



Hangzhou Peptidego Biotech Co.,Ltd

CERTIFICATION OF ANALYSIS

Teriparatide Acetate Powder (Synthetic)	CAS: 99294-94-7
Product No.:800022	Batch No.: 17120011
Date of Mfg: Feb 02, 2018	Date of Exp:Feb 01, 2020
Sequence: Ser-Val-Ser-Glu-Ile-Gln-Leu-Met-His-Asn-Leu-Gly-Lys-His-Leu-Asn-Ser-Met-Glu-Arg-Val-Glu-Trp-Leu-Arg-Lys-Lys-Leu-Gln-Asp-Val-His-Asn-Phe	

Test	Specification	Result																																																
Appearance	White or off-white powder	White powder																																																
Solubility	soluble in H2O	conforms																																																
HPLC	The principal peak in the chromatogram obtained with the test solution is similar in retention time to principal peak in the chromatogram obtained with the reference solution.	conforms																																																
Amino acid analysis	<table border="0"> <tr> <td>Ser</td><td>2.1-3.3</td> <td>His</td><td>2.7-3.3</td> </tr> <tr> <td>Val</td><td>2.7-3.3</td> <td>Asp</td><td>3.6-4.4</td> </tr> <tr> <td>Glu</td><td>4.5-5.5</td> <td>Gly</td><td>0.9-1.1</td> </tr> <tr> <td>Ile</td><td>0.9-1.1</td> <td>Lys</td><td>2.7-3.3</td> </tr> <tr> <td>Leu</td><td>4.5-5.5</td> <td>Arg</td><td>1.8-2.2</td> </tr> <tr> <td>Met</td><td>1.8-2.2</td> <td>Phe</td><td>0.9-1.1</td> </tr> </table> No more than the traces of the other amino acids are present.	Ser	2.1-3.3	His	2.7-3.3	Val	2.7-3.3	Asp	3.6-4.4	Glu	4.5-5.5	Gly	0.9-1.1	Ile	0.9-1.1	Lys	2.7-3.3	Leu	4.5-5.5	Arg	1.8-2.2	Met	1.8-2.2	Phe	0.9-1.1	<table border="0"> <tr> <td>Ser</td><td>2.2</td> <td>His</td><td>2.9</td> </tr> <tr> <td>Val</td><td>2.9</td> <td>Asp</td><td>4.1</td> </tr> <tr> <td>Glu</td><td>4.9</td> <td>Gly</td><td>1.0</td> </tr> <tr> <td>Ile</td><td>1.0</td> <td>Lys</td><td>3.1</td> </tr> <tr> <td>Leu</td><td>4.8</td> <td>Arg</td><td>1.9</td> </tr> <tr> <td>Met</td><td>1.9</td> <td>Phe</td><td>1.0</td> </tr> </table> No more than the traces of the other amino acids are present.	Ser	2.2	His	2.9	Val	2.9	Asp	4.1	Glu	4.9	Gly	1.0	Ile	1.0	Lys	3.1	Leu	4.8	Arg	1.9	Met	1.9	Phe	1.0
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MS	4117.8±1.0	4118.5																																																
Related Substances	Unspecified impurity for each impurity: NMT1.0%	0.86%(single largest impurity)																																																
Purity(HPLC)	NLT 98%	99.14%																																																
Acetic acid	NMT 12.0%	5.6%																																																
Water Content(Karl Fischer)	NMT 7.0%	4.8%																																																
Specific Optical Rotation	-71.0° to -81.0° (anhydrous and acetic acid free substance)	-76.5°																																																

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Test	Specification	Result
Bacterial endotoxins	Less than 5IU/mg	conforms
Assay	97.0%-103.0% (anhydrous and acetic acid free substance)	99.5%
Residual solvent Methanol Acetonitrile Triethylamine	NMT 3000ppm NMT 410 ppm NMT 320 ppm	conforms

Storage: In an air tight container,protected from light at temperature 2-8°C.

Conclusion: the product complies with specification.

It is only supplied as chemical product.

Analysis :Janie.zhang

Date :2018.02.02

Approved by : Christ.zheng

Date :2018.02.02



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