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Gonadorelin for Injection

DEFINITION

Gonadorelin for Injection is a sterile mixture of Gonadorelin Hydrochloride with suitable diluents. It contains the equivalent of NLT 90.0% and NMT 115.0% of the labeled amount of gonadorelin ($C_{55}H_{75}N_{17}O_{13}$).

IDENTIFICATION

• **A.**

Buffer solution, Mobile phase, Standard solution 2, Sample solution, Chromatographic system, and **System suitability:** Proceed as directed in the *Assay*.

Identity sample solution: Mix equal volumes of *Standard solution 2* and the *Sample solution*.

Analysis

Samples: *Standard solution 2*, *Sample solution*, and *Identity sample solution*

Acceptance criteria: The retention time of the major peak of the *Sample solution* corresponds to that of *Standard solution 2*, and the major peak of the *Identity sample solution* elutes as a single peak.

ASSAY

• **Procedure**

[Note—Perform all manipulations involving the weighing of the gonadorelin hydrochloride sample and the Reference Standard in a low-humidity glove box.]

Buffer solution: 6.8 mg/mL of monobasic potassium phosphate in water. Adjust with 1 N potassium hydroxide to a pH of 6.5.

Mobile phase: Acetonitrile and *Buffer solution* (18:82)

Standard solution 1: 80 µg/mL of USP Gonadorelin Hydrochloride RS in *Mobile phase*

Standard solution 2: 100 µg/mL of USP Gonadorelin Hydrochloride RS in *Mobile phase*

Standard solution 3: 120 µg/mL of USP Gonadorelin Hydrochloride RS in *Mobile phase*

[Note—The *Standard solutions* may be stored in a refrigerator for 2 months. Remove suitable portions and warm to room temperature before use.]

Sample solution: Separately dissolve the contents of NLT 5 vials of Gonadorelin for Injection in *Mobile phase* to obtain a nominal concentration of 100 µg/mL of gonadorelin. Sonicate the vials for 5 min, and allow to cool to room temperature. Combine the solutions in the vials to obtain the *Sample solution*.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 220 nm

Column: 4.6-mm × 15-cm; 5-µm packing L1

Flow rate: 1.5 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution 1*

[Note—The retention time for gonadorelin is 8–11 min.]

Suitability requirements

Tailing factor: NMT 2.5

Relative standard deviation: NMT 3.0% for gonadorelin

Analysis

Samples: *Standard solutions* and *Sample solution*

[Note—If more than five specimens are analyzed, reinject the *Standard solutions* before injecting further specimens of the *Sample solution*.]

Plot the responses of the gonadorelin peaks versus concentration, in mg/mL, of gonadorelin in each of the *Standard solutions*, and determine the regression line, using the least-squares method. The coefficient of variation from the regression line is NMT 3.0%. From the graph so obtained, determine the concentration, *C*, of gonadorelin in the *Sample solution* (mg/mL).

Calculate the percentage of the labeled amount of gonadorelin ($C_{55}H_{75}N_{17}O_{13}$) in the portion of Gonadorelin for Injection taken:

$$\text{Result} = C \times (M_{r1}/M_{r2}) \times (V + F) \times (100/L)$$

C = concentration of gonadorelin in the *Sample solution* as obtained from the regression line (µg/mL)

M_{r1} = molecular weight of gonadorelin, 1182.3

M_{r2} = molecular weight of gonadorelin hydrochloride, 1255.2

V = volume of *Mobile phase* used to prepare the *Sample solution* (mL)

F = correction factor for the volume created by the dissolved sample, 0.06 mL

L = label claim (µg)

Acceptance criteria: 90.0%–115.0%

SPECIFIC TESTS

• **Constituted Solution:** At the time of use, it meets the requirements in *Injections and Implanted Drug Products ⟨1⟩, Specific Tests, Completeness and clarity of solutions*.

• **pH ⟨791⟩:** 4.0–8.0, in a solution constituted as directed in the labeling

• **Sterility Tests ⟨71⟩:** Meets the requirements

• **Bacterial Endotoxins Test ⟨85⟩:** It contains NMT 70 USP Endotoxin Units/mg.

• **Other Requirements:** Meets the requirements in *Labeling ⟨7⟩, Labels and Labeling for Injectable Products*

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, well-sealed containers.

• **USP Reference Standards ⟨11⟩**
USP Gonadorelin Hydrochloride RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
GONADORELIN FOR INJECTION	Ying Han Associate Science & Standards Liaison	BIO12020 Biologics Monographs 1 - Peptides

Chromatographic Database Information: Chromatographic Database

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