



EXENDIN-4 ACETATE (EXENATIDE) USP DRUG SUBSTANCE SPECIFICATION		
Molecular weight: 4186.6 u (free base)	Page 1 of 2	
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 1.5 - 2.5	USP
	Thr 1.5 - 2.5	
	Ser 4.2 - 5.5	
	Glx 5.2 - 6.8	
	Pro 3.5 - 4.5	
	Gly 4.5 - 5.5	
	Ala 1.5 - 2.5	
	Val 0.5 - 1.5	
	Met 0.5 - 1.5	
	Ile 0.5 - 1.5	
	Leu 2.5 - 3.5	
	Phe 1.5 - 2.5	
	His 0.5 - 1.5	
	Lys 1.5 - 2.5	
Trp 0.5 - 1.5		
Arg 0.5 - 1.5		
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	≥ 97.5%	In-house

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TEST	ACCEPTANCE CRITERION	ANALYTICAL PROCEDURE
Peptide related impurities, HPLC		In-house
Specified impurities ¹		
Any unspecified impurity	≤ 0.50%	
Total sum of impurities	≤ 2.5%	
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