



Chengdu KaiJie Biopharm Co., Ltd.

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Certification of Analysis

Product Name	<i>Teriparatide Acetate</i>	CAS. No.	52232-67-4
Molecular	$C_{181}H_{291}N_{55}O_{51}S_2$	Batch No.	20090722
Molecular Weight	4117.72	Manufacturing Date	07/22/2009
Storage	2~8 °C	Retest Date	07/21/2011
Sequence	H-Ser-Val-Ser-Glu-Ile-Gln-Leu-Met-His-Asn-Leu -Gly-Lys-His-Leu-Asn-Ser-Met-Glu-Arg-Val-Glu-Trp -Leu-Arg-Lys-Lys-Leu-Gln-Asp-Val-His-Asn-Phe-OH		
TEST		SPECIFICATION	RESULT
1	Appearance	White powder	Conforms
2	Solubility	Soluble in water or 1% acetic acid at a concentration of $\geq 1\text{mg/ml}$ to give a clear, colorless solution	Conforms
3	Identity	Monoisotopic Mass: 4117.7 ± 2.0	4116.0
4	Specific Optical Rotation ($c=0.5$, 1% HAc)	$-65.0 \sim -75.0^\circ$	-69.25°
5	Amino Acid Composition	$\pm 20\%$	Conforms
6	Peptide Purity (By HPLC)	$\geq 95.0\%$ by area integration	98.09%
7	Related Substance (By HPLC)	Total Impurities($\%$) $\leq 5.0\%$ Largest Single Impurity($\%$) $\leq 2.0\%$	1.91% 0.67%
8	Acetate Content	$\leq 15\%$	6.58%
9	Water Content (Karl Fischer)	$\leq 8.0\%$	4.35%
10	Bacterial Endotoxins	$\leq 5\text{ EU/mg}$	Conforms
11	Peptide Content (N determination)	$\geq 80.0\%$	87.6%
12	Assay (By Anhydrous, Acetic Acid-free)	$95.0 \sim 105.0\%$	98.53%

Quality Control By Zhouzhongbin Date: 2010-08-09

Quality Assurance Department