

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

CERTIFICATE OF ANALYSIS

Anastrozole

Batch No.: DR20140228	Quantity: 50g
Manufacture Date: 2014.02.28	Expiry Date: 2016.02.27

TESTS:

Items	Specification	Results
Description	White crystalline powder	Conforms
Solubility	Freely soluble in methanol, ethanol, ethylacetate and chloroform, slightly soluble in water and 0.1M hydrochloric acid solution	Conforms
Identification	IR HPLC	Conform with standard IR Conforms
Related substances		
Related compound B	≤ 0.2%	0.05%
Related compound C	≤ 0.2%	0.05%
Related compound D	≤ 0.1%	0.03%
Related compound E	≤ 0.1%	0.04%
Individual unspecified Impurity	≤ 0.1%	0.06%
Total unspecified Impurity	≤ 0.2%	0.07%
Total Impurities	≤ 0.5%	0.50%
Residual solvents		
Dichloromethane	≤ 0.06%	ND
Chloroform	≤ 0.006%	ND
Ethanol	≤ 0.5%	0.07%
Cyclohexane	≤ 0.08%	0.02%
Ethylacetate	≤ 0.5%	0.10%
Residue on ignition	≤ 0.1%	Conforms
Water	≤ 0.3%	0.1%
Heavy metals	≤ 0.001%	<10ppm
Assay(on dry basis)	98%~102%	99.9%
Storage	Cool and dry	

Conclusion: The results conform with USP34.



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