

Chengdu KaiJie Biopharm Co., Ltd.

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Certification of Analysis

Product Name		Octreotide Acetate			
CAS No.		83150-76-9		Stand	CP-2005
Molecular Formula		$C_{49}H_{66}N_{10}O_{10}S_2$		Batch No.	20100609
Molecular Weight		1019.28		Manufacturing Date	06/09/2010
Storage		2~8℃		Retest Date	06/08/2012
Sequence		D-Phe-Cys-Phe-D-Trp-Lys-Thr-Cys -NH			
TEST			SPECIFICATION		RESULT
1	Appearance		White powder		Conforms
2	2 Solubility		Soluble in water or 1% acetic acid at a concentration of ≥1 mg/ml to give a clear, colorless solution		Conforms
3 Amino Acid Composition		±10% of theoretical		Conforms	
4	4 Peptide Purity (By HPLC)		≥98.0% by area integration		99.94%
5	Related Substance(By HPLC)		Total Impurities(%)≤2.0% Largest Single Impurity(%)≤1.0%		0.06% 0.03%
6	Acetate Content		≤15.0%		9.97%
7	Water Content(Kar	l Fischer)	≤8.0%		3.24%
8	8 Specific Optical Rotation		-45.0~-55.0° (C=0.5, 95%HAc)		-47.88°
9	9 Peptide Content			≥80.0%	
10	0 Bacterial Endotoxins			≤5EU/mg	
11	Assay		95.0~105.0%		99.03%

Quality Control By Shouzhongbing Date: 2010-06-11

Quality Assurance Department