

Microbiology Report

CLIENT: BET Pharmacy-KY
 Web Report

ARL #: 456266-01

LOT #: 29421@2

DESCRIPTION: GnRH 250 mcg/mL

DATE RECEIVED: 03/15/2018

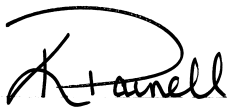
STORAGE: 2°C to 8°C (35.6°F to 46.4°F)

CONTAINER: Five 30 mL amber vials w/ 30 mL each

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility (*Preliminary*)	Sterile / Not Sterile	No Growth at 3 Days	USP <71>	03/16/2018
Endotoxin	119.05 EU/mg	<0.04 EU/mg	USP <85>	03/21/2018
Fungal	Sterile / Not Sterile	No Growth at 4 Days	MBI-114	03/16/2018

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>.

Formulation ID: 16



03/21/2018

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/m²/hour × 1.80 m²)/70 Kg.

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



ARL BIO PHARMA
 840 RESEARCH PARKWAY, SUITE 546
 OKLAHOMA CITY, OK 73104
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 FAX (405) 271-1174

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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>.
 Formulation ID: 16

03/30/2018

Keshia Parnell - Microbiologist II

Date Reported

Sterility – 14 day sterility report. In accordance with the test methodology, the sample was incubated for 14 days.

Fungal – 14 day fungal report. In accordance with the test methodology, the sample was incubated for 14 days.

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Keshia Parnell - Microbiologist II

Date Reported

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