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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 oxytotic 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	<a href="#">Jennifer Tong Sun</a> Senior Scientist II	BI012020 Biologics Monographs 1 - Peptides
REFERENCE STANDARD SUPPORT	RS Technical Services <a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a>	BI012020 Biologics Monographs 1 - Peptides

**Chromatographic Database Information:** [Chromatographic Database](#)

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