Changes required

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