

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



Molecular weight: 3432

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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-NH<sub>2</sub> Acetate salt

Last update: 12 SEP 2007

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

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

TEST	ACCEPTANCE CRITERIA	ANALYTICAL PROCEDURE
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**CHARACTERS**

Appearance	White or almost white powder. Freely soluble in water.	Visual inspection
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**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.
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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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<b>PURITY</b>		
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 <sup>20</sup> ]-Calcitonin and N-Acetyl-Cys(1)-Calcitonin (Impurity A in monograph)	≤ 3.0%	
Any other individual impurity	≤ 0.3%	
Total amount	≤ 5.0%	
<b>ASSAY</b>		
Mass balance	90.0 to 105.0%	Calculation
<b>OTHER TESTS</b>		
Chloride	≤ 0.5%	In-house
Water	≤ 10%	USP/Ph.Eur.
Acetic acid	4.0 to 15.0%	Ph.Eur.
Acetic acid and water	≤ 20%	Ph.Eur.
Trifluoroacetic acid	≤ 100 ppm	In-house

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TEST	ACCEPTANCE CRITERIA	ANALYTICAL PROCEDURE
<b>RESIDUAL SOLVENTS</b>		
Ethanol	≤ 5000 ppm	In-house
Acetonitrile	≤ 400 ppm	In-house
<b>MICROBIOLOGICAL TESTS</b>		
Total viable aerobic count	≤ 100 CFU/g	USP/Ph.Eur.
Bacterial endotoxins	< 25 IU/mg	USP/Ph.Eur.