



QA.15.0.0.3

FORM 39 [RULE 150 - E(F)] APPROVAL NUMBER: T-22/DC TEST REPORT

ISSUED TO: REPORT NO : EFRAC/2023/DRG/RG/03406

Meghalayan Medical Drugs And Services Limited ISSUE DATE : 12/11/2023

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

CUSTOMER REFERENCE: TRF

director,NHM, Shillong, East Khasi Hills Meghalaya, 793003 DATE : 28/09/2023 Shillong, 793003 PAGE NO : 1 of 2

SAMPLE DETAILS

SAMPLE REGISTRATION DETAILS

Sample Name : Ciprofoxacin Eye Drop 0.3% Sample Quantity Received : 15.00 Vial

Sample Registration Date : 26/10/2023 Sample Submitted/Drawn by : Client Batch Size : N/A

Sample Receipt Date : 28/09/2023 Date of Expiry : Jun-2025

Registration No : EFRAC/2023/DRG/RG/03406

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

TEST RESULT

SL No.	TEST PARAMETER	TESTING / REF. PROCEDURE	LABEL CLAIM	UOM	ACCEPTANCE LIMIT	RESULTS
1	Sterility	Indian Pharmacopoeia 2022	-	_	Should be sterile	Sterile, complies
2	Description	Indian Pharmacopoeia 2022	-	_	A clear colourless liquid.	A clear colourless liquid.
3	Identification A	Indian Pharmacopoeia 2022	-	_	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

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SL No.	TEST PARAMETER	TESTING / REF. PROCEDURE	LABEL CLAIM	UOM	ACCEPTANCE LIMIT	RESULTS
4	Identification B	Indian Pharmacopoeia 2022	-	-/-	A curdy white	A curdy white
					precipitate should	precipitate is formed
			2.0		be form which	which is insoluble in
			and the same		should not soluble in	nitric acid but
			- A	_/ a	nitric acid but should	soluble after being
				M. M.	be soluble after	well washed with
			1	Y W	being well washed	water in dilute
				W.	with water in dilute	ammonia solution.
				.0\	ammonia solution.	
5	рН	Indian Pharmacopoeia 2022	シード	_	3.5 - 5.5	4.7
6	Assay	Indian Pharmacopoeia 2022	3 mg/ml	% of L.C.	2.70 - 3.30 mg/ml	2.86 mg/ml i.e.
			187	and the second	i.e. 90.0 - 110.0	95.18

In the opinion of the undersigned, the Sample referred to above <u>is of Standard Quality</u> / <u>is not of Standard Quality</u> as defined in the Act or the Rules made there 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-



