

QA.15.0.0.3

FORM 39

[RULE 150 - E(F)] APPROVAL NUMBER: T-22/DC

TEST REPORT

ISSUED TO:

Meghalayan Medical Drugs And Services Limited

New colony shillong, DHS, laitumkhrah, Office of the mission director, NHM, Shillong, East Khasi Hills Meghalaya, 793003

Shillong - 793003 MFG. LICENCE No :

REPORT NO

ISSUE DATE 12/11/2023

CUSTOMER REFERENCE : TRF

28/09/2023 DATE

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PAGE NO

SAMPLE DETAILS

SAMPLE REGISTRATION DETAILS

Sample Name

: Ciprofoxacin Eye Drop 0.3%

Sample Quantity Received

: 15.00 Vial

Sample Registration Date Sample Submitted/Drawn by 26/10/2023

Batch Size

Client : N/A

Date of Expiry

Jun-2025

Sample Receipt Date

Registration No

28/09/2023

Name of Manufacturer

□ N/A

Batch No.

MMDSL-QC-0012

Date of Mfg.

: Jul-2023

SAMPLE ANALYSIS DETAILS

Analysis Starting Date

27/10/2023

Analysis Completion Date

10/11/2023

			EST RESULT			
SL No.	TEST PARAMETER	TESTING / REF. PROCEDURE	LABEL CLAIM	иом	ACCEPTANCE LIMIT	RESULTS
1	Sterility	Indian Pharmacopoeia 2022	10	-	Should be sterile	Sterile, complies
2	Description	Indian Pharmacopoeia 2022	29	(A)	A clear colourless liquid.	A clear colourless liquid.
з	Identification A	Indian Pharmacopoeia 2022	FI	-	In the assay, the principal peak in the chromatogram obtained with the test solution should correspond to the peak in the chromatogram obtained with the reference solution a.	In the assay, the principal peak in the chromatogram obtained with the test solution corresponds to the peak in the chromatogram obtained with the reference solution a.



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TEST RESULT										
SL No.	TEST PARAMETER	TESTING / REF. PROCEDURE	LABEL CLAIM	UOM	ACCEPTANCE LIMIT	RESULTS				
4	Identification B	Indian Pharmacopoeia 2022		Ξ.	A curdy white precipitate should be form which should not soluble in nitric acid but should be soluble after being well washed with water in dilute ammonia solution.	A curdy white precipitate is formed which is insoluble in nitric acid but soluble after being well washed with water in dilute ammonia solution.				
5	pΗ	Indian Pharmacopoeia 2022	*	==	3.5 - 5.5	4.7				
6	Assay	Indian Pharmacopoeia 2022	3 mg/ml	% of L.C.	2.70 - 3.30 mg/ml i.e. 90.0 - 110.0	2.86 mg/ml i.e. 95.18				

In the opinion of the undersigned, the Sample referred to above is of Standard Quality / is not of Standard Quality as defined in the Act or the Rules madethere under for the reasons given below:

Date

: 12/11/2023

UOM

: Unit of Measurement

REMARKS

: Opinion on Quality is drawn against the result obtained for tested parameters only

Note

: This Report is valid only for use in Indian (Domestic) Market & is Not valid for use in any International Market.

-END OF THE TEST REPORT-
