



Specialized in chemicals

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Certificate of Analysis

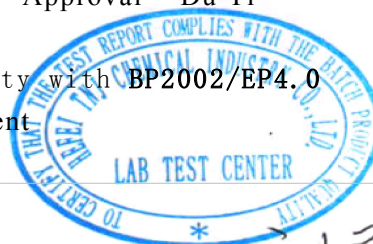
| | | | |
|-------------|-----------------------------|---------------|----------------|
| Product | Gentamycin Sulphate Sterile | Batch No. | TNJ2014032006 |
| CAS No. | 1405-41-0 | N. W. | 25.00kg |
| Packing | 8.333kg/Tin | MFG | March 20, 2014 |
| G.W. | 28.00kg | Analysis Date | March 20, 2014 |
| Retest Date | Feb. 19, 2018 | | |

| Items | Specification | Results |
|----------------------------|--|-----------------------------|
| Characters | White or almost white powder, freely soluble in water, insoluble in alcohol and ether. | Complies |
| Identification | Tests according to monograph | |
| Solution appearance | Clear and not more intensely colored than degree 6 of the range of reference solutions of the most appropriate color | Complies Complies 4.8 |
| PH | 3.50~5.50 | +116 ⁰ |
| Specific Optical rotation | +107 ⁰ - +121 ⁰ | Complies |
| Methanol,% | ≤ 1.00 | 25.50 |
| Composition,% | C ₁ 25.00~50.00 | 28.10 |
| | C _{1a} 10.00~35.00 | 46.40 |
| | C _{2a} +C ₂ 25.00~55.00 | 8.00 |
| Water,% | ≤ 15.00 | 0.30 |
| Sulphated Ash,% | ≤ 1.00 | 34.40 |
| Sulphate,% | 32.00~35.00 | Complies |
| Serility | Complies with the test for sterility | Complies |
| Bacterial Endotoxins,IU/mg | ≤ 1.67 | |
| Assay,IU/mg | ≥ 590.00 | 659.00 |
| | (Anhydrous substance) | 606.00 |
| | (Hydrous substance) | |

Checker Xu Dong Re-checker Lu Xiaoping Approval Du Yi

Conclusion The Quality of the above said is in conformity with BP2002/EP4.0

COA Issuer Quality Control Team-Technology Department



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