

TRIPTORELIN
DRUG SUBSTANCE SPECIFICATION



Molecular weight: 1311.5 (free peptide)

Page 1 of 1

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

Last update: 27 AUG 2021

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	In-house
Peptide related impurities, HPLC ¹		In-house
Any unspecified triptorelin related impurity	≤0.3%	
Any unspecified impurity	≤0.1%	
Sum of impurities	≤1.5%	
Assay of triptorelin	≥80% (w/w)	In-house
Water, Karl Fischer	≤7.0% (w/w)	Ph. Eur./USP
Acetic acid content, HPLC	3.0-8.0% (w/w)	In-house
Trifluoroacetic acid, HPLC	≤0.25% (w/w)	In-house
Residual solvents, GC		In-house
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	

¹ Detailed impurity specification not provided