

COAX BIOREMEDIES PVT. LTD

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

**DEPARTMENT- QUALITY
CONTROL****RECORD OF ANALYSIS-
FINISHED PRODUCTS****CERTIFICATE OF ANALYSIS****CERTIFICATE NO:** ARFP/11-728/23-24**DATE OF ANALYSIS:** 12-11-23**PRODUCT:** CPM INJ 1.0ML**DATE OF RELEASE:** 26-11-23**GENERIC NAME:** CHLORPHENERAMINE MALEATE INJ I.P VET**LABEL CLAIM:** 10MG/ML**BATCH NO:** EE-299**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 | 4.52 |
| 4 | EXTRACTABLE VOLUME | NOT LESS THAN THE NOMINAL VOLUME | 1.05ML |
| 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 | 10.001MG 100.01% 10.0MG/ML |

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

ANALYSED BY

Q.C INCHARGE