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

CERTIFICATE OF ANALYSIS

Tolvaptan

Batch No.: DR20140324	**Piece:** 14.8kg
Manufacture Date: 2014.03.24	**Expiry Date:** 2016.03.23

TESTS:

Items	Specification	Results
Appearance	A white or off-white crystalline powder	White crystalline powder
Identification	HPLC:Retention time of the major peaks is consistent with the standard preparation as obtained in the assay	Conforms
	IR: The infrared absorption spectrophotometry is accordant with the contrast spectrophotometry	Conforms
	Chloride identification： positive reaction	Conforms
PH	5.5~7.5	6.3
Melting point	223~228℃	225.5~226.5℃
Water	≤0.5%	0.07 %
Related substance	Any individual impurity：≤0.1% Total impurities：≤0.3%	0.01% 0.04%
Residual solvent	Methyl alcohol ≤0.3% Ethyl alcohol ≤0.5% Dichloromethane ≤0.06% Ethy acetate ≤0.5% Pyridine ≤0.02%	≤0.003% N,D N,D N,D N,D
Chloride	≤0.014%	Conforms
Residue on ignition	≤0.1%	<0.05%
Heavy metals	≤10ppm	Conforms
Assay	98.0~102.0% of Tolyaptan （C26H25CIN2O3) calculated on the dry anhydrous	98.4%
Conclusion: The results conform to the standard		

杭州东瑞医药科技有限公司 Hangzhou Dawn Ray Pharmaceutical Co.,Ltd.
质检专用章 QUALITY STAMP

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