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

CERTIFICATE OF ANALYSIS

Terbutaline Sulphate

Batch No.: DR20130401	**Piece:**5kg
Manufacture Date: 20130401	**Expiry Date:** 2016.03.31

TESTS:

Items	Specification	Results
Appearance	A white crystalline powder	A white crystalline powder.
Solubility	Freely soluble in water, slightly soluble in ethanol and methanol, practically insoluble in chloroform and ether.	Freely soluble in water, slightly soluble in ethanol and methanol.practically insoluble in chloroform and ether.
Identification	A: IR. Spectrum of the spl. Should concordant with Ref. Std I.R. Spectrum B:Sulphate test as per BP	A :IR. Spectrum is concordant with Ref. Std IR B:Positive Sulphate
Appearance of solution	Absorbance of a 2cm layer at 400nm is ≤0.11	Absorbance of a 2cm layer at 400nm is 0.020
acidity	NMT 1.2ml of 0.01M NaOH required to change the colour of the indicator to yellow	0.30ml of 0.01M NaOH required to change the colour of the indicator to yellow
Optical Rotation	-0.10° - +0.10°	+0.0°
Related substances by HPLC	Impurity C ≤ 0.20% Any other impurity ≤ 0.20% Total impurity ≤ 0.40%	Impurity C NIL Highest single impurity 0.063% 0.28%
Residual Solvent	IPA: ≤ 5000ppm Methanol: ≤ 3000ppm	IPA: 105.7ppm Methanol: 308.95ppm
L.O.D.	≤ 0.5% w/w As per BP	0.30%
Assay on dry basis	98.0-101.0% w/w As per BP	99.80%
Conclusion: The results conform with the BP2007.		

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