



COAX BIOREMEDIES PVT. LTD
PLOT NO 83, SEC-28, INDUSTRIAL AREA, HISAR 125044 (HARYANA)
MFG. LIC NO.- 604-B(H) & 967-OSP(H)

CERTIFICATE OF ANALYSIS
(D&C ACT FORM 39)

Product name : American CPM Inj 1 ml	Certificate no : ARFP/12-921/24-25
Generic name : Chlorpheniramine Maleate Inj I.P	Date of analysis : 19/12/2024
Batch no : EE-318	Date of release : 02/01/2025
Mfg date : Dec-2024	Exp date : Nov-2026
Batch size : 25 Litre	Reference : I.P 2022

S.NO	TEST	SPECIFICATION	RESULT
1	Description	Clear colorless solution should be filled in Amber glass Ampoule.	Clear colorless solution should fill in Amber glass Ampoule.
2	Identification (A) TLC	The principal spot in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with the reference solution.	Complies
3	pH	Between 4.0-5.2	4.68
4	Related substance	Any secondary spot in the chromatogram obtained with the test solution is not more intense than the spot in the chromatogram obtained with the reference solution.	Complies
5	Extractable volume	Not less than the nominal volume	1.1ml
6	Bacterial endotoxin	NMT 8.8 EU/mg of Chlorpheniramine maleate	< 8.8 EU/mg of Chlorpheniramine maleate
7	Particulate matter Visible particles	Solution should be free from particulate matter visible to unaided eyes.	Complies
8	Sterility	Complies with the test for sterility.	Complies
9	Assay	Limit	Result Claim
	Each ml contains: Chlorpheniramine maleate I. P	NLT 90% and NMT 110% the labeled amount of Chlorpheniramine maleate	10.183mg 101.83% 10.0mg/ml

Remark: The Product Complies/Does not comply as per above specification I.P/B.P/U.S.P/I.H.S.
As per the observation of Undersigned.

Dilika
02/01/25
ANALYSED BY

Abdul
02/01/25
Q.C INCHARGE
(For Coax Bioremedies)