

**KAIJIE**

Chengdu KaiJie Biopharm Co., Ltd.

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Certification of Analysis

Product Name	Protirelin Acetate	CAS No.	24305-27-9
Molecular Formula	$C_{16}H_{22}N_6O_4$	Batch No.	20100301
Molecular Weight	362.4	Manufacturing Date	03/01/2010
Storage	2~8℃	Retest Date	02/28/2012
Sequence	Pyr-His-Pro-NH ₂		
TEST		SPECIFICATION	RESULT
1	Appearance	White powder	White powder
2	Solubility	Soluble in water or acetic acid at a to give a clear, colorless solution	Conforms
3	Identification (MS)	362.4±1.0	362.1
4	Amino Acid Composition	±10% of theoretical	Conforms
5	Peptide Purity (By HPLC)	≥98.0% by area integration	99.40%
6	Related Substance (By HPLC)	Total Impurities(%)≤2.0%	0.60%
		Largest Single Impurity(%)≤1.0%	0.40%
7	Acetate Content (By HPLC)	≤10.0%	6.53%
8	Water Content (Karl Fischer)	≤5.0%	1.44%
9	Bacterial Endotoxins	≤5EU/mg	Conform
10	Peptide Content (N determination)	≥80.0%	91.28%
11	Assay (By Anhydrous, Acetic Acid-free)	95.0~105.0%	99.25%

Quality Control By Zhouzhongbing Date: 2010-03-09

Quality Assurance Department