

**GONADORELIN ACETATE
DRUG SUBSTANCE SPECIFICATION**



Molecular weight: 1182.3 (free peptide)

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Sequence: p-Glu-His-Trp-Ser-Tyr-Gly-Leu-Arg-Pro-Gly-NH₂,
supplied as acetate salt

Last update: 09 JUN 2018

Available registration documents (CTD format): DMF

TEST	ACCEPTANCE CRITERION	ANALYTICAL PROCEDURE
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.
Identity, MS	Monoisotopic mass 1181.6 ± 1	In-house
Identity, 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.
Identity, TLC	Corresponds to reference standard	Ph.Eur.
Identity, HPLC	Co-elutes with reference standard	Ph.Eur.
Peptide purity, HPLC	≥ 98%	Ph.Eur.
Related substances, HPLC		Ph.Eur.
Total amount	≤ 2%	
Any individual impurity	≤ 1%	
Assay, peptide content	≥ 80%	Ph.Eur.

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TEST	ACCEPTANCE CRITERION	ANALYTICAL PROCEDURE
Acetic acid content	8.0% to 12.5%	Ph.Eur.
Water, Karl Fischer	≤ 7.0%	USP/Ph.Eur.
Mass balance	95.0% to 102.0%	Calculation
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.
Light absorption (278 nm, 0.1 mg/mL in water)	0.55 to 0.61 (corrected for peptide content)	Ph.Eur.
Any individual residual solvent	≤ 0.1%	In-house
Trifluoroacetic acid	≤ 0.25%	In-house
Inorganic fluoride	≤ 0.1%	In-house
Total viable aerobic count	≤ 300 CFU/g	USP/Ph.Eur.
Bacterial endotoxins	≤ 70 EU/mg	USP/Ph.Eur.