

**CALCITONIN (SALMON) EU
DRUG SUBSTANCE SPECIFICATION**



Molecular weight: 3432 (as free base)

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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-NH₂ Acetate salt

Last update: 15 MAR 2010

Available registration documents (CTD format): CEP/COS certificate

TEST	ACCEPTANCE CRITERIA	ANALYTICAL PROCEDURE
CHARACTERISTICS		
Appearance	White or almost white powder. Freely soluble in water.	Ph.Eur.
IDENTIFICATION		
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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PURITY		
Peptide purity, HPLC:	≥ 95.0%	Ph.Eur.
Related substances, HPLC		Ph.Eur.
O-acetylated Calcitonin with co-eluting peaks (Impurity D in monograph)	≤ 3.0%	
Sum of [Glu ²⁰]-Calcitonin and N-Acetyl-Cys(1)-Calcitonin (Impurity A in monograph)	≤ 3.0%	
Unspecified impurities/degradation products	≤ 0.3%	
Sum of impurities/degradation products	≤ 5.0%	
ASSAY		
Mass balance	90.0 to 105.0%	Ph.Eur.
OTHER TESTS		
Chloride	≤ 0.5% (w/w)	In-house
Water	≤ 10.0% (w/w)	Ph.Eur.
Acetic acid	4.0 to 15.0% (w/w)	Ph.Eur.
Acetic acid and water	≤ 20% (w/w)	Ph.Eur.

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Leu-His-Lys-Leu-Gln-Thr-Tyr-Pro-Arg-Thr-Asn-Thr-Gly-Ser-Gly-Thr-
Pro-NH₂ Acetate salt

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TEST	ACCEPTANCE CRITERIA	ANALYTICAL PROCEDURE
RESIDUAL SOLVENTS		
Trifluoroacetic acid	≤ 100 ppm	In-house
Ethanol	≤ 5000 ppm	In-house
Acetonitrile	≤ 400 ppm	In-house
MICROBIOLOGICAL TESTS		
Microbial enumeration tests:		Ph. Eur.
TAMC	≤ 100 CFU/g	
TYMC	≤ 100 CFU/g	
Bacterial endotoxins	< 25 IU/mg	Ph.Eur.