



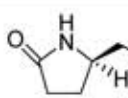
Chengdu KaiJie Biopharm Co., Ltd.

KAIJIE

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Certification of Analysis

Product Name	<i>Leuporelin</i>	Specification	<i>EP6.0</i>
CAS. No.	<i>53714-56-0</i>	Batch No.	<i>20100401</i>
Molecular Formula	<i>C₅₉H₈₄N₁₆O₁₂</i>	Molecular Weight	<i>1209</i>
Manufacturing Date	<i>04/01/2010</i>	Retest Date	<i>03/31/2012</i>
Storage	<i>NMT 30 °C</i>		
Sequence	 <i>His-Trp-Ser-Tyr-D-Leu-Leu-Arg-Pro-NH₂</i>		

TEST		SPECIFICATION	RESULT
1	Appearance	<i>White powder</i>	Conforms
2	Solubility	<i>Soluble in water or 1% acetic acid at a concentration of $\geq 1\text{mg/ml}$ to give a clear, colorless solution</i>	Conforms
3	Identity	<i>A IR</i>	Conforms
		<i>Same with the reference spectrum of Leuporelin</i>	
		<i>B. HPLC</i>	Conforms
		<i>Same with the reference solution</i>	
		<i>C. Amino Acid Analysis</i>	
		<i>Ser: Present</i>	0.90
		<i>Glu: 0.85 ~ 1.1</i>	0.95
		<i>Pro: 0.85 ~ 1.1</i>	1.08
		<i>Leu: 1.80 ~ 2.2</i>	1.98
		<i>Tyr: 0.85 ~ 1.1</i>	1.01
		<i>His: 0.85 ~ 1.1</i>	0.99
		<i>Arg: 0.85 ~ 1.1</i>	0.98
		<i>Trp: Present</i>	present
4	Specific Optical Rotation	<i>-38.0 ~ -42.0° [α]_D²⁰ (c=1, 1% HAc)</i>	-40.56°
5	Related Substance (By HPLC)	<i>Total Impurities (%) $\leq 2.5\%$</i>	0.46%
		<i>Largest Single Impurity (%) $\leq 0.5\%$</i>	0.17%
6	Acetate Content	<i>4.7 ~ 9.0%</i>	7.68%
7	Water Content (Karl Fischer)	<i>$\leq 5.0\%$</i>	2.50%
8	Sulphate ash	<i>$\leq 0.3\%$</i>	Conforms
9	Bacterial Endotoxins	<i>$\leq 16.7 \text{ IU/mg}$</i>	Conforms
10	Assay (By Anhydrous, Acetic)	<i>97.0 ~ 103.0%</i>	99.12%

Quality Control By Zhouzhongbing

Date: 2010-04-15

Quality Assurance Department

Contact us via sales@kjpep.com

