

**杭州东瑞医药科技有限公司**  
**HANGZHOU DAWN RAY PHARMACEUTICAL CO.,LTD.**

**CERTIFICATE OF ANALYSIS**

**Toremifene citrate**

<b>Batch No.:</b> DR20130308	<b>Quantity :</b> 1.0kg
<b>Manufacture Date:</b> 2013.03.08	<b>Expiry Date:</b> 2015.03.07

**TESTS:**

Items	Specification	Results
Description	White or like white crystalline powder	White crystalline powder
Solubility	Freely soluble in pyridine and acetic acid(100), sparingly soluble in methanol, slightly soluble in ethanol, very slightly soluble in water, and practically insoluble in diethyl ether	Freely soluble in pyridine and acetic acid(100), sparingly soluble in methanol, slightly soluble in ethanol, very slightly soluble in water, and practically insoluble in diethyl ether
Melting point	159~163℃	160.0-161.5℃
Identification		
(a)Positive reaction	Must comply	Complies
(b)Positive reaction	Must comply	Complies
(c) UV	There is the strongest absorption at the wavelength of 234~238nm and 275~278nm.	There is the strongest absorption at the wavelength of 236.8nm and 275.6nm.
(d) IR	There is absorption at 1741, 1703, 1585, 1241 and 706cm-1 .	There is absorption at 1741, 1703, 1585, 1241 and 706cm-1 .
Purity		
Relative substances	E-isomer≤0.5%	0.001%
	Other single impurity≤0.1%	0.05%
	Total relative substances≤1.0%	0.1%
Heavy metals	≤10ppm	<10ppm
Loss on drying	≤0.5%	0.2%
Toluene	≤0.089%	0.0003%
Ethanol	≤0.5%	0
Acetone	≤0.5%	0.25%
Tetrahydrofuran	≤0.072%	0.0001%
Chlorobenzen	≤0.036%	0
Benzene	≤0.0002%	0
Residue on ignition	≤0.1%	0.02%
Assay	≥98.5% (Calculated on dry basis)	99.6%
Conclusion: The results conform with the standard.		

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