

**DESLORELIN ACETATE  
DRUG SUBSTANCE SPECIFICATION**



Molecular weight: 1282.5 (free peptide)

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

Last update: 30 AUG 2007

Available registration documents (CTD format): EU and US DMF

Please note that regional minor differences in analytical procedures and acceptance criteria might occur.

TEST	ACCEPTANCE CRITERIA	ANALYTICAL PROCEDURE
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**CHARACTERS**

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	Ph.Eur.

**IDENTIFICATION**

Identification, MS	Monoisotopic mass 1281.6 ± 1	Ph.Eur.
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.
Identification, HPLC	Co-elutes with reference standard	In-house

**PURITY**

Peptide purity, HPLC:	≥ 98.5%	In-house
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<b>Related substances, HPLC:</b>		
[D-pGlu <sup>1</sup> ]Deslorelin	≤ 0.5%	In-house
[D-His <sup>2</sup> ]Deslorelin	≤ 0.5%	
Ser(Ac) <sup>4</sup> -Deslorelin	≤ 0.5%	
Any other individual impurity	≤ 0.3%	
Total amount	≤ 1.5%	
<b>ASSAY</b>		
Mass balance	95 to 105%	Calculation
<b>OTHER TESTS</b>		
Acetic acid	≤ 12%	In-house
Water	≤ 4%	USP/Ph.Eur.
Specific optical rotation [α] <sub>D</sub> <sup>20</sup> (c = 0.1, 1% acetic acid)	-70 to -82 (corrected for peptide content)	Ph.Eur.
Trifluoroacetic acid	≤ 0.3%	In-house
Inorganic fluoride	≤ 0.1%	In-house
pH (1% w/V in water)	4.0 to 6.0	USP
<b>RESIDUAL SOLVENTS</b>		
Any individual residual solvent	≤ 0.1%	In-house

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**MICROBIOLOGICAL TESTS**

Total viable aerobic count	≤ 100 CFU/g	Ph.Eur.
Bacterial endotoxins	≤ 2 IU/mg	USP/Ph.Eur.