



Chengdu KaiJie Biopharm Co., Ltd.

KAIJIE

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Certification of Analysis

Product Name		Calcitonin Salmon	
CAS No	47931-85-1	Standard	USP31-NF26
Molecular Formula	C ₁₄₅ H ₂₄₀ N ₄₄ O ₄₈ S ₂	Batch No.	20100710
Molecular Weight	3432	Manufacturing Date	07/10/2010
Storage	2~8℃	Retest Date	07/09/2012
Sequence	$\text{H-Cys-Ser-Asn-Leu-Ser-Thr-Cys-Val-Leu-Gly-Lys-Leu-Ser-Gln-Glu-Leu-His-Lys-Leu-Gln-Thr-Tyr-Pro-Arg-Thr-Asn-Thr-Gly-Ser-Gly-Thr-Pro-NH}_2$		
TEST		SPECIFICATION	RESULT
1	Appearance	White powder	Conforms
2	Solubility	Soluble in water	Conforms
3	Identity by HPLC	The retention is same with the reference substance	Conforms
4	Amino Acid Composition	Asp:1.8~2.2 Glu: 2.7~3.3 Pro: 1.7~2.3 Gly: 2.7~3.3 Val: 0.9~1.1 Leu: 4.5~5.3 His: 0.9~1.1 Arg: 0.9~1.1 Lys: 1.8~2.2 Ser: 3.2~4.2 Thr: 4.2~5.2 Tyr: 0.7~1.1 Cys:1.4~2.1	1.91 2.96 2.12 3.08 1.02 5.15 1.00 1.00 1.98 3.68 4.76 0.98 1.82
5	Biodentity	3840~9360IU/mg(By Anhydrous, Acetic Acid-free)	6344IU
6	Acetate Content(By HPLC)	4~15.0%	7.16%
7	Peptide Purity (By HPLC)	≥95.0% by area integration	99.31%
8	Related Substance(By HPLC)	Total Impurities(%)≤5.0% Largest Single Impurity(%)≤3.0%	0.69% 0.31%
9	Water Content(Karl Fischer)	≤10.0%	4.72%
10	Bacterial Endotoxins	≤25 IU/mg	Conforms
11	Assay	90.0~105.0%(By Anhydrous, Acetic Acid-free)	100.71%

 Quality Control By Zhouzhongbing

 Date: 2010-07-12

Quality Assurance Department