

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



Molecular weight: 4117.8 (free peptide)

Page 1 of 3

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: 30 AUG 2007

Available registration documents (CTD format): Contact PolyPeptide Laboratories
Please note that regional minor differences in analytical procedures and acceptance criteria might occur.

TEST	ACCEPTANCE CRITERIA	ANALYTICAL PROCEDURE
CHARACTERS		
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.
IDENTIFICATION		
Identification, MS	Monoisotopic mass 4115.1 ± 1	In-house
Amino acid analysis	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

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



Molecular weight: 4117.8 (free peptide)

Page 2 of 3

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: 30 AUG 2007

Available registration documents (CTD format): Contact PolyPeptide Laboratories
Please note that regional minor differences in analytical procedures and acceptance criteria might occur.

TEST	ACCEPTANCE CRITERIA	ANALYTICAL PROCEDURE
Identification, HPLC	Co-elutes with reference standard System I and XI	In-house
PURITY		
Peptide purity, HPLC:	≥ 98.5% System I and XI	In-house
Related substances, HPLC:		
Total amount	≤ 1.5%	
Any individual impurity	≤ 0.5% System I and XI	In-house
ASSAY		
Mass balance	95 to 105%	Calculation
OTHER TESTS		
Acetic acid	≤ 10%	In-house
Water	≤ 10%	USP/Ph.Eur.
Specific optical rotation [α] _D ²⁰ (c = 0.1, 1% acetic acid)	Report result (corrected for water and acetate)	In-house
Trifluoroacetic acid	≤ 0.25%	In-house
Perchlorate	≤ 0.1%	In-house

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



Molecular weight: 4117.8 (free peptide)

Page 3 of 3

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: 30 AUG 2007

Available registration documents (CTD format): Contact PolyPeptide Laboratories
Please note that regional minor differences in analytical procedures and acceptance criteria might occur.

TEST	ACCEPTANCE CRITERIA	ANALYTICAL PROCEDURE
RESIDUAL SOLVENTS		
Any individual residual solvent	≤ 0.1%	In-house
MICROBIOLOGICAL TESTS		
Total viable aerobic count	Report result (CFU/g)	In-house
Bacterial endotoxins	Report result (IU/mg)	USP/Ph.Eur.