

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
CONTROLRECORD OF ANALYSIS-
FINISHED PRODUCTS**CERTIFICATE OF ANALYSIS**

CERTIFICATE NO: ARFP/11-703/23-24

DATE OF ANALYSIS: 05-11-23

PRODUCT: AMERICAN CPM INJ 1.0ML

DATE OF RELEASE: 19-11-23

GENERIC NAME: CHLORPHENERAMINE MALEATE INJ I.P VET

LABEL CLAIM: 10MG/ML

BATCH NO: EE-295

MFG DATE: NOV/2023

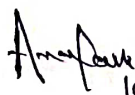
BATCH SIZE: 52 LIT

EXP DATE: OCT/2025


S.NO	TEST	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	pH	BETWEEN 4.0 TO 5.2	4.67
4	EXTRACTABLE VOLUME	NOT LESS THAN THE NOMINAL VOLUME	1.02ML
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 MATTER		
	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	9.913MG 10.0MG/ML 99.13%

REMARK: THE PRODUCT COMPLIES FOR (I.P. 2022 VET) SPECIFICATION.
STORAGE: STORE PROTECTED FROM LIGHT.

ANALYSED BY


19/11/2023

Q.C INCHARGE


19/11/2023