DESLORELIN ACETATE
DRUG SUBSTANCE SPECIFICATION

PolyPeptide GROUP

Molecular weight: 1282.5 (free peptide)

Sequence: p-Glu-His-Trp-Ser-Tyr-D-Trp-Leu-Arg-Pro-NHEt, supplied as acetate salt

Last update: 08 SEP 2020

Available registration documents (CTD format): DMF

TEST	ACCEPTANCE CRITERION	ANALYTICAL PROCEDURE
Appearance	White to off-white powder	Visual inspection
Solubility	Soluble in water and 1% acetic acid at a concentration of 1 mg/mL to give a clear, colorless solution	Visual inspection
Identity, MS	Monoisotopic mass 1281.6 ± 1	Ph.Eur.
Identity, Amino acid analysis	Ser 0.8 to 1.1 Glx 0.9 to 1.1 Pro 0.9 to 1.1 Leu 0.9 to 1.1 Tyr 0.9 to 1.1 His 0.9 to 1.1 Arg 0.9 to 1.1 Trp Present	Ph.Eur. / USP
Identity, LC-UV	Conforms to reference standard	In-house
Peptide purity, LC-UV	≥ 98.5 area%	In-house
Peptide related impurities, LC-UV		In-house
Sum of impurities	≤ 1.5 area%	
Specified impurities[1]		
Any unspecified impurity	≤ 0.3 area%	
Peptide content, Amino acid analysis	≥ 80%	Ph. Eur. / USP

[1] Detailed impurity specification not provided

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TEST	ACCEPTANCE CRITERION	ANALYTICAL PROCEDURE
Deslorelin content (anhydrous and acetic-acid free substance)	95.0 to 105.0% (w/w)	Calculation (sum of water, acetic acid and peptide content)
Water content, Karl Fischer titration	≤ 4% (w/w)	Ph. Eur. / USP
Acetic acid content, LC-UV	≤ 12% (w/w)	In-house
Trifluoroacetic acid, LC-UV	≤ 0.3% (w/w)	In-house
Residual solvents, GC		In-house
Ethanol	≤ 5000 ppm (w/w)	
Acetonitrile	≤ 410 ppm (w/w)	
Triethylamine	≤ 1000 ppm (w/w)	
Phosphate, IC	≤ 1000 ppm (w/w)	In-house
pH (1% w/V solution in water)	4.0 to 6.0	Ph. Eur. / USP
Specific optical rotation $[\alpha]_D^{20}$ (anhydrous and acetic-acid free substance)	-70 to -82	Ph. Eur. / USP
Microbiological tests		Ph. Eur. / USP
TAMC	≤ 100 CFU/g	
TYMC	≤ 100 CFU/g	
Bacterial endotoxins	≤ 2 IU/mg	