

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

CERTIFICATE OF ANALYSIS

Silodosin (CAS:160970-54-7)

Batch No.: DR20141012	Piece: 10kg
Manufacture Date: 2014.10.12	Expiry Date: 2016.10.11

TESTS:

Items	Specification	Results
Appearance	White or almost white powder	White powder
Solubility	Soluble in methanol ethanol slightly soluble in water	Conforms
Identification	High-performance liquid chromatograph HPLC	Almost the same
	Infrared absorption	Almost the same
Enantiomeric purity	$\leq 1.0\%$	0.01%
Water	$\leq 1.0\%$	0.7%
Loss on drying	$\leq 1.0\%$	0.6%
Heavy metals	$\leq 20\text{ppm}$	$< 20\text{ppm}$
Melting point	104~107°C	105~107°C
Residue on ignition	$\leq 0.2\%$	0.02%
Related impurity	Total impurity $\leq 1.0\%$	0.31%
Assay (on dried basis)	98.0%~102.0%	99.7%

Conclusion: The results conform with the Enterprise standard



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