OCTREOTIDE ACETATE
DRUG SUBSTANCE SPECIFICATION

PolyPeptide GROUP

Molecular weight: 1019.3 (free peptide)

Sequence: H-D-Phe-Cys-Phe-D-Trp-Lys-Thr-Cys-Thr(ol), supplied as acetate salt

Last update: 14 SEP 2020

Available registration documents (CTD format): DMF

TEST	ACCEPTANCE CRITERION	ANALYTICAL PROCEDURE
Appearance	White to off-white powder	Visual inspection
Identity, AAA (relative ratios)	Thr 0.7-1.1 Cys 1.0-2.2 Phe 1.8-2.2 Lys 0.9-1.3 Trp 0.4-1.1 Thr-ol 0.6-1.3	USP
Identity, LC-UV	The retention time of the major peak of the sample solution corresponds to that of the standard solution and the major peak of the identification sample solution elutes as a single peak	USP
Octreotide content of the total mass of substance, LC-UV	To be noted	USP
Octreotide content (anhydrous and acetic acid-free substance)	95.0 – 105.0% (w/w)	Calculation
Peptide related impurities, LC-UV		USP
Total impurities	≤ 1.5 area%	
Peptide related impurities[1]		
Any unspecified impurity	≤ 0.30 area%	

[1] Detailed impurity specification not provided

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TEST	ACCEPTANCE CRITERION	ANALYTICAL PROCEDURE
Water content, Karl Fisher method	≤ 10.0% (w/w)	USP
Acetic acid content, LC-UV	5.0-12.8% (w/w)	USP
TFA, LC-UV	≤ 0.25% (w/w)	USP
Residual solvents, GC		
Acetonitrile	≤ 410 ppm (w/w)	In-house
DMSO	≤ 5000 ppm (w/w)	In-house
Microbial enumeration tests		
TAMC	≤ 100 CFU/g	USP
TYMC	≤ 100 CFU/g	USP
Bacterial endotoxins	≤ 466 EU/mg	USP