

**GONADORELIN ACETATE
DRUG SUBSTANCE SPECIFICATION**



Molecular weight: 1182.3 (free peptide)	Page 1 of 3
Sequence: p-Glu-His-Trp-Ser-Tyr-Gly-Leu-Arg-Pro-Gly-NH ₂ , 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
CHARACTERS		
Appearance	White to off-white powder	Visual inspection
Solubility	Soluble in water at a concentration of 10 mg/mL to give a clear solution not more intensely colored than reference solution Y ₅	Ph.Eur.
IDENTIFICATION		
Identification, MS	Monoisotopic mass 1181.6 ± 1	In-house
Amino acid analysis	Ser: 0.7 to 1.05 Glx: 0.95 to 1.05 Pro: 0.95 to 1.05 Gly: 1.9 to 2.1 Leu: 0.9 to 1.1 Tyr: 0.7 to 1.05 His: 0.95 to 1.05 Trp: Present Arg: 0.95 to 1.05 Isoleucine and Lysine absent; not more than traces of other amino acids except Tryptophan	Ph.Eur.
Identification, TLC	Corresponds to reference standard	Ph.Eur.

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TEST	ACCEPTANCE CRITERIA	ANALYTICAL PROCEDURE
Identification, HPLC	Co-elutes with reference standard System I System II	In-house Ph.Eur.
PURITY		
Peptide purity, HPLC	≥ 98% System I System II	In-house Ph.Eur.
Related substances, HPLC		
Total amount	≤ 2%	
Any individual impurity	≤ 1% System I System II	In-house Ph.Eur.
ASSAY		
Mass balance	95.0 to 102.0%	Calculation
OTHER TESTS		
Acetic acid	8.0 to 12.5%	Ph.Eur.
Water	≤ 7.0%	USP/Ph.Eur.
Specific optical rotation [α] _D ²⁰ (c = 1.0, 1% acetic acid)	-54 to -66 (corrected for peptide content)	Ph.Eur.

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TEST	ACCEPTANCE CRITERIA	ANALYTICAL PROCEDURE
Light absorption (278 nm, 0.1 mg/mL in water)	0.55 to 0.61 (corrected for peptide content)	Ph.Eur.
Trifluoroacetic acid	≤ 0.25%	In-house
Inorganic fluoride	≤ 0.1%	In-house
RESIDUAL SOLVENTS		
Any individual residual solvent	≤ 0.1%	In-house
MICROBIOLOGICAL TESTS		
Total viable aerobic count	≤ 300 CFU/g	Ph.Eur.
Bacterial endotoxins	≤ 70 IU/mg	USP/Ph.Eur.