

**LEUPROLIDE (LEUPRORELIN)
DRUG SUBSTANCE SPECIFICATION**



Molecular weight: 1209.4 (free peptide)

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Sequence: p-Glu-His-Trp-Ser-Tyr-D-Leu-Leu-Arg-Pro-NH₂

Last update: 30 AUG 2007

Available registration documents (CTD format): CEP/COS certificate

Please note that regional minor differences in analytical procedures and acceptance criteria might occur.

TEST	ACCEPTANCE CRITERIA	ANALYTICAL PROCEDURE
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CHARACTERS

Appearance	A hygroscopic, white or almost white powder	Visual inspection
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Solubility	Soluble in water and 1% (V/V) aqueous acetic acid at a concentration of ≥ 10 mg/mL to give a clear, colorless solution	Ph.Eur.
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IDENTIFICATION

Identification, MS	Monoisotopic mass 1208.7 \pm 1	Ph.Eur.
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Amino acid analysis	Ser: Present Glx: 0.85 to1.1 Pro: 0.85 to1.1 Leu: 1.8 to 2.2 Tyr: 0.85 to1.1 His: 0.85 to1.1 Arg: 0.85 to1.1 Trp: Present	Ph.Eur.
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Identification, HPLC	Co-elutes with reference standard	Ph.Eur.
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PURITY

Peptide purity, HPLC:	$\geq 97.5\%$	Ph.Eur.
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TEST	ACCEPTANCE CRITERIA	ANALYTICAL PROCEDURE
Related substances, HPLC:		Ph.Eur.
O-acetyl-Ser-Leuprolide	≤ 1%	
Any other individual impurity	≤ 0.5%	
Total amount	≤ 2.5%	
ASSAY		
Mass balance	97.0 to 103.0%	Calculation
OTHER TESTS		
Acetic acid	4.7 to 9.0%	In-house
Water	≤ 5.0%	USP/Ph.Eur.
Specific optical rotation [α] _D ²⁰ (c = 1, 1% acetic acid)	-38 to -42	Ph.Eur.
Trifluoroacetic acid	≤ 0.1%	In-house
Inorganic fluoride	≤ 0.05%	In-house
Residue on ignition	≤ 0.3%	USP
RESIDUAL SOLVENTS		
Any individual residual solvent	≤ 0.1%	In-house
MICROBIOLOGICAL TESTS		
Total viable aerobic count	Report value (CFU/g)	In-house.
Bacterial endotoxins	< 16.7 IU/mg	USP/Ph.Eur.