

CERTIFICATE OF ANALYSIS			
Name of Product:	Octreotide Acetate D-Phe-Cys-Phe-D-Trp-Lys-Thr-Cys-Thr(ol)		
Batch No:	0907004	Analyzed on:	2009-8-21
Date of Manufacture:	2009-7-31	Quantity:	40g
TEST	SPECIFICATION		RESULTS
1. Appearance	White or almost white powder		Complies
2. Solubility	Soluble in water at a concentration of 1.2mg/ml to give a clear, colorless solution		Complies
3. RT	According with ST		Complies
4. UV	214nm, 280nm		Complies
5. pH	5.0-7.0		6.4
6. Amino acids	Cys: 0.70~1.15 Lys: 0.85~1.15 Phe: 1.80~2.20 Thr: 0.85~1.15 Trp: Present		Complies
7. Peptide Purity (By HPLC)	≥98.0%		99.7%
8. Related Substances (By HPLC)	[des-Thr-ol ⁸] – Octreotide ≤2.0% Largest single impurity ≤1.0% Total impurities ≤2.0%		Complies 0.24% 0.3%
9. Assay (By HPLC)	95.0~103.0%		99.0%
10. Acetic acid	≤12%		9%
11. Water (K.F.)	≤10.0%		2.3 %
12. Specific Optical Rotation	-17° ~ -23°		-19°
13. Abnormal toxicity	Ch.P 2005 Part II Appendix XI C I.V. method		Complies
14. Pyrogen	Ch.P 2005 Part II Appendix XI D 1ml/kg Injection		Complies

Conclusion: in accordance with YBH02732006