

TRIPTORELIN
DRUG SUBSTANCE SPECIFICATION



Molecular weight: 1311.5 (free peptide)

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Sequence: pGlu-His-Trp-Ser-Tyr-D-Trp-Leu-Arg-Pro-Gly-NH₂ x (HOAc)_n n = 1-2

Last update: 09 JUN 2017

Available registration documents (CTD format): DMF

TEST	ACCEPTANCE CRITERION	ANALYTICAL PROCEDURE
Appearance	White to off-white powder	Visual inspection
Identity, MS	Correct monoisotopic mass 1310.6 ± 0.4 u	Ph. Eur.
Identity, HPLC	Conforms to reference	Internal
Peptide related impurities, HPLC		Internal
endo-Gly ^{10a} -triptorelin	≤0.5%	
Sum of:		
desGly ¹⁰ -triptorelin	≤0.5%	
[DLeu ⁷]triptorelin		
Sum of:		
[Gly ¹⁰ -OH]triptorelin ^{a)}	≤0.5%	
Ac[2-10]NH ₂ -triptorelin		
Any unspecified triptorelin related impurity	≤0.3%	
Any unspecified impurity	≤0.1%	
Sum of impurities	≤1.5%	
Assay of triptorelin	≥80% (w/w)	Internal
Water, Karl Fischer	≤7.0% (w/w)	Ph. Eur./USP
Acetic acid content, HPLC	3.0-8.0% (w/w)	Internal
Trifluoroacetic acid, HPLC	≤0.25% (w/w)	Internal
Residual solvents, GC		Internal
Acetonitrile	≤410 ppm (w/w)	
Microbiological tests		Ph. Eur./USP
TAMC	≤10 ³ CFU/g	
TYMC	≤10 ² CFU/g	
Bacterial endotoxins	≤10 IU/mg	

a) Also named triptorelin (free acid)