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

CERTIFICATE OF ANALYSIS

Bumetanide

Batch No.: DR20130806	**Quantity:** 6.154kg
Manufacture Date: 2013.08.06	**Expiry Date:** 2018.08.05

TESTS:

Items	Specification	Results
Appearance	White or crystal white crystalline powder	Conforms
Identification： Infrared absorption UV TLC	 Conforms to the spectrum obtained from bumetanide RS Conforms to the spectrum obtained from bumetanide RS Rf corresponding to standard solution	Conforms
Loss on drying	≤0.5%	0.07%
Residue on ignition	≤0.1%	0.04%
Heavy metsal	≤0.002%	Conforms
Related compounds	Bumetanide related compound A ≤0.1% Bumetanide related compound B≤0.2% Butyl-3-(butylamino)-4-phenoxy-5-sulfamoylbenzoate≤0.1% Any other individual impurity ≤0.2% The sum of all other impurities ≤0.4%(excluding Bumetanide related compound A ,,and Butyl-3-(butylamino)-4-phenoxy-5-sulfamoylbenzoate)	Conforms
Particle fineness	＜54μm,≥85% ＞106μm≤3%	Conforms

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Toluene residual	≤500ppm	Conforms
3-propylamino-4-phenoxy -5-sulfamylbenzoic acid	≤0.2%	ND
Tap bulk density	0.1-0.3g/ml	0.2g/ml
Assay	98-102% (C17H20N2O5S),calculated on the dried basis	99.9%
Conclusion: The results conform with the USP34.		

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