



<b>DESLORELIN ACETATE</b> <b>DRUG SUBSTANCE SPECIFICATION</b>		 <b>PolyPeptide</b> GROUP
Molecular weight: 1282.5 (free peptide)		Page 1 of 2
Sequence:	p-Glu-His-Trp-Ser-Tyr-D-Trp-Leu-Arg-Pro-NHEt, supplied as acetate salt	
Last update:	29 AUG 2019	
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
Peptide related impurities, LC-UV		In-house
Sum of impurities	≤ 1.5 area%	
[D-His <sup>2</sup> ]deslorelin (RRt 0.94)	≤ 0.5 area%	
Any unspecified impurity	≤ 0.3 area%	

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TEST	ACCEPTANCE CRITERION	ANALYTICAL PROCEDURE
Peptide content, Amino acid analysis	$\geq 80\%$	Ph. Eur. / USP
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	$\leq 4\%$ (w/w)	Ph. Eur. / USP
Acetic acid content, LC-UV	$\leq 12\%$ (w/w)	In-house
Trifluoroacetic acid, LC-UV	$\leq 0.3\%$ (w/w)	In-house
Residual solvents, GC		In-house
Ethanol	$\leq 5000$ ppm (w/w)	
Acetonitrile	$\leq 410$ ppm (w/w)	
Triethylamine	$\leq 1000$ ppm (w/w)	
Phosphate, IC	$\leq 1000$ 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	$\leq 100$ CFU/g	
TYMC	$\leq 100$ CFU/g	
Bacterial endotoxins	$\leq 2$ IU/mg	