



# Chengdu KaiJie Biopharm Co., Ltd.

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## Certification of Analysis

<b>Product Name</b>	<b>Buserelin Acetate</b>	<b>Standard</b>	<b>EP6.0</b>
<b>CAS. No.</b>	68630-75-1	<b>Molecular Weight</b>	1239
<b>Molecular Formula</b>	$C_{60}H_{86}N_{16}O_{13}$	<b>Batch No.</b>	20100715
<b>Storage</b>	2~8℃	<b>Expiry Date</b>	2 years
<b>Manufacturing Date</b>	07/15/2010	<b>Retest Date</b>	07/14/2012
<b>Sequence</b>	<b>Pyr-His-Trp-Ser-Tyr-D-Ser(tBu)-Leu-Arg-Pro-NHEt</b>		
<b>TEST</b>		<b>SPECIFICATION</b>	<b>RESULT</b>
1	<b>Appearance</b>	White or slightly yellowish powder	Complies
2	<b>Appearance of Solution</b>	Clear, colorless to slightly colored solution in water(10mg/ml)	Complies
3	<b>Identification by HPLC</b>	The retention is same with the reference substance	Complies
4	<b>Specific Optical Rotation</b>	$-49.0 \sim -58.0^{\circ}[\alpha]_{D(20)}^{20}(c=1, \text{water})$	-50.5°
5	<b>Specific Absorbance</b> (By anhydrous,acetic acid-free)	49~56(278nm)	49.86
6	<b>Amino Acid Composition</b>	Arg: 0.9~1.1 Leu: 0.9~1.1 Tyr: 0.9~1.1 Glu: 0.9~1.1 Pro: 0.8~1.2 His: 0.9~1.1 Ser:1.4~2.0 Trp: Detected	0.96 0.95 1.05 0.98 1.10 1.01 1.78 Detected
7	<b>Related Substance</b> (By HPLC)	Total Impurities(%)≤5.0% Largest Single Impurity(%)≤1.0%	0.84% 0.09%
8	<b>Acetate Content</b> (By HPLC)	3~7%	6.10%
9	<b>Water Content</b> (Karl Fischer)	≤4.0%	2.05%
10	<b>Sterility</b>	≤10 CFU/100 mg	Complies
11	<b>Bacterial Endotoxins</b>	≤55.5 IU/mg	Complies
12	<b>Assay</b> (By anhydrous,acetic acid-free)	95%~102%	98.5%

Quality Control By Zhouzhongbing Date: 2010-08-09

Quality Assurance Department