



**ARL BIO PHARMA**  
 840 RESEARCH PARKWAY, SUITE 546  
 OKLAHOMA CITY, OK 73104  
 PHONE (405) 271-1144  
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# Microbiology Report

CLIENT: BET Pharmacy-KY  
 Web Report

ARL #: 461862-01  
 LOT #: 29509@3  
 DESCRIPTION: GnRH 250 mcg/mL  
 DATE RECEIVED: 04/12/2018  
 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 7 Days	USP <71>	04/12/2018
Endotoxin	119.05 EU/µg	<0.04 EU/µg	USP <85>	04/18/2018
Fungal	Sterile / Not Sterile	No Growth at 6 Days	MBI-114	04/17/2018

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

04/23/2018

Kerri Hirst - 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.



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Sterility	Sterile / Not Sterile	Sterile	USP <71>	04/12/2018
Fungal	Sterile / Not Sterile	No Growth at 7 Days	MBI-114	04/17/2018

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Formulation ID: 16

04/26/2018

Kerri Hirst - 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.*

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



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ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility	Sterile / Not Sterile	Sterile	USP <71>	04/12/2018
Fungal	Sterile / Not Sterile	Sterile	MBI-114	04/17/2018

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

05/01/2018

Kerri Hirst - 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.*

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