

## Microbiology Report

CLIENT: BET Pharmacy-KY  
Web Report

ARL #: 461863-01

LOT #: 29504@3

DESCRIPTION: Oxytocin 25 IU/mL

DATE RECEIVED: 04/12/2018

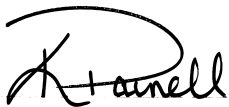
STORAGE: 2°C to 8°C (35.6°F to 46.4°F)

CONTAINER: Five 30 mL clear vials w/30 mL each in a clear bag

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility (*Preliminary*)	Sterile / Not Sterile	Sterile	USP <71>	04/12/2018
Endotoxin	416.16 EU/U	<0.04 EU/U	USP <85>	04/16/2018
Fungal	Sterile / Not Sterile	Sterile	MBI-114	04/12/2018

Formulation ID: 2

The citation to USP <71> is conditioned on the accuracy of our customer's verification that the sampling program complies with the provisions of USP <71>.



05/01/2018

Keshia Parnell - Microbiologist II

Date Reported

*Sterility – This preliminary report was issued after approximately 72 hours of incubation. In accordance with the test methodology, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.*

*Fungal – This preliminary report was issued after approximately 4 days of incubation. In accordance with the test methodology, the sample will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.*

*Endotoxin - To calculate the endotoxin limit use the following formulae:  $EL = K/M$  where  $K$  = tolerance limit (EU/kg) and  $M$  = Maximum dose/kg/hour or Maximum dose/kg*

*Parenteral:  $K$  is 5 EU/kg for any route of administration /Intrathecal:  $K$  is 0.2 EU/kg body weight)*

*Radiopharmaceutical parenteral:  $K$  is  $175/V$  or Intrathecal radiopharmaceuticals:  $K$  is  $14/V$ , where  $V$  is the maximum recommended dose in mL.*

*Dermal Application:  $K/M$ , where  $K$  = 5 EU/kg and  $M$  is the (maximum dose/m<sup>2</sup>/hour × 1.80 m<sup>2</sup>)/70 Kg.*

Results reported above relate only to the sample that was tested.