



上海立科药物化学有限公司
Shanghai Record Pharmaceuticals Co., Ltd.

Certificate of Analysis

Product Name: Trilostane

CAS No.: 13647-35-3

Batch No.: 1909002

Quantity: 139.6Kg

Manufacturing Date: September, 2019

Expiry date: September, 2022

Testing date: September 27, 2019

Testing standard: company standard

| Analysis Content | | Specification | Analysis Result |
|---------------------------|------------------------|--|-------------------|
| Appearance | | White to off-white powder | Conformed |
| Purity(HPLC) | | $\geq 99.0\%$ | 99.6% |
| Identification | | IR absorption spectrum of the test sample complies with the spectrum of RS | Conformed |
| Single impurity | | $\leq 0.30\%$ | 0.06% |
| Water(K.F) | | $\leq 0.50\%$ | 0.19% |
| Loss on Drying | | $\leq 0.50\%$ | 0.10% |
| Residue on ignition | | $\leq 0.10\%$ | 0.01% |
| Heavy metals | | $\leq 20\text{ppm}$ | Conformed |
| Specific optical rotation | | $+137.0^\circ \sim +139.0^\circ$ | $+138.2^\circ$ |
| Residual solvents | Tetrahydrofuran | $\leq 0.072\%$ | 0.01 % |
| | Tert-buty methyl ether | $\leq 0.50\%$ | 0.01 % |
| | Ethanol | $\leq 0.50\%$ | 0.23 % |
| | Dimethyl sulfoxide | $\leq 0.50\%$ | 0.32 % |
| | Dichloromethane | $\leq 0.060\%$ | $\leq \text{LOD}$ |

Conclusion: This is to certify that we, the undersigned, have inspected/tested the quality of the above mentioned material and found the result meet the standard as above.

Analyst 刘如雷
Date: 2019.09.28

Checker 朱志军
Date: 2019.09.28

Approver 朱志军
Date: 2019.09.28

