



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.: 2004004

Quantity: 18Kg

Manufacturing Date: April, 2020

Expiry date: April, 2023

Testing date: April 21, 2020

Testing standard: company standard

Analysis Content		Specification	Analysis Result
Appearance		White to off-white powder	Conformed
Purity(HPLC)		$\geq 99.0\%$	99.7%
Identification		IR absorption spectrum of the test sample complies with the spectrum of RS	Conformed
Single impurity		$\leq 0.30\%$	0.05%
Water(K.F)		$\leq 0.50\%$	0.18%
Loss on Drying		$\leq 0.50\%$	0.12%
Residue on ignition		$\leq 0.10\%$	0.04%
Heavy metals		$\leq 20\text{ppm}$	Conformed
Specific optical rotation		$+137.0^\circ \sim +139.0^\circ$	$+137.8^\circ$
Residual solvents	Tetrahydrofuran	$\leq 0.072\%$	$\leq \text{LOD}$
	Tert-butyl methyl ether	$\leq 0.50\%$	$\leq \text{LOD}$
	Ethanol	$\leq 0.50\%$	0.23 %
	Dimethyl sulfoxide	$\leq 0.50\%$	0.34 %
	Dichloromethane	$\leq 0.060\%$	$\leq \text{LOD}$

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 刘文峰

Date: 2020-04-26

Checker 王明

Date: 2020-04-26

Approver 唐华

Date: 2020-04-26

