



# Chengdu KaiJie Biopharm Co., Ltd.

**KAIJIE**

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## Certification of Analysis

<b>Product Name</b>	Bivalirudin	<b>Molecular Formula</b>	$C_{98}H_{138}N_{24}O_{33}$
<b>Molecular Weight</b>	2180.29	<b>CAS No.</b>	128270-60-0
<b>Storage</b>	2~8°C	<b>Batch No.</b>	20100830
	D-Phe-Pro-Arg-Pro-Gly-Gly-Gly-Gly-Asn-Gly- Asp-Phe-Glu-Glu-Ile-Pro-Glu-Glu-Tyr-Leu-OH		

TEST	SPECIFICATION	RESULT
1 <b>Appearance</b>	White powder	White powder
2 <b>MS</b>	2180.3±1	2080.2
3 <b>Specific Optical Rotation</b>	-100 ~ -120.0°[a] <sub>D</sub> <sup>20</sup> (c=0.5, 1% HAc)	-114.26
4 <b>Water Content(K.F.)</b>	≤5.0%	2.36%
5 <b>TFA Content(by HPLC)</b>	≤12%	10.59%
6 <b>Amino Acid Composition</b>	Asp:1.6~2.4 Glu:3.4~4.6 Gly:4.2~5.8 Arg:0.8~1.2 Pro:2.4~3.6 Tyr:0.8~1.2 Ile:0.8~1.2 Leu:0.8~1.2 Phe:1.6~2.4	Complies
7 <b>Purity(by HPLC)</b>	≥98.0%	99.00%
8 <b>Impurity(by HPLC)</b>	Any other individual Impurity≤1.0% Total Impurity≤2.0%	0.38% 1.00%
9 <b>MeCN(by GC)</b>	≤0.041%	Complies
10 <b>DMF(by GC)</b>	≤0.088%	Complies
11 <b>Bacterial Endotoxins</b>	≤5EU/mg	Complies
12 <b>Assay(by HPLC)</b>	95~105%	100.86%

 Quality Control By Zhouzhongbing

 Date: 2010-09-03

Quality Assurance Department