CALCITONIN (SALMON) US
DRUG SUBSTANCE SPECIFICATION

PolyPeptide GROUP

Molecular weight: 3432 (as free base)

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: 17 AUG 2020

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	Asp	1.8 to 2.2	USP
	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	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 Geometric mean 80% to 125% of assay value		USP

CALCITONIN (SALMON) US **DRUG SUBSTANCE SPECIFICATION**	PolyPeptide GROUP
Molecular weight: 3432 (as free base)	
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: 17 AUG 2020	
Available registration documents (CTD format): DMF	

TEST	ACCEPTANCE CRITERION	ANALYTICAL PROCEDURE
Peptide purity, HPLC	≥ 97.0%	USP
Peptide related impurities, HPLC		USP
Specified impurities[1]		
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
Heavy metals, ICP	≤ 20 ppm	In-house
Mass balance	90.0 to 105.0%	USP
Peptide content, HPLC	Report result %(w/w)	USP
Biological activity Calculated as: $\frac{\text{peptide content x 6000 IU/mg}}{100}$	Report result, IU/mg	USP
Trifluoroacetic acid, IC	≤ 100 ppm	In-house

[1] Detailed impurity specification not provided

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:	17 AUG 2020
Available registration documents (CTD format): DMF	

TEST	ACCEPTANCE CRITERION	ANALYTICAL PROCEDURE
Ethanol, GC-HS	≤ 2000 ppm	In-house
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