# AMERICAN REMEDIES HEALTHCARE PVT. LTD.

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

| Title | : | Certificate of Analysis Finished Product |
|---|---|---|

| | | | |
|---|---|---|---|
| **Product Name** | **AZTREOCAN** Injection | **A.R. No.** | ARB/FP/26/015 |
| **Generic Name** | Aztreonam for Injection USP 1gm | **Sampled qty.** | 45 vials |
| **Batch No.** | ARB2611A | **Sampled by** | Rakesh |
| **Batch Size** | 5100 Vials | **Sampled on** | 05/06/2026 |
| **Mfg. Date** | 05/2026 | **Date of Testing** | 06/06/2026 |
| **Exp. Date** | 04/2028 | **Date of Conditionally Release** | 18/06/2026 |

| 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 | The retention times the major peaks of the sample solution correspond to those of the working standard solution. | Complies |
| 3. | Uniformity of Weight | Average weight ±10% | -0.87% & +0.75% |
| 4. | Average weight | Informative ±2%. | 1788.0 mg |
| 5. | pH | 4.5 to 7.5 | 6.43 |
| 6. | Particulate Matter | | |
| | (A.) Light Obscuration Particle Count Test | | |
| | 1.Particles ≥10 µm | NMT 6000/vial | 576/vial |
| | 2.Particles ≥25 µm | NMT 600/vial | 3/vial |
| | (B.) Visual Particle | The reconstituted solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally that can be observed on visual inspection. | Complies |
| 7. | Water | NMT 2.0%w/w | 1.51%w/w |
| 8. | Contents of Arginine | 42% to 46% | 45.18% |
| 9. | Sterility | No microbial growth should be observed. | Under Process |
| 10. | Bacterial Endotoxins | NMT 0.17 USP EU/mg of Aztreonam. | Less than 0.17 USP EU/mg of Aztreonam. |
| 11. | Assay: (By HPLC) Each glass vial contains | | |

| Ingredients | Labeled Claim | Found | % of labeled amount | Limits % of labeled amount |
|---|---|---|---|---|
| Aztreonam (Sterile) USP Eq. to anhydrous Aztreonam (A mixture of Aztreonam & L-Arginine) | 1000 mg | 1028.9919mg | 102.90% | 90.0% to 105.0% |

**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 | Checked by | Approved by |
|---|---|---|
| 18/06/26 | 18/06/26 | 18/06/26 |
| NAME: NIKHIL SHARMA | NAME: RAMANJEET SINGH | NAME: MRS. SWATI DHAWAN |