



## Chengdu KaiJie Biopharm Co., Ltd.

**KAIJIE**

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### Certification of Analysis

<b>Product Name</b>		<b>MGF Acetate</b>	
<b>Molecular Formula</b>		$C_{121}H_{200}N_{42}O_{39}$	<b>Batch No.</b> 20091010
<b>Molecular Weight</b>		2867.2	<b>Manufacturing Date</b> 10/10/2009
<b>Storage</b>		2~8°C	<b>Retest Date</b> 10/09/2011
<b>Sequence</b>		Tyr-Gln-Pro-Pro-Ser-Thr-Asn-Lys-Asn-Thr-Lys-Ser-Gln- Arg-Arg-Lys-Gly-Ser-Thr-Phe-Glu-Glu-Arg-Lys-NH <sub>2</sub>	
<b>TEST</b>		<b>SPECIFICATION</b>	<b>RESULT</b>
1	<b>Appearance</b>	White powder	White powder
2	<b>Solubility</b>	Soluble in water or 1% acetic acid at a concentration of $\geq 1$ mg/ml to give a clear, colorless solution	Conforms
3	<b>Specific Optical Rotation</b>	-85~ -100°(c=1, 1% HAc)	-92.8°
4	<b>Peptide Purity (By HPLC)</b>	$\geq 95.0\%$ by area integration	98.7%
5	<b>Related Substance (By HPLC)</b>	Total Impurities(%) $\leq 5.0\%$ Largest Single Impurity(%) $\leq 2.0\%$	1.3% 1.3%
6	<b>Acetate Content (By HPLC)</b>	$\leq 15.0\%$	1.0%
7	<b>Water Content (Karl Fischer)</b>	$\leq 8.0\%$	3.6%
8	<b>Bacterial Endotoxins</b>	$\leq 5$ IU/mg	Conforms
9	<b>Assay (By HPLC)</b>	95.0~105.0%	98.5%

 Quality Assurance By Zhouzhongbing

 Date: 2009-10-12

Quality Control Department