EXENDIN-4 ACETATE (EXENATIDE) US DRUG SUBSTANCE SPECIFICATION

Molecular weight:	4186.6 u (free base)
Sequence:	H-His-Gly-Glu-Gly-Thr[5]-Phe-Thr-Ser-Asp-Leu[10]-Ser-Lys-Gln-Met-Glu[15]-Glu-Glu-Ala-Val-Arg[20]-Leu-Phe-Ile-Glu-Trp[25]-Leu-Lys-Asn- Gly-Gly[30]-Pro-Ser-Ser-Gly-Ala[35]-Pro-Pro-Pro-Ser-NH_2
Last update:	25 AUG 2021
Available registration documents (CTD format): DMF	

TEST	ACCEPTANCE CRITERION	ANALYTICAL PROCEDURE
Appearance	White to off-white powder	Visual inspection
Identity, MS	Monoisotopic mass 4184.0 ± 1u	USP
Identity, AAA	Asx 1.8 - 2.2 Thr 1.8 - 2.2 Ser 4.2 - 5.5 Glx 5.4 - 6.6 Pro 3.6 - 4.4 Gly 4.5 - 5.5 Ala 1.8 - 2.2 Val 0.8 - 1.2 Met 0.9 - 1.1 Ile 0.9 - 1.1 Leu 2.7 - 3.3 Phe 1.8 - 2.2 His 0.9 - 1.1 Lys 1.8 - 2.2 Trp 0.5- 1.1 Arg 0.9 - 1.1	USP
Identity, HPLC	The retention time of the major peak of the sample solution corresponds to that of the standard solution, and the major peak from the identity sample solution elutes as a single peak.	In-house
Assay of exenatide, HPLC	≥ 80% (w/w)	In-house
Exenatide content (anhydrous and acetic acid-free substance)	95 - 105% (w/w)	In-house
Peptide purity, HPLC	≥ 97.0%	In-house
Peptide related impurities, HPLC		In-house

EXENDIN-4 ACETATE (EXENATIDE) US DRUG SUBSTANCE SPECIFICATION	PolyPeptide GROUP
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Last update: 25 AUG 2021	
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TEST	ACCEPTANCE CRITERION	ANALYTICAL PROCEDURE
Specified impurities[1]		
Any unspecified impurity	≤ 0.10%	
Total sum of impurities	≤ 3.0%	
Chiral impurity analysis by GC-MS[1]		
Acetic acid content, HPLC	≤ 5.0% (w/w)	In-house
Water content, Karl Fischer	≤ 7.0% (w/w)	USP
Trifluoroacetic acid, HPLC	≤ 0.25% (w/w)	In-house
Residual solvents, GC		In-house
Acetonitrile	≤ 410 ppm (w/w)	
Triethylamine	≤ 320 ppm (w/w)	
Phosphate, IC	≤ 0.1% (w/w)	USP
Microbiological tests		USP
TAMC	≤ 200 CFU/g	
TYMC	≤ 200 CFU/g	
Bacterial endotoxins	≤ 10 EU/mg	

[1] Detailed impurity specification not provided