ARL BIO PHARMA
840 RESEARCH PARKWAY, SUITE 546
OKLAHOMA CITY, OK 73104
PHONE (405) 271-1144
FAX (405) 271-1174

Microbiology Report

CLIENT: BET Pharmacy-KY
Web Report

ARL #: 448265-01
LOT #: 29307@1
DESCRIPTION: Estradiol in BioRelease 3.3 mg / mL
DATE RECEIVED: 01 / 26 / 2018
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Five 100 mL amber vials w / 100 mL each

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility (*Preliminary*)	Sterile / Not Sterile	No Growth at 3 Days	MBI-144	01 / 26 / 2018
Endotoxin	16.67 EU / µg	<3.58 EU / µg	USP <85>	01 / 31 / 2018
Fungal	Sterile / Not Sterile	No Growth at 4 Days	MBI-114	01 / 26 / 2018

Kerri Hirst - Microbiologist II

01 / 31 / 2018
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.

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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>.

MBI-144 is listed as the sterility test method due to sampling not being performed per USP <71> guidelines and/or method suitability cannot be traced to your specific formulation.

Kerri Hirst

Kerri Hirst - Microbiologist II

01 / 31 / 2018

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
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Kerri Hirst

Kerri Hirst - Microbiologist II

01 / 31 / 2018

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
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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	No Growth at 14 Days (subcultured) *	MBI-144	01 / 26 / 2018
Fungal	Sterile / Not Sterile	No Growth at 14 Days (subcultured) *	MBI-114	01 / 26 / 2018

MBI-144 is listed as the sterility test method due to sampling not being performed per USP <71> guidelines and/or method suitability cannot be traced to your specific formulation.

* This is not a final result. After 14 days of incubation, the material being tested rendered the media turbid so that the presence or absence of microbial growth cannot be readily determined by visual examination. Per USP <71>, the sample will be inoculated into new growth media and incubated for an additional 4 days before the test is complete. An updated report will be issued at the conclusion of the test.

Kerri Hirst

Kerri Hirst - Microbiologist II

02 / 09 / 2018
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	MBI-144	01 / 26 / 2018
Fungal	Sterile / Not Sterile	Sterile	MBI-114	01 / 26 / 2018

MBI-144 is listed as the sterility test method due to sampling not being performed per USP <71> guidelines and/or method suitability cannot be traced to your specific formulation.

Kerri Hirst

Kerri Hirst - Microbiologist II

02 / 13 / 2018
Date Reported

Sterility – 18 day sterility report. In accordance with the test methodology, the sample was incubated for a minimum of 18 days.

Fungal – 18 day fungal report. In accordance with the test methodology, the sample was incubated for a minimum of 18 days.

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