



# AMERICAN REMEDIES HEALTHCARE PVT. LTD.

Vill. Surajpur, Nahan Road, Paonta Sahib, Dist. Sirmour (H.P) 173025

## Title : Certificate of Analysis Finished Product

|                     |   |                        |               |
|---------------------|---|------------------------|---------------|
| <b>Product Name</b> | Colistican Injection                        | <b>A.R. No.</b>        | ARN/FP/25/043 |
| <b>Generic Name</b> | Colistimethate Sodium for Injection IP 2MIU | <b>Sampled qty.</b>    | 45 Vials      |
| <b>Batch No.</b>    | ARN2555A                                    | <b>Sampled by</b>      | Rakesh        |
| <b>Batch Size</b>   | 6990 Vials                                  | <b>Sampled on</b>      | 24/10/2025    |
| <b>Mfg. Date</b>    | 10/2025                                     | <b>Date of Testing</b> | 25/10/2025    |
| <b>Exp. Date</b>    | 09/2027                                     | <b>Date of Release</b> | 08/11/2025    |

| S. No. | Tests   | Specifications   | Observations  |
|--------|---|--|---|
| 1.     | Description   | A white dry powder filled in clear glass vial.   | A white dry powder filled in clear glass vial.                  |
| 2.     | Identification (By TLC)   | <p>A. The spots in the chromatogram obtained with the test solution correspond to those in the chromatogram obtained with the reference solutions (a) and (b), but shows no spots corresponding to those in the chromatograms obtained with reference solutions (c) and (d). It also shows a spot with a very low RF value (2, 4-diaminobutyric acid).</p> <p>B. A purple colour is produced (distinction from colistin Sulphate).</p> <p>C. The solution is decolorized and gives the reaction (a) of sulphates.</p> <p>D. It gives the reaction (b) of sodium salts.</p> | <p>Complies</p> <p>Complies</p> <p>Complies</p> <p>Complies</p> |
| 3.     | Uniformity of weight  | Average weight $\pm 10\%$  | -2.17% & +3.84%   |
| 4.     | Average weight  | Informative $\pm 2\%$ .  | 176.4 mg  |
| 5.     | Free colistin   | Dissolve a quantity containing 1,000,000 IU in 3 ml of water, add 0.1 ml of a 10.0 % solution of silicotungstic acid and allow to stand for 10 to 20 seconds the solution is not more opalescence than opalescence standard OS <sub>2</sub> .  | Complies  |
| 6.     | pH  | 6.5 to 8.5   | 7.02  |
| 7.     | Loss on drying  | NMT 5.0%w/w  | 2.47%w/w  |
| 8.     | Particulate Matter  | <p>Reconstituted the injection vial; the solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be observed on visual inspection.</p>   | <p>975/vial</p> <p>11/vial</p> <p>Complies</p>                  |
|        | <p>(A.) Light Obscuration Particle Count Test</p> <p>(1.) Particles <math>\geq 10\mu\text{m}</math></p> <p>(2.) Particles <math>\geq 25\mu\text{m}</math></p> <p>(B.) Visual Particle</p> |  |   |

Analysis by *[Signature]*

Checked by *[Signature]*

Approved by *[Signature]*



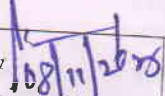

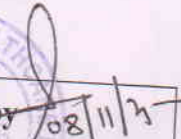
Title :

**Certificate of Analysis Finished Product**

|                     |   |                        |               |
|---------------------|---|------------------------|---------------|
| <b>Product Name</b> | Colistican Injection                        | <b>A.R. No.</b>        | ARN/FP/25/043 |
| <b>Generic Name</b> | Colistimethate Sodium for Injection IP 2MIU | <b>Sampled qty.</b>    | 45 Vials      |
| <b>Batch No.</b>    | ARN2555A                                    | <b>Sampled by</b>      | Rakesh        |
| <b>Batch Size</b>   | 6990 Vials                                  | <b>Sampled on</b>      | 24/10/2025    |
| <b>Mfg. Date</b>    | 10/2025                                     | <b>Date of Testing</b> | 25/10/2025    |
| <b>Exp. Date</b>    | 09/2027                                     | <b>Date of Release</b> | 08/11/2025    |

|                                  |   |  |  |                     |                            |
|----------------------------------|---|--|--|---------------------|----------------------------|
| 9.                               | Sterility   | No microbial growth should be observed.  | Complies   |                     |                            |
| 10.                              | Bacterial Endotoxins                                  | NMT 43.75 EU/ml of a solution containing 250,000 IU/ml of water for Injection. | Less than 43.75 EU/ml of a solution containing 250,000 IU/ml of water for Injection. |                     |                            |
| 11.                              | Assay: (By Microbiology)<br>Each glass vial contains: |  |  |                     |                            |
| Ingredients                      |   | Labeled Claim  | Found  | % of labeled amount | Limits % of labeled amount |
| Sterile Colistimethate Sodium IP |   | 2,000,000 IU   | 2,007,778.521 IU   | 100.39%             | 90.0 to 120.0%             |

**Remarks:** In the opinion of the undersigned the sample referred to above is/ is not of the standard quality as The Drug & Cosmetic Act 1940 and the rules made there under. Complies/ not complies as per IP/BP/USP/IHS.

|  |   |  |
|--|---|--|
| Analysis by <br>NAME: NIKHIL SHARMA | Checked by <br>NAME: SUFIYAN ANSARI | Approved by <br>NAME: MRS. SWATI DHAWAN |
|--|---|--|

