GONADORELIN HYDROCHLORIDE
DRUG SUBSTANCE SPECIFICATION

PolyPeptide GROUP

Molecular weight:	1182.3 (free peptide)
Sequence:	p-Glu-His-Trp-Ser-Tyr-Gly-Leu-Arg-Pro-Gly-NH_2, supplied as hydrochloride salt
Last update:	19 SEP 2019
Available registration documents (CTD format):	DMF

pTEST	ACCEPTANCE CRITERION	ANALYTICAL PROCEDURE
Appearance	White to off-white powder free from visible evidence of contamination	Visual inspection
Solubility	Soluble in water and 1% acetic acid at a concentration of 10 mg/mL to give a clear, essentially colorless solution	Visual inspection
Identity, Mass spectral	Monoisotopic mass 1181.6 ± 1	Ph. Eur. / USP
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 0.3 to 1.1 Arg 0.95 to 1.05	Ph. Eur. / USP
Identity, HPLC	Co-elutes with reference standard	USP
Peptide purity, HPLC	≥ 97.0%	USP
Related substances, HPLC		USP
Total amount	≤ 3.0%	
Any individual impurity	≤ 2.0%	
Assay, HPLC	Report value	USP
Chloride content, titration	4.0% to 6.0%	USP

GONADORELIN HYDROCHLORIDE DRUG SUBSTANCE SPECIFICATION	PolyPeptide GROUP
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TEST	ACCEPTANCE CRITERION	ANALYTICAL PROCEDURE
Water content, Karl Fischer	≤ 7.0%	USP
Content Gonadorelin 2 HCl	94.0% to 104.0% (calculated on anhydrous basis)	USP
Specific optical rotation $[\alpha]_D^{20}$ (c = 1.0, water)	-57 to -63 (calculated on an anhydrous, chloride free basis)	USP
Residual solvents		In-house
Acetonitrile	≤ 0.1% (w/w)	
Anisole	≤ 0.1% (w/w)	
DIPEA	≤ 0.1% (w/w)	
DMF	≤ 0.1% (w/w)	
Ethyl ether	≤ 0.1% (w/w)	
IPA	≤ 0.1% (w/w)	
Methanol	≤ 0.1% (w/w)	
DCM	≤ 0.05% (w/w)	
TEA	≤ 0.1% (w/w)	
Acetic acid content	≤ 1.0%	In-house
Trifluoroacetic acid	≤ 0.25%	In-house
Inorganic fluoride	≤ 0.1%	In-house
Micro testing, TAMC	≤ 300 CFU/g	Ph.Eur. / USP
Bacterial endotoxins	≤ 70 EU/mg	Ph.Eur. / USP
Sequence confirmation, CID MS/MS	Analysis confirms correct sequence	Ph.Eur. / USP