

**PTH (1-34), HUMAN, ACETATE
DRUG SUBSTANCE SPECIFICATION**



Molecular weight: 4117.8 (free peptide)

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Sequence: H-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-OH, supplied as acetate salt

Last update: 28 SEP 2020

Available registration documents (CTD format): DMF

TEST	ACCEPTANCE CRITERION	ANALYTICAL PROCEDURE																										
Appearance	White to off-white powder	Visual inspection																										
Solubility	Soluble in 1% acetic acid at a concentration of 1 mg/mL to give a clear, colorless solution	Ph.Eur.																										
Identity, Mass Spectrometric Analysis	Monoisotopic mass 4115.1 ± 1	In-house																										
Amino acid analysis	<table border="0"> <tr><td>Asx</td><td>3.6 to 4.4</td></tr> <tr><td>Ser</td><td>2.55 to 3.45</td></tr> <tr><td>Glx</td><td>4.5 to 5.5</td></tr> <tr><td>Gly</td><td>0.9 to 1.1</td></tr> <tr><td>Val</td><td>2.55 to 3.45</td></tr> <tr><td>Met</td><td>1.8 to 2.2</td></tr> <tr><td>Ile</td><td>0.85 to 1.15</td></tr> <tr><td>Leu</td><td>4.5 to 5.5</td></tr> <tr><td>Phe</td><td>0.9 to 1.1</td></tr> <tr><td>His</td><td>2.7 to 3.3</td></tr> <tr><td>Lys</td><td>2.7 to 3.3</td></tr> <tr><td>Trp</td><td>0.4 to 1.15</td></tr> <tr><td>Arg</td><td>1.8 to 2.2</td></tr> </table>	Asx	3.6 to 4.4	Ser	2.55 to 3.45	Glx	4.5 to 5.5	Gly	0.9 to 1.1	Val	2.55 to 3.45	Met	1.8 to 2.2	Ile	0.85 to 1.15	Leu	4.5 to 5.5	Phe	0.9 to 1.1	His	2.7 to 3.3	Lys	2.7 to 3.3	Trp	0.4 to 1.15	Arg	1.8 to 2.2	In-house
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HPLC	Co-elutes with reference standard	In-house																										
Peptide purity, HPLC:	≥ 98.5%	In-house																										
Related substances, HPLC ¹ :		In-house																										
Sum of impurities	≤ 1.5%																											
Any unspecified impurity	≤ 0.10%																											
Other specified impurities	≤ 0.4%																											
Peptide Content, HPLC	≥ 80%	USP																										

¹ Detailed impurity specification not provided

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TEST	ACCEPTANCE CRITERION	ANALYTICAL PROCEDURE
Assay, HPLC (anhydrous, acetic acid free basis)	95.0% - 105.0%	USP
Acetic acid content, HPLC	≤ 10%	In-house
Water, Karl Fischer	≤ 10%	In-house
Peptide Mapping, HPLC	Corresponds to Reference Standard	USP
Bioassay ²	60% - 120%	USP
Specific optical rotation [α] _D ²⁵ (c = 0.1, 1% acetic acid)	-66° to 81° (corrected for water and acetate)	In-house
Residual Organic Solvents, GC		In-house
Any individual residual solvent	≤ 0.1%	
Total	≤ 0.25%	
Trifluoroacetic acid content, HPLC	≤ 0.25%	In-house
Perchlorate, IC	≤ 0.1%	In-house
Bioburden		In-house ³
TAMC	≤ 10 CFU/0.1 g	
TYMC	≤ 10 CFU/0.1 g	
	Absence of the following organisms: Bile-tolerant gram negative bacteria: Pseudomonas aeruginosa; Staphylococcus aureus	
Bacterial endotoxins	≤ 10 EU/mg	In-house

² Performed by Contractor Laboratory

³ Performed by Contractor Laboratory