

Chengdu KaiJie Biopharm Co., Ltd.

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Certification of Analysis

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Product Name		Pramlintide Acetate		CAS. No.	196078-30-5	
Molecular		$C_{171}H_{267}N_{51}O_{53}S_2$		Batch No.	20090203	
Molecular Weight		3949.37		Manufacturing Date	02/03/2009	
torage		2~8°C		Retest Date	02/02/2011	
Sequence		Lys-Cys-Asn-Thr-Ala-Thr-Cys-Ala-Thr-Gln-Arg- Leu-Ala-Asn-Phe-Leu-Val-His-Ser-Ser-Asn-Asn- Phe-Gly-Pro-Ile-Leu-Pro-Pro-Thr-Asn-Val-Gly- Ser-Asn-Thr-Tyr-NH ₂				
		TEST	SPECIFICATION		RESULT	
1	Appearance		White powder		Conform	
2	Solubility		Soluble in water and 1% acetic acid		Conforms	
3	Identity by HPLC		The retention is same with the reference substance		Conforms	
4	Specific Option	cal Rotation	-90 ~-105 °(c=0.5, 1% HAc)		-100.35°	
5	Amino Acid Composition ±20%		conforms			
6	Peptide Purity (By HPLC) ≥		≥98.0	≥98.0% by area integration		
7	Related Substance(By HPLC)		Total Impurities(%)≤2.0% Largest Single Impurity(%)≤1.0%		0.35% 0.23%	
8	Acetate Conte	Acetate Content(By HPLC)		≤12.0%		
9	Water Content(Karl Fischer)		≤8.0%		3.33%	
10	Bacterial Endotoxins		≤50 IU/mg		Conforms	

Quality Control By	Zhouzhongbing	Date:	2008-09-10
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95.0~105.0%

98.85%

Quality Assurance Department

11 | **Assay**(By Anhydrous, Acetic Acid-free)