

**GOSERELIN ACETATE
DRUG SUBSTANCE SPECIFICATION**



Molecular weight: 1269.4 (free peptide)	Page 1 of 2
Sequence: p-Glu-His-Trp-Ser-Tyr-D-Ser(tBu)-Leu-Arg-Pro-AzaGly-NH ₂ , supplied as acetate salt	
Last update: 30 AUG 2007	
Available registration documents (CTD format): Contact PolyPeptide Laboratories Please note that regional minor differences in analytical procedures and acceptance criteria might occur.	

TEST	ACCEPTANCE CRITERIA	ANALYTICAL PROCEDURE
CHARACTERS		
Appearance	White to off-white powder of low density	Visual inspection
Solubility	Soluble in water at a concentration of 30% (w/w) to give a clear, colorless solution. Time to gelling is > 15 minutes.	In-house
IDENTIFICATION		
Identification, MS	Monoisotopic mass 1268.6 ± 1	In-house
Amino acid analysis	Ser: 1.7 to 2.3 Glx: 0.85 to 1.15 Pro: 0.85 to 1.15 AzaGly: Not detected Leu: 0.85 to 1.15 Tyr: 0.85 to 1.15 His: 0.85 to 1.15 Trp: Present Arg: 0.85 to 1.15	In-house
Identification, HPLC	Co-elutes with reference standard System I and II	In-house

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TEST	ACCEPTANCE CRITERIA	ANALYTICAL PROCEDURE
PURITY		
Peptide purity, HPLC:	≥ 97% System I and II	In-house
Related substances, HPLC:		
Total amount	≤ 3%	
Any individual impurity	≤ 1% System I and II	In-house
ASSAY		
Mass balance	95 to 105%	Calculation
OTHER TESTS		
Acetic acid	≤ 12%	In-house
Water	≤ 10%	USP/Ph.Eur.
Specific optical rotation [α] _D ²⁰ (c = 1.0, 1% acetic acid)	Report value (corrected for peptide content)	In-house
Trifluoroacetic acid	≤ 0.25%	In-house
RESIDUAL SOLVENTS		
Any individual residual solvent	≤ 0.1%	In-house