

**LEUPROLIDE (LEUPRORELIN) JP
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: 29 AUG 2019

Available registration documents (CTD format): DMF

TEST	ACCEPTANCE CRITERION	ANALYTICAL PROCEDURE
Description	White to yellowish white powder	JP
Solubility	Very soluble in water Very soluble in acetic acid (100) Freely soluble in methanol Sparingly soluble in ethanol (99.5)	JP
Identity, IR	The obtained spectrum exhibit similar intensities of absorption at the same wave numbers as the Reference Spectrum or the spectrum of Leuprorelin Acetate JP RS.	JP
Identity, MS	Monoisotopic mass 1208.7 ± 1 u	JP general test method
Optical Rotation $[\alpha]_D^{20}$ (Calculated on the anhydrous and residual acetic acid-free basis)	-38° to -41°	JP
pH	5.5 to 7.5	JP
Constituent amino acids	Glu 1 Pro 1 Leu 2 Tyr 1 His 1 Arg 1	JP general test method
Purity, LC	Impurity : RRT 0.65 : ≤ 0.5% RRT 0.77 : ≤ 0.5% RRT 0.78 : ≤ 0.5% RRT 0.90 : ≤ 0.5% Any individual impurity: ≤ 0.5% Total impurities: ≤ 2 %	JP

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TEST	ACCEPTANCE CRITERION	ANALYTICAL PROCEDURE
Water, Karl Fischer coulometric titration	≤ 5.0%	JP
Residue on ignition	≤ 0.2%	JP
Acetic acid	4.7% to 8.0%	JP
Assay (Calculated on the anhydrous and residual acetic acid-free basis)	96.0 to 102.0%	JP
Residual solvents	Acetonitrile ≤ 410 ppm (w/w) Ethanol ≤ 1000 ppm (w/w) Methanol ≤ 1000 ppm (w/w) Triethylamine ≤ 320 ppm (w/w)	In-house
Trifluoroacetic acid	≤ 0.25%	In-house
Phosphate	≤ 0.1%	In-house
TAMC	≤ 2000 cfu/g	JP
TYMC	≤ 200 cfu/g	JP
Bacterial endotoxins	≤ 16.7 EU/mg	JP