



# Chengdu KaiJie Biopharm Co., Ltd.

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## Certification of Analysis

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

Quality Control By Zhouzhongbing Date: 2010-08-09

Quality Assurance Department