## COAX BIOREMEDIES PVT. LTD

PLOT NO 83, SEC-28, INDUSTRIAL AREA, HISAR 125044 (HARYANA)

MFG. LIC NO.- 604-B(H) & 967-OSP(H)

**DEPARTMENT- QUALITY** CONTROL

**RECORD OF ANAYLSIS-**FINISHED PRODUCTS

## CERTIFICATE OF ANALYSIS

CERTIFICATE NO: ARFP/10-666A/23-24

**DATE OF ANALYSIS:24-10-23** 

PRODUCT: CPM INJ 1.0ML

DATE OF RELEASE:07-11-23

GENERIC NAME: CHLORPHENERAMINE MALEATE INJ I.P VET

BATCH NO: EE-293

LABELCLAIM: 10MG/ML MFG DATE: OCT/2023

	CH SIZE: 52 LIT	EXP DATE: SEP/2025	
S.NO		SPECIFICATION	RESULTS
1	DESCRIPTION	CLEAR COLOURLESS SOLUTION SHOULD BE FILLED IN AMBER GLASS AMPOULES.	CLEAR COLOURLESS SOLUTION SHOULD FILL IN AMBER GLASS AMPOULES.
2	IDENTIFICATION	SHOULD COMPLY WITH STATED SPECIFICATIONS	COMPLIES
3	pН	BETWEEN 4.0 TO 5.2	4.64
4	EXTRACTABLE VOLUME	NOT LESS THAN THE NOMINAL VOLUME	1.03ML
5	BACTERIAL ENDOTOXIN	NMT 8.8 EU/MG OF CHLORPHENIRAMINE MALEATE	< 8.8 EU/MG OF CHLORPHENIRAMINE MALEATE
6	RELATED SUBSTANCE	SHOULD COMPLY WITH STATED SPECIFICATIONS	COMPLIES
7	PARTICULATE MATTE	R	
	VISIBLE PARTICLES	SOLUTION SHOULD BE FREE FROM PARTICULATE MATTER VISIBLE TO UNAIDED EYES.	COMPLIES
8	STERILITY	SHOULD PASS THE STERILITY TEST	COMPLIES
9	ASSAY	LIMITS	RESULT CLAIM
	EACH ML CONTAINS: CHLORPHENERAMINE MALEATE I. P	NLT 90% AND NMT 110% THE LABELLED AMOUNT OF CHLORPHENERAMINE MALEATE	10.008MG 10.0MG/ML 100.08%

REMARK: THE PRODUCT COMPLIES FOR (I.P. 2022 VET) SPECIFICATION.

STORAGE: STORE PROTECTED FROM LIGHT.

ANALYSED BY

Agrafam 7/11/2023 **O.C INCHARGE**