



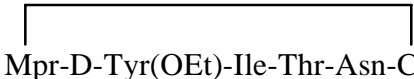
# Chengdu Kaijie Bipharm Co., Ltd.

**KAIJIE**

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## Certification of Analysis

<b>Product Name</b>		<i>Atosiban Acetate</i>	
<b>CAS. No.</b>	90779-69-4	<b>Molecular Weight</b>	1167.3
<b>Molecular Formula</b>	$C_{43}H_{67}N_{11}O_{12}S_2$	<b>Batch No.</b>	200100401
<b>Storage</b>	2 ~ 8 °C	<b>Expiry Date</b>	2 years
<b>Manufacturing Date</b>	04/2010	<b>Retest Date</b>	03/2012
<b>Sequence</b>	 Mpr-D-Tyr(OEt)-Ile-Thr-Asn-Cys-Pro-Orn-Gly-NH <sub>2</sub>		
<b>TEST</b>		<b>SPECIFICATION</b>	<b>RESULT</b>
1	<b>Appearance</b>	White powder or almost white powder	Complies
2	<b>Identity by HPLC</b>	The retention is same with the reference substance	Complies
3	<b>Specific Optical Rotation</b>	-45.0 ~ -55.0° [ $\alpha$ ] <sub>D</sub> <sup>20</sup> (c=1, 1%HAc)	-49.79
4	<b>Amino Acid Composition</b>	Asp: 0.8~1.2 Thr: 0.8~1.2 Gly: 0.8~1.2 Pro: 0.8~1.2 Tyr: 0.8~1.2 Ile: 0.8~1.2 Cys: 0.6~1.2	1.19 1.04 1.08 1.17 0.81 1.09 1.18
5	<b>Related Substance(By HPLC)</b>	Total Impurities(%) ≤ 2.0% Largest Single Impurity(%) ≤ 1.0%	0.26% 0.12%
6	<b>Acetate Content(By HPLC)</b>	≤ 15%	8.85%
7	<b>Water Content(Karl Fischer)</b>	≤ 5.0%	3.50%
8	<b>Bacterial Endotoxins</b>	≤ 5IU/mg	Complies
9	<b>Assay(By anhydrous, acetic acid-free)</b>	97% ~ 103%	98.00%

QC By Zhouzhongbing Date: 2010-05-04

Quality Department, K. J. Bio.