



Anhui Ailead Pharmaceutical Co., Ltd.

Certificate of Analysis

Betahistine mesylate

Cas # 54856-23-4

Report No. :Y2022101801

| | | | |
|-----------|------------------------------|-------------|--------------|
| Batch No. | 221018 | Quantity | 10.0 kg |
| Package | LDPE | Test Date | Oct.18. 2022 |
| Storage | Preserve in tight containers | Retest Date | Oct.17. 2024 |

Test Standards: In-house Standards

| Items | Specification | Results |
|------------------------|---|------------------|
| 【Appearance】 | White or white crystalline powder,easily moisture absorption | Conforms |
| 【Melting point】 | 110°C ~ 114°C | 111.3 °C~112.2°C |
| 【Solubility】 | Very easily soluble in water,easily soluble in Ethanol;soluble in Hydrochloride,very slightly soluble in Isopropyl Alcohol | Conforms |
| 【HPLC Identification】 | The retention time of the main peak of the solution should be consistent with the retention time of the main peak of the reference solution | Conforms |
| 【IR Identification】 | The IRS should be consistent with that of standard sample | Conforms |
| 【Clarity】 | It should be clear and colorless | Conforms |
| 【Sulphate】 | 2.0 ~ 3.0 | 2.28 |
| 【Related Substance】 | Impurity A not more than 0.15 % | Not detected |
| | Other unknown single impurity not more than 0.10 % | 0.01% |
| | Total Impurity not more than 0.50 % | 0.03% |
| 【Residual Solvents】 | Isopropyl Alcohol not more than 0.50% | 0.06% |
| | Methylene Chloride not more than 0.06 % | Not detected |
| 【Chloride】 | Not more than 35 ppm | Conforms |
| 【Sulphate】 | Not more than 250 ppm | Conforms |
| 【Water】 | Not more than 2.0 % | 0.18% |
| 【Residue on Ignition】 | Not more than 0.10 % | 0.03% |
| 【Heavy metal】 | Not more than 20 ppm | Conforms |
| 【Microbial limits】 | Total aerobic bacteria count (TAMC) not more than 1000 cfu/g | Conforms |
| | Total Yeast and Mold count (TYMC) not more than 100 cfu/g | |
| | Escherichia coli not detected | |
| 【Assay】 | On dry basis, it should be 98.0% ~102.0% | 98.60% |
| Analyst/Date | Oct.18. 2022 | |
| Checker/Date: | Oct.19. 2022 | |
| Supervisor/Date | Oct.19. 2022 | |

FINAL BATCH DISPOSITION

Approved (√)

By/Date: _____