

**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: 13 AUG 2020

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

TEST	ACCEPTANCE CRITERION	ANALYTICAL PROCEDURE																										
Appearance	White or almost white powder. Freely soluble in water.	Ph.Eur.																										
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.																										
Identity, Amino acid analysis	<table border="0"> <tr><td>Asp</td><td>1.8 to 2.2</td></tr> <tr><td>Glu</td><td>2.7 to 3.3</td></tr> <tr><td>Pro</td><td>1.7 to 2.3</td></tr> <tr><td>Gly</td><td>2.7 to 3.3</td></tr> <tr><td>Val</td><td>0.9 to 1.1</td></tr> <tr><td>Leu</td><td>4.5 to 5.3</td></tr> <tr><td>His</td><td>0.9 to 1.1</td></tr> <tr><td>Arg</td><td>0.9 to 1.1</td></tr> <tr><td>Lys</td><td>1.8 to 2.2</td></tr> <tr><td>Ser</td><td>3.2 to 4.2</td></tr> <tr><td>Thr</td><td>4.2 to 5.2</td></tr> <tr><td>Tyr</td><td>0.7 to 1.1</td></tr> <tr><td>Half-cystine</td><td>1.4 to 2.1</td></tr> </table>	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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Half-cystine	1.4 to 2.1																											
Peptide purity, HPLC	≥ 95.0 area %	Ph.Eur.																										
Related substances ¹ , HPLC		Ph.Eur.																										
Unspecified impurities/degradation products	≤ 0.3 area %																											
Sum of impurities/degradation products	≤ 5.0 area %																											

¹ Detailed impurity specification not provided

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TEST	ACCEPTANCE CRITERION	ANALYTICAL PROCEDURE
Chloride, IC	≤ 0.5% (w/w)	In-house
Water, Karl Fischer	≤ 10.0% (w/w)	Ph.Eur.
Acetic acid, HPLC	4.0 to 15.0% (w/w)	Ph.Eur.
Acetic acid and water	≤ 20% (w/w)	Ph.Eur.
Mass balance, HPLC (Content of Calcitonin (free base) in percentage of the anhydrous/acetic acid free substance)	90.0 to 105.0%	Ph.Eur.
Trifluoroacetic acid, IC	≤ 100 ppm	In-house
Ethanol, GC	≤ 5000 ppm	In-house
Acetonitrile, GC	≤ 400 ppm	In-house
Microbial enumeration tests:		Ph. Eur.
TAMC	≤ 100 CFU/g	
TYMC	≤ 100 CFU/g	
Bacterial endotoxins	< 25 IU/mg	Ph.Eur.