

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

**CERTIFICATE OF ANALYSIS**

**Busulfan**

<b>Batch No.:</b> DR20130420	<b>Quantity:</b> 10.0g
<b>Manufacture Date:</b> 2013.04.20	<b>Expiry Date:</b> 2016.04.19

**TESTS:**

Items	Specification	Results
Appearance	White, or almost white powder	Conforms
Solubility	Very slightly soluble in water Sparingly soluble in acetone Slightly soluble in alcohol	Conforms
Identification A	A) IR vs Standard: The I.R. absorption spectrum of the preparation of the test specimen exhibits maxima only at the same wavelengths as that of a similar preparation of the standard. B) A white precipitate is formed C) An odor characteristic of methanesulfonic acid is perceptible D) The color of permanganate is not discharged.	Conforms
Melting range	Between 115°C and 118°C	116.4
Loss on drying	Not more than 2.0%	0.43
Residue on ignition	Not more than 0.1%	0.02%
Residual Solvents	In accordance with Q3C and Q3C (M) ICH	Conforms
Assay	Between 98.0% and 100.5%	99.22

Conclusion: The results conform with USP

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