



Chengdu KaiJie Biopharm Co., Ltd

KAIJIE

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Certification

Product	<i>Sermorelin acetate</i>	CAS No.	86168-78-7
Molecular	$C_{149}H_{246}N_{44}O_{42}S$	Molecular Weight	3358.03
Batch No.	20100716	Manufacture Date	07/16/2010
Storage	2 ~ 8 °C	Retest Date	07/15/2012
Sequence	Tyr-Ala-Asp-Ala-Ile-Phe-Thr-Asn-Ser-Tyr-Arg-Lys-Val-Leu-Gly-Gln -Leu-Ser-Ala-Arg-Lys-Leu-Leu-Gln-Asp-Ile-Met-Ser-Arg-NH ₂		
TEST		SPECIFICATION	RESULT
1	Appearance	White powder	White powder
2	Identity by HPLC	The retention is same with the reference substance	Conforms
3	Solubility	Soluble in water or 1% acetic acid at a concentration of ≥ 1 mg/ml to give a clear, colorless solution	Conforms
4	Amino Acid Composition	$\pm 10\%$ of theoretical	Conforms
5	Specific Optical Rotation	-70.0 ~ -90.0° (c=0.5, 1% HAc)	-72.32°
6	Peptide Purity (By HPLC)	$\geq 98.0\%$	98.74%
7	Related Substance (By HPLC)	Total Impurities (%) $\leq 2.0\%$ Largest Single impurity (%) $\leq 1.0\%$	1.26% 0.56%
8	Acetate Content (HPLC)	$\leq 15.0\%$	8.56%
9	Water Content (Karl Fischer)	$\leq 6.0\%$	2.45%
10	Sterility	≤ 200 cfu/g	Conforms
11	Bacterial Endotoxins	≤ 5 EU/mg	Conforms
12	Assay (by anhydrous, acetic acid-free)	95.0 ~ 105.0%	98.55%

Quality Control By Zhouzhongbing Date: 2010-07-19

Quality Assurance Department