



## Edward Food Research & Analysis Centre Limited

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/03249

Meghalayan Medical Drugs And Services Limited ISSUE DATE : 24/10/2023

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 MFG. LICENCE NO : 1 of 2

## SAMPLE DETAILS

SAMPLE REGISTRATION DETAILS

Sample Name : Ciprofloxacin 0.3% Eye Drop Sample Quantity Received : 150.00 ml Sample Registration Date : 09/10/2023

Sample Submitted/Drawn by : Client
Batch Size : N/A

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

Registration No : EFRAC/2023/DRG/RG/03249

Name of Manufacturer : N/A

Batch No. : MMDSL-QC-0010

Date of Mfg. : Jun-2023

**SAMPLE ANALYSIS DETAILS** 

Analysis Starting Date : 10/10/2023 Analysis Completion Date : 24/10/2023

**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** 

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
			,		be form which	which is insoluble in
			_ <		should not soluble in	nitric acid but
			-	27	nitric acid but should	soluble after being
					be soluble after	well washed with
			( ) '		being well washed	water in dilute
					with water in dilute	ammonia solution.
			_		ammonia solution.	
5	рН	Indian Pharmacopoeia 2022	-	_	3.5 - 5.5	4.6
6	Assay	Indian Pharmacopoeia 2022	-	% of L.C.	2.70 - 3.30 mg/ml ,	3mg / ml , i.e. 100.0
					i.e. 90.0 - 110.0	

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 : 24/10/2023

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-

