



American Remedies Healthcare Pvt. Ltd.

Surajpur, Nahan Road Paonta sahib Dist. Sirmour (H.P)

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF FINISH PRODUCT ANALYSIS

| | | | |
|--------------------|---|-----------------|----------------|
| Product Name: | Numbon-ADR Injection (Lignocaine and Adrenaline Injection IP) | | |
| Batch No. | 25AR011A | A.R. No. | AFP250015 |
| Batch Size | 25100 Vials | Sample Quantity | 60 Nos |
| Mfg. Date | 08/2025 | Date of Testing | 30/08/2025 |
| Exp. Date | 07/2027 | Date of Release | 17/09/2025 |
| Reference Batch No | 25AR012 | MFG. Lic. No. | HP-MB-LL-00235 |

| Sr. No. | Test | Specification | Observation |
|---------|---|--|-----------------------------|
| 1. | Description | A clear colourless solution | A clear colourless solution |
| 2. | Identification A. By Chemically B. By Chemically C. By Melting Point | <p>A. To 5 ml add 1 ml of hydrochloric acid, cool to 0°, add 5 ml of a 1 per cent w/v solution of sodium nitrite and pour the mixture into 2 ml of 2-naphthol solution containing 1 g of sodium acetate; no red colour is produced.</p> <p>B. To 10 ml add 4 ml of disodium hydrogen phosphate solution and sufficient 0.1 M iodine to produce a distinct brown colour, Add 0.01 M sodium thiosulphate to remove the excess of iodine; a pink colour is produced.</p> <p>C. To 3 ml add 3 ml of water and 6 ml of picric acid solution, shake gently and allow to stand until the precipitate becomes crystalline; the precipitate, after washing with water and drying at 105°, melts at about 229°</p> | Complies |
| 3. | pH | 3.0 to 4.5 | 3.85 |
| 4. | Extractable Volume | NLT 30.0 ml | 30.0 ml |
| 5. | Particulate Matter | Injections that are solutions, when examined under suitable conditions of visibility, are clear and practically free from particles that can be observed on visual inspection by the unaided eye. | Complies |



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| | | | |
|----|---|--|-----------------------|
| 6. | Bacterial Endotoxins | NMT 17.5 EU/mg | Less than 17.5 EU/mg |
| 7. | Sterility | Should be complies | Sterile |
| 8. | Assay: Each ml contains Lignocaine Hydrochloride IP 20 mg | 19.0 mg to 21 mg 95.0 % to 105.0 % | 20.68mg 103.4% |
| | Adrenaline Bitartrate IP eq. to Adrenaline 0.01 mg | 0.00875 mg to 0.01125 mg 87.50 % to 112.5 % | 0.0105 mg 105.48 % |

Remark: The sample is complies as per IP /BP/ USP/IH specification.

| | Prepared By | Checked By | Approved By |
|-------------|---|---|---|
| Sign/Date |  17/09/2025 |  17/09/2025 |  17/09/2025 |
| Name | Prayash | Manisha Thakur | Bhupinder Navet |
| Designation | Officer QC | Executive-QC | Head-QC |

