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/11-699/23-24

PRODUCT: CPM INJ 1.0ML

DATE OF ANALYSIS:05-11-23

DATE OF RELEASE:19-11-23

GENERIC NAME: CHLORPHENERAMINE MALEATE INJ I.P VET

BATCH NO: EE-294 BATCH SIZE: 52 LIT

LABELCLAIM: 10MG/ML MFG DATE: NOV/2023 EXP DATE: OCT/2025

S.NO	O TEST	CDECUTION CAPTURE CONTINUES	
1	DESCRIPTION	SPECIFICATION	RESULTS
1	DESCRIPTION	CLEAR COLOURLESS	CLEAR COLOURLESS
		SOLUTION SHOULD BE	SOLUTION SHOULD FILL IN
		FILLED IN AMBER	AMBER GLASS AMPOULES.
		GLASS AMPOULES.	
2	IDENTIFICATION	SHOULD COMPLY	COMPLIES
		WITH STATED	COMPLIES
		SPECIFICATIONS	·
3	pH	BETWEEN 4.0 TO 5.2	4.61
4	-		4.61
4	EXTRACTABLE	NOT LESS THAN THE	1.02ML
_	VOLUME	NOMINAL VOLUME	
5	BACTERIAL	NMT 8.8 EU/MG OF	< 8.8 EU/MG OF
	ENDOTOXIN	CHLORPHENIRAMINE	CHLORPHENIRAMINE
		MALEATE	MALEATE
6	RELATED	SHOULD COMPLY	COMPLIES
	SUBSTANCE	WITH STATED	
		SPECIFICATIONS	
7	PARTICULATE MATTI	ER	
	VISIBLE PARTICLES	SOLUTION SHOULD BE	COMPLIES
		FREE FROM	COMPLIES
		PARTICULATE MATTER	
		VISIBLE TO UNAIDED	
		EYES.	
8	STERILITY	SHOULD PASS THE	COMPLIES
		STERILITY TEST	COMPLIES
9	ASSAY	LIMITS	DECLIA
	EACH ML CONTAINS:	EIMITS	RESULT CLAIM
	CHLORPHENERAMINE	NI TI 000/ 1375 375	
	MALEATE I. P	NLT 90% AND NMT	9.978MG 10.0MG/ML
	MALEATE I. P	110% THE LABELLED	99.78%
		AMOUNT OF	
		CHLORPHENERAMINE	
	3.5.1	MALEATE	

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

STORAGE: STORE PROTECTED FROM LIGHT.

fun 19/11/2023

Q.C INCHARGE