



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.: 2008006
Quantity: 48Kg
Manufacturing Date: August, 2020
Expiry date: August, 2023
Testing date: August 27, 2020
Testing standard: company standard

METAPHARMACEUTICAL

N DE LOTE:

0260421

Handwritten signature and date: 20/08/2024

Analysis Content		Specification	Analysis Result
Appearance		White to off-white powder	Conformed
Purity(HPLC)		≥99.0 %	99.6%
Identification		IR absorption spectrum of the test sample complies with the spectrum of RS	Conformed
Single impurity		≤0.30%	0.061%
Water(K.F)		≤0.50%	0.14%
Loss on Drying		≤0.50%	0.071%
Residue on ignition		≤0.10%	0.013%
Heavy metals		≤20ppm	Conformed
Specific optical rotation		+137.0° ~ +139.0°	+137.8°
Residual solvents	Tetrahydrofuran	≤0.072%	≤LOD
	Tert-buty methyl ether	≤0.50%	≤LOD
	Ethanol	≤0.50%	0.29 %
	Dimethyl sulfoxide	≤0.50%	0.44 %
	Dichloromethane	≤0.060%	≤LOD

Storage: Store in a well-filled, airtight container, protected from light at room temperature.

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 *刘文雷*
Date: 2020.08.28.

Checker *2014*
Date: 2020.08.28

Approver
Date:

