

**GONADORELIN HYDROCHLORIDE USP
DRUG SUBSTANCE SPECIFICATION**



Molecular weight: 1182.3 (free peptide)

Page 1 of 2

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

Last update: 31 AUG 2007

Available registration documents (CTD format): Contact PolyPeptide Laboratories
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 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 | 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: 0.3 to 1.1 Arg: 0.95 to 1.05 | In-house |
| Identification, HPLC | Co-elutes with reference standard | USP |
| PURITY | | |
| Peptide purity, HPLC: | ≥ 97.0% | USP |

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| Related substances, HPLC: | | USP |
| Total amount | ≤ 3.0% | |
| Any individual impurity | ≤ 2.0% | |
| ASSAY | | |
| Mass balance | 94.0 to 104.0% | Calculation |
| OTHER TESTS | | |
| Chloride | 4.0 to 6.0% | USP |
| Water | ≤ 7.0% | USP/ Ph.Eur. |
| Specific optical rotation [α] _D ²⁰ (c = 1.0, water) | -57 to -63 (calculated on the anhydrous, chloride-free basis) | USP |
| Acetic acid | ≤ 1.0% | In-house |
| 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 | In-house |
| Bacterial endotoxins | ≤ 70 IU/mg | USP/Ph.Eur. |