



Chengdu KaiJie Biopharm Co., Ltd.

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Certification of Analysis

Product Name		Enfuvirtide Acetate	CAS. No.	159519-65-0
Molecular Formula		$C_{204}H_{301}N_{51}O_{64}$	Batch No.	20100619
Molecular Weight		4492.01	Manufacturing Date	06/19/2010
Storage		2~8 °C	Retest Date	06/18/2012
Sequence		Ac-Tyr-Thr-Ser-Leu-Ile-His-Ser-Leu-Ile-Glu-Glu-Ser-Gln-Asn-Gln-Gln-Glu-Lys-Asn-Glu-Gln-Glu-Leu-Leu-Glu-Leu-Asp-Lys-Trp-Ala-Ser-Leu-Trp-Asn-Trp-Phe-NH ₂		
TEST			SPECIFICATION	RESULT
1	Appearance		White powder	Conforms
2	Solubility		Soluble in acetic acid	Conforms
3	Identity		Monoisotopic Mass: 4492.01±2.0Da	4492.0Da
4	Specific Optical Rotation		-47.0 ~ -57.0°[α] _D ²⁰ (c=1, 1%HAc)	-54.53°
5	Amino Acid Composition		Ala:0.8~1.2 Asp:3.2~4.8 Glu:8.0~12.0 His: 0.8~1.2 Ile: 1.6~2.4 Leu:4.8~7.2 Lys:1.6~2.4 Phe:0.8~1.2 Thr: 0.8~1.2 Tyr: 0.8~1.2 Ser: 3.2~4.8	1.19 3.45 11.21 0.87 2.21 6.49 2.20 1.05 1.02 0.92 3.16
6	Peptide Purity (By HPLC)		≥ 95.0% by area integration	98.82%
7	Related Substance (By HPLC)		Total Impurities(%) ≤ 5.0% Largest Single impurity(%) ≤ 2.0%	1.18% 0.53%
8	Acetate Content (By HPLC)		≤ 10.0%	6.78%
9	Water Content (Karl Fischer)		≤ 8.0%	2.04%
10	Bacterial Endotoxins		≤ 5EU/mg	Conforms
11	Peptide Content (N determination)		≥ 80.0%	90.48%
12	Assay (By Anhydrous, Acetic Acid-free)		95.0 ~ 105.0%	99.30%

Quality Control By Zhouzhongbing

Date: 2010-06-24

Quality Assurance Department