CALCITONIN (SALMON) US
DRUG SUBSTANCE SPECIFICATION

PolyPeptide Laboratories

Molecular weight: 3432

Sequence: H-Cys-Ser-Asn-Leu-Ser-Thr-Cys-Val-Leu-Gly-Lys-Leu-Ser-Gln-Glu-Leu-His-Lys-Leu-Gln-Thr-Tyr-Pro-Arg-Thr-Asn-Thr-Gly-Ser-Gly-Thr-Pro-NH_2 Acetate salt

Last update: 12 SEP 2007

Available registration documents (CTD format): US DMF

Please note that regional minor differences in analytical procedures and acceptance criteria might occur.

TEST	ACCEPTANCE CRITERIA	ANALYTICAL PROCEDURE
CHARACTERS		
Appearance	White or almost white powder. Freely soluble in water.	Visual inspection
IDENTIFICATION		
Identification, TLC	Complies with reference	In-house
Identification, HPLC	Retention time of the principle peak in the sample is similar to the retention time of the principle peak in the reference	Ph.Eur.
Amino acid analysis	Asp: 1.8 to 2.2 Glu: 2.7 to 3.3 Pro: 1.7 to 2.3 Gly: 2.7 to 3.3 Val: 0.9 to 1.1 Leu: 4.5 to 5.3 His: 0.9 to 1.1 Arg: 0.9 to 1.1 Lys: 1.8 to 2.2 Ser: 3.2 to 4.2 Thr: 4.2 to 5.2 Tyr: 0.7 to 1.1 Half-cystine: 1.4 to 2.1	Ph.Eur.

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TEST	ACCEPTANCE CRITERIA	ANALYTICAL PROCEDURE
PURITY		
Peptide purity, HPLC:	≥ 97.0%	Ph.Eur.
Related substances, HPLC:		Ph.Eur.
RRt 0.84 (molecular weight 3473.7 and 3431.7)	≤ 0.3%	
RRt 0.92 (molecular weight 3431.7)	≤ 0.3%	
RRt 0.95 (molecular weight 3463.7)	≤ 0.3%	
Sum of identified related peptides with RRt 1.05 to 1.07 (Impurity D in monograph)	≤ 1.0%	
[Glu^{14}]-Calcitonin	≤ 1.0%	
Sum of [Glu^{20}]-Calcitonin and N-Acetyl-Cys(1)-Calcitonin (Impurity A in monograph)	≤ 1.0%	
[Glu^{20}]-Calcitonin	≤ 1.0%	
N-Acetyl-Cys(1)-Calcitonin (Impurity A in monograph)	≤ 1.0%	
Any other individual impurity	≤ 0.2%	
Total amount	≤ 3.0%	
ASSAY		
Peptide content	Report result (%)	Ph.Eur.
Mass balance	90.0 to 105.0%	Calculation

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TEST	ACCEPTANCE CRITERIA	ANALYTICAL PROCEDURE
OTHER TESTS		
Chloride	≤ 0.2%	In-house
Water	≤ 10%	USP/Ph.Eur.
Acetic acid	4.0 to 15.0%	Ph.Eur.
Acetic acid and water	≤ 20%	Ph.Eur.
pH of 1 % (w/V) solution in water	4.9 to 5.7	Ph.Eur.
Heavy metals	≤ 20 ppm	In-house
Trifluoroacetic acid	≤ 100 ppm	In-house
RESIDUAL SOLVENTS		
Ethanol	≤ 0.2%	In-house
Acetonitrile	≤ 0.04%	In-house
Methylene chloride	≤ 600 ppm	In-house
MICROBIOLOGICAL TESTS		
Total viable aerobic count	≤ 100 CFU/g	USP/Ph.Eur.
Bacterial endotoxins	< 25 IU/mg	USP/Ph.Eur.