

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 ANALYSIS-FINISHED PRODUCTS

CERTIFICATE OF ANALYSIS

CERTIFICATE NO: ARFP/11-726/23-24

DATE OF ANALYSIS:11-11-23

PRODUCT: CPM INJ 1.0ML

DATE OF RELEASE:25-11-23

GENERIC NAME: CHLORPHENERAMINE MALEATE INJ I.P VET

LABEL CLAIM:10MG/ML

BATCH NO: EE-298

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	4.57	
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	10.021MG 100.21%	10.0MG/ML

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

ANALYSED BY

Ameyan
25/11/2023

Q.C INCHARGE

Ameyan
25/11/2023