

TRIPTORELIN
DRUG SUBSTANCE SPECIFICATION



Molecular weight: 1311.5 (free peptide)

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Sequence: pGlu-His-Trp-Ser-Tyr-D-Trp-Leu-Arg-Pro-Gly-NH₂ x (HOAc)_n n = 1-2

Last update: 28 SEP 2020

Available registration documents (CTD format): DMF

| TEST | ACCEPTANCE CRITERION | ANALYTICAL PROCEDURE |
|---|---|----------------------|
| Appearance | White to off-white powder | Visual inspection |
| Identity, MS | Correct monoisotopic mass 1310.6 ± 0.4 u | Ph. Eur. |
| Identity, HPLC | Conforms to reference | In-house |
| Peptide related impurities, HPLC ¹ | | In-house |
| Any unspecified triptorelin related impurity | ≤0.3% | |
| Any unspecified impurity | ≤0.1% | |
| Sum of impurities | ≤1.5% | |
| Assay of triptorelin | ≥80% (w/w) | In-house |
| Water, Karl Fischer | ≤7.0% (w/w) | Ph. Eur./USP |
| Acetic acid content, HPLC | 3.0-8.0% (w/w) | In-house |
| Trifluoroacetic acid, HPLC | ≤0.25% (w/w) | In-house |
| Residual solvents, GC | | In-house |
| Acetonitrile | ≤410 ppm (w/w) | |
| Microbiological tests | | Ph. Eur./USP |
| TAMC | ≤10 ³ CFU/g | |
| TYMC | ≤10 ² CFU/g | |
| Bacterial endotoxins | ≤10 IU/mg | |

¹ Detailed impurity specification not provided