



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

Shillongce793003:

REPORT NO : EFRAC/2023/DRG/RG/03405

ISSUE DATE : 12/11/2023

CUSTOMER REFERENCE : TRF

DATE : 28/09/2023 PAGE NO : 1 of 2

SAMPLE DETAILS

SAMPLE REGISTRATION DETAILS

Sample Name : Ciprofoxacin Eye Drop 0.3%

Sample Quantity Received

Sample Registration Date Sample Submitted/Drawn by

: Client

15.00 Vial

26/10/2023

Batch Size

: N/A : May-2025

Date of Expiry

Sample Receipt Date : 28/09/2023

Registration No : EFRAC/2023/DRG/RG/03405

Name of Manufacturer : N/

Batch No. : MMDSL-QC-0011

Date of Mfg. : Jun-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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Shillong CENCENO: **PAGE NO** : 2 of 2

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
			_A		be form which	which is insoluble in
			and the same		should not soluble in	nitric acid but
				_/ a	nitric acid but should	soluble after being
			()	M. M.	be soluble after	well washed with
			-7	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	4.5
6	Assay	Indian Pharmacopoeia 2022	3 mg/ml	% of L.C.	2.70 - 3.30 mg/ml	3.12mg/ml i.e.
		A	100	and the second	i.e. 90.0 - 110.0	104.01

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 made there under for the reasons given below:

Date : 12/11/2023

UOM : Unit of Measurement

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

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-



