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Oxytocin Injection

(This monograph has been updated to the current USP style. No revisions or changes to tests have been made.)

DEFINITION

Oxytocin Injection is a sterile solution of Oxytocin in a suitable diluent. Each milliliter of Oxytocin Injection possesses an oxytocic activity of NLT 90.0% and NMT 110.0% of that stated on the label in USP Oxytocin Units.

ASSAY

• PROCEDURE

Solution A: [0.1 M monobasic sodium phosphate](#)

Solution B: [Acetonitrile](#) in [water](#) (1:1). Filter and degas before use. Make adjustments if necessary (see [Chromatography \(621\), System Suitability](#)).

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	70	30
20	50	50

Diluent: Dissolve 5.0 g of [chlorobutanol](#) in 5.0 mL of [glacial acetic acid](#). Add 5.0 g of [alcohol](#), 1.1 g of [sodium acetate](#), and 1000 mL of [water](#), and mix.

Standard solution: Dissolve the entire contents of a vial of [USP Oxytocin RS](#) in a known volume of *Diluent*. [NOTE—The solution may be diluted as necessary to a working concentration range for the Assay.]

Sample solution: Undiluted Oxytocin Injection. [NOTE—Allow NLT 25 min between injections.]

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

Column: 4.6-mm × 12.0-cm; 5-μm packing [L1](#)

Column temperature: Room temperature

Flow rate: About 1.5 mL/min

Injection volume: About 100 μL

System suitability

Sample: *Standard solution*

[NOTE—Adjust the flow rate or the composition of the *Mobile phase* such that the retention time of oxytocin is approximately 10 min and between 15 and 17 min for chlorobutanol.]

Suitability requirements

Resolution: NLT 1.5 between oxytocin and the nearest adjacent peak

Relative standard deviation: NMT 2.0% for oxytocin from replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Separately inject three equal volumes of the *Standard solution* and the *Sample solution* into the chromatograph allowing NLT 25 min between injections, and record the chromatograms as described in *Chromatographic system*. Identify the peaks, and determine the area

of the oxytocin peak.

Calculate the percentage of the labeled amount of oxytocin in the portion of Oxytocin Injection taken:

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

 r_U = mean values of the peak response of the *Sample solution* r_S = mean values of the peak response of the *Standard solution* C_S = concentration of USP Oxytocin Units/mL in the *Standard solution* (Units/mL) C_U = label concentration of USP Oxytocin Units/mL in the *Sample solution* (Units/mL)**Acceptance criteria:** 90.0%–110.0% of that stated on the label in USP Oxytocin Units**SPECIFIC TESTS**

- [BACTERIAL ENDOTOXINS TEST \(85\)](#): It contains NMT 35.7 Endotoxin Units/USP Oxytocin Unit.
- [pH \(791\)](#): 3.0–5.0
- [PARTICULATE MATTER IN INJECTIONS \(788\)](#): Meets the requirements for small-volume injections
- [INJECTIONS AND IMPLANTED DRUG PRODUCTS \(1\)](#): Meets the requirements

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE**: Preserve in single-dose or multiple-dose containers, preferably of Type I glass, or in suitable plastic containers.
- **LABELING**: Label it to indicate its oxytocic activity in USP Oxytocin Units/mL. Label it also to state the animal source if naturally derived, or to state that it is synthetic.
- [USP REFERENCE STANDARDS \(11\)](#).

[USP Oxytocin RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
OXYTOCIN INJECTION	Jennifer Tong Sun Senior Scientist II	BIO12020 Biologics Monographs 1 - Peptides
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	BIO12020 Biologics Monographs 1 - Peptides

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