

Certification of Analysis

Product Name	<i>Exenatide Acetate</i>	CAS. No.	<i>141732-76-5</i>
Molecular Formula	<i>C₁₈₄H₂₈₂N₅₀O₆₀S</i>	Batch No.	<i>20150501</i>
Molecular Weight	<i>4186.6</i>	Manufacturing Date	<i>05/2015</i>
Storage	<i>2 ~ 8 °C</i>	Retest Date	<i>04/2017</i>
Sequence	His-Gly-Glu-Gly-Thr-Phe-Thr-Ser-Asp-Leu-Ser-Lys- Gln-Met-Glu-Glu-Glu-Ala-Val-Arg-Leu-Phe-Ile-Glu- Trp-Leu-Lys-Asn-Gly-Gly-Pro-Ser-Ser-Gly-Ala-Pro- Pro-Pro-Ser-NH ₂		

TEST		SPECIFICATION	RESULT
1	Appearance	<i>White powder</i>	<i>White powder</i>
2	Solubility	<i>Soluble in water or 1% acetic acid at a concentration of ≥ 1 mg/ml to give a clear, colorless solution</i>	<i>Conforms</i>
3	Identification (By HPLC)	<i>The retention is same with the reference</i>	<i>Conforms</i>
4	Amino Acid Composition	<i>$\pm 10\%$ of theoretical except for Trp</i>	<i>Conforms</i>
5	Specific Optical Rotation	<i>$-45^{\circ} \sim -65^{\circ}$ ($c=1$, 1% HAc)</i>	<i>-53.0°</i>
6	Peptide Purity (By HPLC)	<i>$\geq 97.5\%$ by area integration</i>	<i>99.15%</i>
7	Related Substance (By HPLC)	<i>Total Impurities (%) $\leq 2.5\%$ Largest Single Impurity (%) $\leq 1.0\%$</i>	<i>0.85% 0.39%</i>
8	Acetate Content (By HPLC)	<i>Less than 15%</i>	<i>4.7%</i>
9	TFA Content (By HPLC)	<i>$\leq 0.25\%$</i>	<i>Conforms</i>
10	Water Content (Karl Fischer)	<i>$\leq 10.0\%$</i>	<i>1.7%</i>
11	Peptide Content (N determination)	<i>$\geq 80.0\%$</i>	<i>91.0%</i>
12	Assay (By Anhydrous, Acetic Acid-free)	<i>95.0 ~ 105.0%</i>	<i>97.4%</i>
		<i>ACN ≤ 410 ppm</i>	<i>13 ppm</i>
		<i>DMF ≤ 880 ppm</i>	<i>Not Determined</i>
13	Residual solvent	<i>MeOH ≤ 1000 ppm</i>	<i>Not Determined</i>
		<i>EtOH ≤ 1000 ppm</i>	<i>Not Determined</i>
		<i>IPA ≤ 1000 ppm</i>	<i>Not Determined</i>

Quality Control By Wangjun Date: 2015-06-15

Quality Assurance Department