



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

CERTIFICATE OF ANALYSIS
(D&C ACT FORM 39)

Product name : PART-A NumbOn-B Combi Inj 10ml	Certificate No : ARFP/08-471/25-26
Generic name : Lignocaine Inj I.P 10ml	Date of analysis : 22-08-2025
Batch No : LB-25082A	Date of release : 05-09-2025
Mfg date : 08-2025	Exp date : 07-2028
Batch size : 270 Litre	Reference : IP 2022

S.NO	TEST	SPECIFICATION	RESULT
1	Description	Clear colorless solution should be filled clear glass vial.	Clear colorless solution is filled clear glass vial.
2	Identification		
	(A) Chemically	Bluish green precipitate should be formed.	Complies
	(B) Precipitate's Melting Point	Melt about 229°	Complies
	(C) Chlorides	Should complies with the reaction of chloride	Complies
3	pH	Between 5.0-7.0	6.67
4	Extractable volume	Not less than the nominal volume	10.1 ml
5	Particulate matter		
	Visible particles	Solution should be free from particulate matter visible to unaided eyes.	Complies
6	2,6-dimethylaniline	Yellow color produce is not more intense than the color produce by reference solution.	complies
7	Sterility	Complies with the test for sterility.	Complies
8	Bacterial Endotoxin	NMT 1.1 EU/mg of lignocaine HCL	<1.1 EU/mg lignocaine HCL
9	Assay	Limit	Result Claim
	Each ml Contains: Lignocaine HCL I.P	NLT 95% and NMT 105% the labeled amount lignocaine HCL	20.45 mg/ml 102.25% 20.00 mg/ml

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

Dilika
05/09/25

ANALYSED BY

T. U. S. P. H. S.
05/09/2021

Q.C INCHARGE
(For Coax Bioremedies)



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

CERTIFICATE OF ANALYSIS
(D&C ACT FORM 39)

Product name : PART-B NumbOn-B Combi Inj 20ml	Certificate No : ARFP/08-483/25-26
Generic name : Bupivacaine Inj I.P 20ml	Date of analysis : 25-08-2025
Batch No : LB-25082B	Date of release : 09-09-2025
Mfg date : 08-2025	Exp date : 07-2028
Batch size : 530 Litre	Reference : IP 2022

S.NO	TEST	SPECIFICATION	RESULT
1	Description	Clear colorless solution should be filled clear glass vial.	Clear colorless solution is filled clear glass vial.
2	Identification		
	(A) I.R	Compare the spectrum with that obtained with Bupivacaine hydrochloride IPRS with the reference spectrum of bupivacaine	Complies
	(B) Chemically	As per I.P	Complies
3	pH	Between 4.0-6.5	5.71
4	Extractable volume	Not less than the nominal volume	20.1 ml
5	Particulate matter		
	Visible particles	Solution should be free from particulate matter visible to unaided eyes.	Complies
6	2,6-dimethylaniline	Yellow color produce is not more intense than the color produce by reference solution.	complies
7	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
8	Bacterial Endotoxin	NMT 2.5 EU/mg of Bupivacaine hcl	<2.5 EU/mg Bupivacaine hcl
9	Assay	Limit	Result Claim
	Each ml contains: Bupivacaine hcl I.P	NLT 92.5% and NMT 107.5% the labeled amount Bupivacaine hcl	5.021 mg/ml 100.42% 5.0 mg/ml

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

Dilika
09/09/25
ANALYSED BY

[Signature]
09/09/2025
Q.C INCHARGE
(For Coax Bioremedies)