



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.: LK38-2112001

Quantity: 130Kg

Manufacturing Date: December, 2021

Expiry date: December, 2024

Testing date: January 04, 2022

Testing standard: company standard

METAPHARMACEUTICAL

N DE LOTE:

0200122

31/01/2022

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%	0.071%
Water(K.F)		≤0.50%	0.11%
Loss on Drying		≤0.50%	0.24%
Residue on ignition		≤0.10%	0.0035%
Heavy metals		≤20ppm	Conformed
Specific optical rotation		+137.0° ~ +139.0°	+138.4°
Residual solvents	Tetrahydrofuran	≤0.072%	0.0030%
	Tert-buty methyl ether	≤0.50%	0.0052%
	Ethanol	≤0.50%	0.35 %
	Dimethyl sulfoxide	≤0.50%	0.44 %
	Dichloromethane	≤0.060%	N/D

Storage: Store in a sealed container, protect 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

李强

Date:

2022.01.06

Checker

刘永南

Date:

2022.01.06

Approver

Date:

