

Microbiology Report

CLIENT: BET Pharmacy-KY
Web Report

ARL #: 448264-01

LOT #: 29309@2

DESCRIPTION: Estradiol in BioRelease 10 mg/mL

DATE RECEIVED: 01/26/2018

STORAGE: 20°C to 25°C (68°F to 77°F)

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

| ANALYSIS | Limits | Results | Test Method | Date Tested |
|---------------------------|-----------------------|---------------------|-------------|-------------|
| Sterility (*Preliminary*) | Sterile / Not Sterile | No Growth at 5 Days | USP <71> | 02/21/2018 |
| Endotoxin | 16.67 EU/µg | <0.001 EU/µg | USP <85> | 02/01/2018 |
| Fungal | Sterile / Not Sterile | Sterile | MBI-114 | 01/29/2018 |

Formulation ID: 12

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>.



02/26/2018

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.

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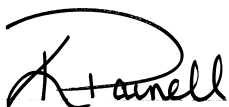
CONTAINER: Five 30 mL amber vials w/30 mL each in a clear bag

| ANALYSIS | Limits | Results | Test Method | Date Tested |
|-----------|-----------------------|--------------------------------------|-------------|-------------|
| Sterility | Sterile / Not Sterile | No Growth at 14 Days (subcultured) * | USP <71> | 02/21/2018 |
| Fungal | Sterile / Not Sterile | No Growth at 14 Days (subcultured) * | MBI-114 | 01/29/2018 |

Formulation ID: 12

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* 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.



03/07/2018

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.

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



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

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| ANALYSIS | Limits | Results | Test Method | Date Tested |
|-----------|-----------------------|---------|-------------|-------------|
| Sterility | Sterile / Not Sterile | Sterile | USP <71> | 02/21/2018 |
| Fungal | Sterile / Not Sterile | Sterile | MBI-114 | 01/29/2018 |

Formulation ID: 12

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>.

03/12/2018

Keshia Parnell - Microbiologist II

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.