



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.: LK38-2207002
Quantity: 147.6Kg
Manufacturing Date: July, 2022
Expiry date: July, 2025
Testing date: July 27, 2022
Testing standard: company standard

METAPHARMACEUTICAL

N DE LOTE:

0170123

30/01/2023

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%	0.08%
Water(K.F)		≤0.50%	0.10%
Loss on Drying		≤0.50%	0.15%
Residue on ignition		≤0.10%	0.06%
Heavy metals		≤20ppm	Conformed
Specific optical rotation		+137.0° ~ +139.0°	+138.4°
Residual solvents	Tetrahydrofuran	≤0.072%	N/D
	Tert-buty methyl ether	≤0.50%	N/D
	Ethanol	≤0.50%	0.37 %
	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 刘小南
Date: 2022.07.28

Checker 207
Date: 2022.07.28

Approver
Date: 2022.07.28

