

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



Molecular weight: 3432 (as free base)

Page 1 of 3

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 AUG 2021

Available registration documents (CTD format): DMF

TEST	ACCEPTANCE CRITERION	ANALYTICAL PROCEDURE																										
Appearance	White or almost white powder	Visual inspection																										
Solubility	Freely soluble in water	USP																										
Identification, HPLC	Retention time of the principle peak in the sample is similar to the retention time of the principle peak in the reference	USP																										
Identification, Amino acid analysis	<table style="width: 100%; border-collapse: collapse;"> <tr><td style="width: 30%;">Asp</td><td style="width: 40%;">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	USP
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																											
Bioidentity	<p>The potency levels determined from at least three performances of the test are homogeneous, and the confidence limits for all determinations are between 64% and 156% of the calculated potency</p> <p>Geometric mean 80% to 125% of assay value</p>	USP																										

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



Molecular weight: 3432 (as free base)

Page 2 of 3

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 AUG 2021

Available registration documents (CTD format): DMF

TEST	ACCEPTANCE CRITERION	ANALYTICAL PROCEDURE
Peptide purity, HPLC	≥ 97.0%	USP
Peptide related impurities, HPLC		USP
Specified impurities <sup>1</sup>		
Any unspecified impurities/degradation products	≤ 0.2%	
Sum of impurities/degradation products	≤ 3.0%	
Chloride, IC	≤ 0.2% (w/w)	In-house
Water, Karl Fischer	≤ 10% (w/w)	USP
Acetic acid, HPLC	4.0 to 15.0% (w/w)	USP
Mass balance	90.0 to 105.0%	USP
Peptide content, HPLC	Report result %(w/w)	USP
Biological activity	Report result, IU/mg	USP
Calculated as: <u>peptide content x 6000 IU/mg</u> 100		
Trifluoroacetic acid, IC	≤ 100 ppm	In-house
Ethanol, GC-HS	≤ 2000 ppm	In-house

<sup>1</sup> Detailed impurity specification not provided

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



Molecular weight: 3432 (as free base)

Page 3 of 3

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 AUG 2021

Available registration documents (CTD format): DMF

TEST	ACCEPTANCE CRITERION	ANALYTICAL PROCEDURE
Acetonitrile, GC-HS	≤ 410 ppm	In-house
Microbial enumeration tests:		USP
TAMC	≤ 100 CFU/g	
TYMC	≤ 100 CFU/g	
Bacterial endotoxins	≤ 1000 EU/mg	USP