

Chengdu Kaijie Biopharm Co., Ltd.

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Nesiritide Acetate (BNP-32)

Product Name		Nesiritide Acetate			
Molecular Formula C ₁₄₃ H ₂₄₄ N ₅₀ O		C ₁₄₃ H ₂₄₄ N ₅₀ O ₄₂ S	S_4	Batch No.	20100702
Molecular Weight 3464.04		Manufacturing Date		07/2010	
Storage 2~8°C		2~8℃		Retest Date	06/2012
Sequence		Ser-Pro-Lys-Met-Val-Gln-Gly-Ser-Gly-Cys-Phe-Gly-Arg- Lys-Met-Asp-Arg-Ile-Ser-Ser-Ser-Ser-Gly-leu-Gly-Cys- Lys-Val-Leu-Arg-Arg-His-OH			
TEST		SPECIFICATION		RESULT	
1	Appearance		White to off-white powder		white powder
2	Solubility		Soluble in 1% acetic acid to give a clear, colorless solution		Complies
3	Identification(By HPLC)		Major peak in the sample is similar to that in the standard		Complies
4	Specific Optical Rotation		$-75.0 \sim -90.0^{\circ} [a]_D^{20} (c=0.5, 1\% HAc)$		-86.2°
5	Water Content(Karl Fischer)		≤8.0%		2.48%
6	Acetic Acid(By HPLC)		7~15.0%		13.76%
7	Amino Acid Composition		Arg: 3.60~4.40 Asp,Glu,His,Ile,Phe,Pro: 0.80~1.20 Cys, Leu, Met,Val: 1.60~2.40 Gly: 4.50~5.50 Lys: 2.70~3.30 Ser: 5.40~6.60		Complies
8	Purity (By HPLC)		≥95.0%		98.89%
9	Largest Single Impurity(By HPLC)		≤2.0%		1.11%
10	Bacterial Endotoxins		≤5EU/mg		Complies
11	Assay		95.0~103.0%		100.05%

Quality Control By Shouzhongbing Date: 2010-07-22

Quality Assurance Department