

## **CERTIFICATE OF ANALYSIS**

The Power to Question

Catalog Number: sc-210845 Lot Number: SAMPLE

Product Name: Atracurium Besylate

CAS Number: 64228-81-5 Molecular Formula:  $C_{65}H_{82}N_2O_{18}S_2$ Molecular Weight: 1243.48

| Test                    | Specification   | Result                           |
|-------------------------|---|----------------------------------|
| Appearance              | White to yellowish-white powder, slightly hygroscopic, odorless                                     | Complies                         |
| Assay (HPLC, dry basis) | 96.0 - 102.0%   | 98.9%                            |
| Chromatographic Purity  | Laudanosine: ≤ 0.5%<br>Any other individual impurity: ≤ 1.0%<br>Total impurities: ≤ 3.5%            | 0.04%<br>0.38%<br>0.90%          |
| Identification          | IR: Conforms<br>HPLC: Conforms  | Complies<br>Complies             |
| Isomer Ratio            | Trans-trans isomer: 5.0% - 6.5%<br>Cis-trans isomer: 34.5% - 38.5%<br>Cis-cis isomer: 55.0% - 60.0% | 5.6%<br>35.5%<br>58.9%           |
| Residual Solvents       | Dichloromethane: ≤ 600 ppm<br>Acetonitrile: ≤ 410 ppm<br>Ethyl ether: ≤ 5000 ppm                    | Negative<br>Negative<br>3474 ppm |
| Residue on Ignition     | ≤ 0.2%  | 0.2%                             |
| Solubility              | Very soluble in acetonitrile and chloroform, soluble in water and practically insoluble in ether    | Complies                         |
| Heavy Metals            | ≤ 20 ppm  | < 20 ppm                         |
| Methyl benzenesulfonate | ≤ 0.01%   | 0.00004%                         |
| Toluene                 | ≤ 890 ppm (ICH)   | 91 ppm                           |
| Water Content           | ≤ 5.0%  | 0.5%                             |

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