

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

**CERTIFICATE OF ANALYSIS**

**Bivalirudin**

<b>Batch No.:</b> DR20130710	<b>Quantity:</b> 5g
<b>Manufacture Date:</b> 2013.07.10	<b>Expiry Date:</b> 2016.07

**TESTS:**

<b>Items</b>	<b>Specification</b>	<b>Results</b>
Appearance	White or almost white powder	Conforms
Specific optical rotation	-100.0° ~ -120.0°	-113.9°
Identification	1.Biuret test: positive 2.HPLC: retention time of substance tested complies with that of the reference standard. 3.IR: intensity of infrared absorption detected complies with that of the reference standard.	Positive conforms conforms
Clarity and color of solution	Clear,colorless,solution(If any color shows in the test solution,it should be no thicker than the yellow standard colorimetric solution)	Conforms
PH	2.0~4.0	3.2
Absorbance	Absorbance of substance detected at a wavelength of 280nm is no more than 0.35.	Conforms
Amino acids	Asp: 1.8~2.2 Glu: 3.6~4.4 Gly: 4.5~5.5 Arg: 0.9~1.1 Pro: 2.7~3.3 Tyr: 0.8~1.2 Ile: 0.9~1.1 Leu: 0.9~1.1 Phe: 1.8~2.2	Conforms
Related peptides(HPLC)	Single impurity: ≤1.0% Total impurity:≤2.0%	0.29% 0.6%
Trifluoroacetic acid	5.0%~12.0%	7.6%

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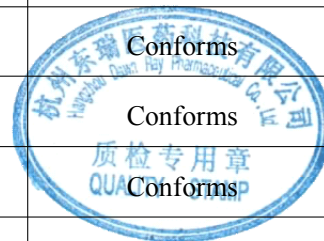
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Water(KF)	≤ 6.0%	3.2%
Bacterial endotoxins	≥ 1.0EU/mg	Conforms
N,N-Dimethylformamide	≤ 0.088%	Conforms
Acetonitrile	≤ 0.041%	Conforms
Methanol	≤ 0.3%	Conforms
Assay	97.0%~103.0% (anhydrous and trifluoroacetic acid free substance,C <sub>98</sub> H <sub>138</sub> N <sub>24</sub> O <sub>23</sub> )	100.8%
Storage	Store protected from light at a temperature between 2°C~8°C。	
Conclusion: The results conform with In-house standard.		



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