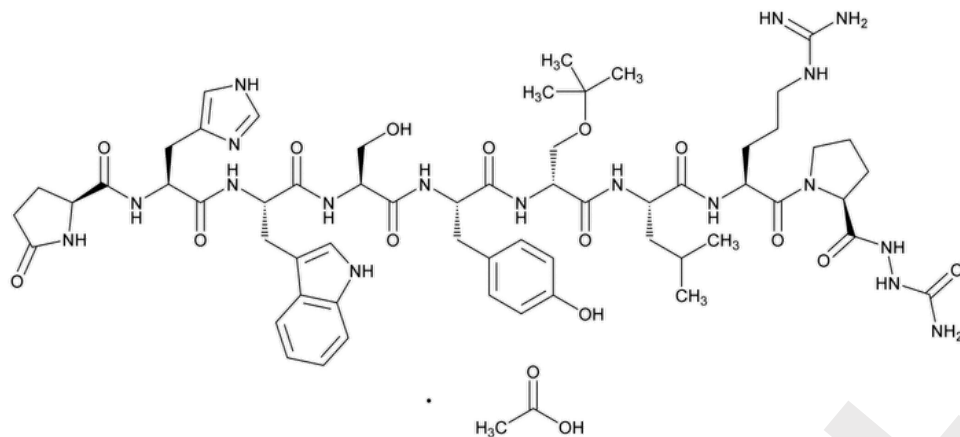


Status: Currently Official on 15-Feb-2025
 Official Date: Official as of 01-Dec-2020
 Document Type: USP Monographs
 DocId: GUID-AAC6B8E4-86F7-4DC5-A256-89E658ADC7D2_3_en-US
 DOI: https://doi.org/10.31003/USPNF_M35835_03_01
 DOI Ref: ojk31

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Goserelin Acetate



$C_{59}H_{84}N_{18}O_{14} \cdot xC_2H_4O_2$

1269.43 (as free base)

Luteinizing hormone-releasing factor (pig), 6-[O-(1,1-Dimethylethyl)-D-serine]-10-deglycinamide-, 2-(aminocarbonyl)hydrazide, acetate (salt); 1-(5-Oxo-L-prolyl-L-histidyl-L-tryptophyl-L-seryl-L-tyrosyl-O-tert-butyl-D-seryl-L-leucyl-L-arginyl-L-prolyl)semicarbazide (goserelin free base);

Free base: CAS RN®: 65807-02-5; UNII: 0F65R8P09N.

Acetate salt: CAS RN®: 145781-92-6; UNII: 6YUU2PV0U8.

DEFINITION

Goserelin Acetate is a synthetic nonapeptide analog of the hypothalamic decapeptide, gonadorelin. It is obtained by chemical synthesis and is available as an acetate salt. It contains NLT 94.5% and NMT 103.0% of goserelin ($C_{59}H_{84}N_{18}O_{14}$), calculated on the anhydrous and acetic acid-free basis.

IDENTIFICATION

- **A.** The retention time of the goserelin peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

PROCEDURE

Mobile phase: Prepare a filtered and degassed mixture of [water](#), [acetonitrile](#), and [trifluoroacetic acid](#) (1600:400:1).

Standard solution: 1 mg/mL of [USP Goserelin Acetate RS](#) in [water](#)

Diluted standard solution: Transfer 1 mL of the *Standard solution* to a 10-mL volumetric flask, and dilute with [water](#) to volume.

System suitability solution 1: Prepare a solution of 0.1 mg/mL [USP Goserelin Related Compound A RS](#) in [water](#), and mix with an equal volume of *Diluted standard solution*.

System suitability solution 2: Prepare [USP Goserelin System Suitability Mixture RS](#) as indicated on the label.

Sample solution: 1 mg/mL of Goserelin Acetate in [water](#)

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 220 nm

Column: 4.6-mm × 15-cm; 3.5-μm packing [L1](#)

Column temperature: 50°–55°

Flow rate: 1 mL/min

Injection volume: 10 μL

System suitability

Samples: *Standard solution*, *System suitability solution 1*, and *System suitability solution 2*

[NOTE—For *System suitability solution 1*, the retention time for the goserelin peak is between 40 and 50 min; see [Table 1](#) for the relative retention times. Two minor peaks are visible prior to the elution of the principal peak, *System suitability solution 2*.]

Suitability requirements

Resolution: NLT 7.0 between the goserelin and goserelin related compound A (4-D-Ser-goserelin) peaks, *System suitability solution 1*

Relative standard deviation: NMT 2.0% for the goserelin peak from replicate injections, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of goserelin ($C_{59}H_{84}N_{18}O_{14}$) in the portion of Goserelin Acetate taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of the *Standard solution* (mg/mL)

C_U = concentration of the *Sample solution* (mg/mL)

Acceptance criteria: 94.5%–103.0% on the anhydrous, acetic acid-free basis

OTHER COMPONENTS

- [ACETIC ACID IN PEPTIDES \(503\)](#): 4.5%–15.0%

IMPURITIES

Change to read:

- **ORGANIC IMPURITIES: RELATED COMPOUNDS**

Mobile phase, Standard solution, Diluted standard solution, System suitability solution 1, System suitability solution 2, Sample solution, and **Chromatographic system:** Proceed as directed in the Assay.

Diluted sample solution: Transfer 1 mL of the *Sample solution* into a 100-mL volumetric flask, and dilute with [water](#) to volume.

System suitability

Samples: *System suitability solution 1* and *System suitability solution 2*

[NOTE—For *System suitability solution 1*, the retention time for the goserelin peak is between 40 and 50 min; see [Table 1](#) for the relative retention times. For *System suitability solution 2*, two peaks, corresponding to decarbamoylgoserelin and 2-D-His-goserelin and eluting prior to the principal peak, are visible.]

Resolution: NLT 7.0, *System suitability solution 1*

Column efficiency: NLT 2000 theoretical plates, *System suitability solution 1*

Tailing factor: NMT 2.0, *System suitability solution 1*

Relative standard deviation: NMT 2.0%, *System suitability solution 2*

Table 1

Name	Relative Retention Time
4-D-Ser-goserelin	0.67
Decarbamoylgoserelin	0.89
5-D-Tyr-goserelin	0.92
2-D-His-goserelin	0.94
▲Goserelin▲ (ERR 1-Dec-2020)	1.0

Analysis

Samples: *Sample solution* and *Diluted sample solution*

Calculate the percentage of goserelin-related impurities in the portion of Goserelin Acetate taken: