



Add Pace To Health

Pace Biotech

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

Title : Certificate of Analysis Finished Product

| | | | |
|--------------|---|-------------------------------|--------------|
| Product Name | ATRANIUM Injection | A.R. No. | NL/FP/23/609 |
| Generic Name | Atracurium Besylate Injection IP 50mg/5ml | Sampled qty. | 45 Ampoules |
| Batch No. | A23489A | Sampled by | Arvind |
| Batch Size | 10,010 Ampoules | Sampled on | 22/12/2023 |
| Mfg. Date | 12/2023 | Date of Testing | 22/12/2023 |
| Exp. Date | 11/2025 | Date of Conditionally Release | 05/01/2024 |

| S. No. | Tests | Specifications | Observations |
|--------|--|--|--|
| 1. | Description | A clear colourless solution filled in clear glass ampoule. | A clear colourless solution filled in clear glass ampoule. |
| 2. | Identification | In the assay, the principle peaks of three isomers of Atracurium Besylate in the chromatogram obtained with the test solution corresponds to the peaks in the chromatogram obtained with the reference solution. | Complies |
| 3. | Nominal fill volume | NLT-5 ml | 5.0 ml |
| 4. | Extractable Volume | NLT Nominal volume or NMT 110% of Nominal volume. | 5.1 ml |
| 5. | pH | 3.0 to 3.65 | 3.45 |
| 6. | Related substance | The test is not valid unless the resolution between the peaks due to Atracurium and the Cis-Trans isomer is not more than 1.5 and the resolution between the peaks due to Atracurium Cis-Trans isomer and the Cis-Cis isomer is not less than 1.5. | Complies |
| 7. | Particulate Matter (a.) Sub-Visible particle count (1.) Particles $\geq 10\mu\text{m}$ (2.) Particles $\geq 25\mu\text{m}$ (b.) Visual | NMT-6000/Ampoule NMT-600/ Ampoule The solution should be essentially free from extraneous, mobile undissolved particles, other than gas bubbles, unintentionally. | 14/Ampoule 2/Ampoule Complies |
| 8. | Sterility | No microbial growth should be observed. | Under process |
| 9. | Bacterial Endotoxins | NMT- 5.56 EU/mg of Atracurium Besylate. | Less than- 5.56 EU/mg of Atracurium Besylate. |
| 10. | Assay: Each ml contains: | | |

| Ingredients | Labeled Claim | Found | % of labeled amount | Limits % of labeled amount |
|------------------------|---------------|----------|---------------------|----------------------------|
| Atracurium Besylate IP | 10 mg | 9.973 mg | 99.73% | 90.0% to 115.0% |

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 | |
|-------------|------------|--|