



Chengdu KaiJie Biopharm Co., Ltd.

KAIJIE

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Certification of Analysis

Product Name	Cetorelix Acetate	CAS NO.	120287-85-6
Molecular Formula	$C_{70}H_{92}ClN_{17}O_{14}$	Molecular Weight	1431.04
Batch No.	20100504	Manufacturing Date	05/04/2010
Storage	2 ~ 8 °C	Retest Date	05/03/2012
Sequence	Ac-D-Nal-D-Cpa-D-Pal-Ser-Tyr-D-Cit-Leu-Arg-Pro-D-Ala-NH₂		
TEST		SPECIFICATION	RESULT
1	Appearance	White powder	White powder
2	Identity by HPLC	The retention is same with the reference substance	Conforms
3	Specific Optical Rotation	-20~-30 (c=1, 50%HA ₂)	-27.0°
4	Amino Acid Composition	±20% of theoretical	Conforms
5	Purity (by HPLC)	≥ 98.0%	99.33%
6	Related Substance (By HPLC)	Total Impurities(%) ≤ 2.0% Largest Single Impurity(%) ≤ 1.0%	0.67% 0.43%
7	Acetate Content (by HPLC)	≤ 15.0%	7.25%
8	Water Content (by Karl Fischer)	≤ 10.0%	2.55%
9	Bacterial Endotoxins	≤ 5EU/mg	Conforms
10	Assay (by anhydrous, acetic acid-free)	95.0 ~ 105.0%	98.15%

Quality Control By ZhouzhongbingDate: 2010-05-28

Quality Assurance Department