

**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: 09 JUN 2017

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, MS	Monoisotopic mass 4115.1 ± 1	In-house
Identity, Amino acid analysis		In-house
	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	
Identity, HPLC	Co-elutes with reference standard	In-house
Peptide purity, HPLC:	≥ 98.5%	In-house
Related substances, HPLC:		In-house
Total amount	≤ 1.5%	
Any individual impurity	≤ 0.5%	

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TEST	ACCEPTANCE CRITERION	ANALYTICAL PROCEDURE
Assay, Amino acid analysis	≥ 80%	In-house
Acetic acid content, HPLC	≤ 10%	In-house
Water, Karl Fischer	≤ 10%	USP/Ph.Eur.
Mass balance	95% to 105%	In-house
Specific optical rotation [α] _D ²⁰ (c = 0.1, 1% acetic acid)	-66° to 81° (corrected for water and acetate)	In-house
Any individual residual solvent	≤ 0.1%	In-house
Trifluoroacetic acid content	≤ 0.25%	In-house
Perchlorate, IC	≤ 0.1%	In-house
Total viable aerobic count	≤ 500 CFU/g	USP/Ph.Eur.
Bacterial endotoxins	≤ 10 EU/mg	USP/Ph.Eur.