



Certification of Analysis

Product Name	Gonadorelin Acetate	Standard	EP 6.0
CAS No.	71447-49-9	Molecular Formula	C ₅₅ H ₇₅ N ₁₇ O ₁₃
Molecular Weight	1242	Batch No.	20100517
Manufacturing Date	05/17/2010	Expiri date	2 years
Storage	2~8℃	Retest Date	05/16/2012
Sequence	pGlu-His-Trp-Ser-Tyr-Gly-Leu-Arg-Pro-Gly-NH ₂		
TEST		SPECIFICATION	RESULT
1	Appearance	White to Off-white powder	Complies
2	Solubility	Soluble in water and in a 1% glacial acetic acid	Complies
3	Identity by HPLC	The retention is same with the reference substance	Complies
4	Identity by TLC	The principal spot corresponds in position and size to the reference substance	Complies
5	Appearance of Solution	10 mg/ml solution is clear and not more intensely colored than reference solution Y ₅	Complies
6	Specific Optical Rotation	-54.0~-66.0°(1% in 1%HAc)	-64.14°
7	Absorbance(by UV)	0.55~0.61(c=0.1mg/ml H ₂ O,λ _{max} =278nm)	0.575
8	Amino Acid Composition	Ser:0.70~1.05	0.88
		Glu:0.95~1.05	0.99
		Pro:0.95~1.05	1.03
		Gly:1.90~2.10	2.00
		Leu:0.90~1.10	0.98
		Tyr:0.70~1.05	1.01
		His:0.95~1.05	0.99
		Arg:0.95~1.05	1.02
		Trp: Present	Present
9	Related Substance(By HPLC)	Total Impurities(%)≤5.0% Largest Single Impurity(%)≤2.0%	0.56% 0.39%
10	Acetate Content (By HPLC)	4.0~7.5%	6.90%
11	Water Content(Karl Fischer)	≤7.0%	1.57%
12	Bacterial Endotoxins	≤70IU/mg	Complies
13	Assay(By Anhydrous, Acetic Acid-free)	95.0~102.0%	99.25%

 Quality Control By Zhouzhongbing

 Date 2010-05-26
