

## Chengdu KaiJie Biopharm Co., Ltd.

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## **Certification of Analysis**

Product Name		Deslorelin Acetate			
CAS. No.		57773-65-6		Molecular Weight	1281.64
Molecular Formula		$C_{64}H_{83}N_{17}O_{12}$		Batch No.	20100814
Storage		2~8°C		Expiry Date	2 years
Manufacturing Date		08/14/2010		Retest Date	08/13/2012
Sequ	uence	O H	His-	Trp-Ser-Tyr-D-Trp-Leu-Arg	-Pro-NHEt
TEST			SPECIFICATION		RESULT
1	Appearance		White powder or almost white powder		Complies
2	Identity by HPLC		The retention is same with the reference substance		Complies
3	Amino Acid Composition		Glu:0.85~1.10		0.95
			Pro:0.85~1.10		1.03
			Leu:0.90~1.10		1.01
			Tyr: 0.85~1.10		0.99
			His:0.85~1.10		1.00
			Arg:0.85~1.10		0.98
			Ser:Present		0.90
			Trp:Present		determined
4	Purity(By HPLC)		≥98.0%		99.01%
	Related Substance(By HPLC)		Total Impurities(%)≤2.0%		0.99%
5			Largest Single Impurity(%)≤0.5%		0.35%
6	Acetate Content(By	HPLC)	≤12.0%		9.58%
7	Water Content(Karl	l Fischer)	≤8.0%		2.75%
8	Peptide Content(N%)			≥ 80.0%	
9	Bacterial Endotoxii	ns	≤70 IU/mg		Complies
10	Assay(By anhydrous	s. acetic acid-free)	95%~105%		98.55%

Quality Control By **Zhouzhougbing** Date: 2010-08-19

**Quality Assurance Department**