



Chengdu KaiJie Biopharm Co., Ltd.

KAIJIE

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Certification of Analysis

Product Name		<i>Desmopressin Acetate</i>	Standard	<i>EP6.0</i>
CAS. No.		16789-98-3	Molecular Weight	1069.24(net)
Molecular Formula		$C_{46}H_{64}N_{14}O_{12}S_2$	Batch No.	20100111
Storage		2~8 °C	Expiry Date	2 years
Manufacturing Date		01/11/2010	Retest Date	01/10/2012
Sequence		SCH 2 CH 2 CO-Tyr-Phe-Gln-Asn-Cys-Pro-D-Arg-Gly-NH ₂		
TEST		SPECIFICATION		RESULT
1	Appearance	White fluffy powder		Complies
2	Identity by HPLC	The retention is same with the reference substance		Complies
3	Specific Optical Rotation	$-72.0 \sim -82.0^\circ [a]_D^{20} (c=1, 1\% \text{HAc})$		-76.22°
4	Amino Acid Composition	Asp: 0.95 ~ 1.05 Glu: 0.95 ~ 1.05 Pro: 0.95 ~ 1.05 Gly: 0.95 ~ 1.05 Arg: 0.95 ~ 1.05 Phe: 0.95 ~ 1.05 Tyr: 0.70 ~ 1.05 Cys: 0.30 ~ 1.05		0.97 0.98 1.03 1.00 1.02 0.97 0.95 0.85
5	Peptide Purity (By HPLC)	$\geq 98.5\%$		99.35%
6	Related Substance (By HPLC)	Total Impurities (%) $\leq 1.5\%$ Largest Single Impurity (%) $\leq 0.5\%$		0.65 % 0.22%
7	Acetate Content (By HPLC)	3~8%		7.45%
8	Water Content (Karl Fischer)	$\leq 6.0\%$		3.11 %
9	Sterility	$\leq 50 \text{ CFU/100 mg}$		Complies
10	Bacterial Endotoxins	$\leq 5 \text{ IU/mg}$		Complies
11	Assay (By anhydrous, acetic acid-free)	95% ~ 105%		98.50%

Quality Control By Zhouzhongbing

Date: 2010-01-15

Quality Assurance Department