

Chengdu KaiJie Biopharm Co., Ltd.

Segment 1, Industrial Road, Dayi County, Chengdu, Sichuan, P. R. China, 611330 Tel: 86-28-88208155, Fax: 86-28-88203632 WEB:www.kjpep.com

Certification of Analysis

				1	
Product Name		Eptifibatide Acetate		CAS No.	148031-34-9
Molecular Formula		C ₃₅	₅ H ₄₉ N ₁₁ O ₉ S ₂	Batch No.	20100811
Molecular Weight			831.96	Manufacturing Date	08/11/2010
Storage		2~8°C	Retest Date	08/10/2012	
Sequence		Mpr-Harg-Gly-Asp-Trp-Pro-Cys-NH ₂			
TEST		SPECIFICATION		RESULT	
1	Appearance		White to Off-white powder		Conforms
2	Specific Optical Rotation		-75.0~-95.0° (c=1%, HAc)		-78.66°
3	Water Content(Karl Fischer)		≤ 8.0%		2.67%
4	Amino Acid Composition		±20%		Conforms
5	5 Acetate Content (By HPLC)		≤ 15.0 %		5.08%
6 Peptide Purity (By HPLC)		≥ 98.0% by area integration		99.16%	
7 Related Substance(By		By HPI (C)	Total Impurities(%)≤ 2.0%		0.84%
		by III Le)	Largest Single Impurity(%)≤ 1.0%		0.21%
8	8 MeCN (By GC)		≤0.041%		Conforms
9	9 Bacterial Endotoxins		\leq 5EU/mg		Conforms
10	Peptide content (By N %)		≥80.0%		90.89%
11	Assay		95.0~103.0%(By Anhydrous, Acetic Acid-free)		98.64%

Quality Control By **Zhouzhongbing** Date: <u>2010-08-16</u>

Quality Assurance Department