



# Certificate of analysis

Product name: Cisatracurium besilate

Cas number: 96946-42-8

Molecular Formula:  $C_{53}H_{72}N_2O_{12} \cdot 2(C_6H_5O_3S); C_{65}H_{82}N_2O_{18}S_2$ 

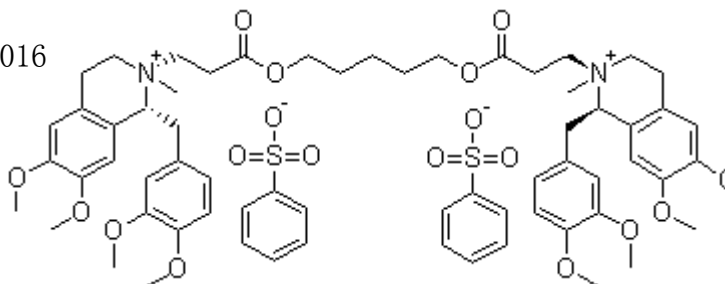
Molecular Weight: 1243.48

Date of production: Apr. 18, 2016

Expiry Date: Apr. 17, 2018

Batch NO: 20160418

Chemical structure:



| Items                          | Specifications  | Results  |
|--------------------------------|---|--|
| <b>Description</b>             | White to off-white powder   | Conform  |
| <b>Identification</b>          | NMR HPLC  | Conform  |
| <b>Solubility</b>              | Freely soluble in chloroform and ethanol, soluble in acetone, sparingly soluble in water.   | Conform  |
| <b>Methyl benzenesulfonate</b> | NMT 10PPM   | Conform  |
| <b>Specific rotation</b>       | -54° ~ -60°   | -58.9°   |
| <b>PH</b>                      | PH 5.0~6.5  | 5.7  |
| <b>Organic impurities</b>      | (1) Cis-Quaternary acid:NMT 0.2%<br>(2) (R)-N-Methylaudanosine:NMT 0.2%<br>(3) (R)-Laudanosine:NMT 0.6%<br>(4) Cis-Quaternary methyl ester:NMT 0.4%<br>(5) Cis- Quaternary alcohol:NMT 0.5%<br>(6) R-trans-R'-trans-Atracurium:NMT 0.2%<br>(7) R-cis-R'-trans-Atracurium:NMT 0.8%<br>(8) Trans-Monoquaternary compound:NMT 0.5%<br>(9) Trans-Monoacrylate:NMT 0.5%<br>(10) Cis-Monoquaternary compound:NMT 0.7%<br>(11) Cis-cis-Triester analog:NMT 0.4%<br>(12) Cis-Monoacrylate:NMT 1.0%<br>(13) Any individual unspecified impurity:NMT 0.1%<br>(14) Total impurity:NMT 3.0% | 0.03%<br>Undetected<br>0.06%<br>Undetected<br>0.07%<br>Undetected<br>0.06%<br>Undetected<br>Undetected<br>Undetected<br>0.05%<br>Undetected<br>0.52% |
| <b>Water</b>                   | NMT 5.0%  | 1.1%   |
| <b>Residue on ignition</b>     | NMT 0.1%  | 0.05%  |
| <b>Residual solvents</b>       | (1) Acetonitrile:NMT 410ppm<br>(2) Dichloromethane:NMT 600ppm<br>(3) Ethyl ether:NMT 5000ppm<br>(4) Toluene:NMT 890ppm  | 33ppm<br>Undetected<br>305ppm<br>Undetected  |
| <b>Assay</b>                   | 97.0%~102.0%<br>(calculated on the anhydrous and solvent-free basis)  | 99.6%  |

**Conclusion: It complies with the USP39 Standard.**

Analyst:Zhao

Checker:Liu

Q.C Director. Fang F