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

Certificate Of Analysis

CLIENT: BET Pharmacy-KY
Web Report

ARL #: 448664-01
LOT #: 29311@1
DESCRIPTION: Histrelin Acetate 0.5 mg/mL
DATE RECEIVED: 01/30/2018
STORAGE: 2°C to 8°C (35.6°F to 46.4°F)
CONTAINER: Twelve 10 mL amber vials w/10 mL each

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Histrelin Specifications = 90.0% - 110.0%	0.5	mg/mL	0.5272	105.4%	HPLC	2/5/2018

Formulation ID: 05

The potency method(s) used for testing passed system suitability requirements per ARL SOP AMP-012 for non-cGMP analysis. Product specific method validation is not available for this sample and specification(s) are for informational purposes only. Client should verify the specification and analyte reported are correct for the compounded formulation.

Potency results obtained by comparison to reference material provided by client.

Ryan Kostuck - Laboratory Supervisor

02/05/2018
Date Reported

ARL Form QUF-078-V4 03/05/2010

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

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Microbiology Report

CLIENT: BET Pharmacy-KY
Web Report

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DESCRIPTION: Histrelin Acetate 0.5 mg / mL
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STORAGE: 2°C to 8°C (35.6°F to 46.4°F)
CONTAINER: Twelve 10 mL amber vials w / 10 mL each

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility (*Preliminary*)	Sterile / Not Sterile	No Growth at 3 Days	USP <71>	02 / 05 / 2018
Endotoxin	20000 EU / mg	<8 EU / mg	USP <85>	02 / 01 / 2018
Fungal	Sterile / Not Sterile	No Growth at 7 Days	MBI-114	01 / 30 / 2018

Formulation ID: 05

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>.

Potency results obtained by comparison to reference material provided by client.

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.

Kerri Hirst - Microbiologist II

02 / 08 / 2018
Date Reported

ARL Form QUF-078-V6 11/26/2012

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

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Microbiology Report

CLIENT: BET Pharmacy-KY
Web Report

ARL #: 448664-01
LOT #: 29311@1
DESCRIPTION: Histrelin Acetate 0.5 mg / mL
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CONTAINER: Twelve 10 mL amber vials w / 10 mL each

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility	Sterile / Not Sterile	No Growth at 14 Days (subcultured) *	USP <71>	02 / 05 / 2018
Fungal	Sterile / Not Sterile	Sterile	MBI-114	01 / 30 / 2018

Formulation ID: 05

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>.

Potency results obtained by comparison to reference material provided by client.

* 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 / 19 / 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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Microbiology Report

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CONTAINER: Twelve 10 mL amber vials w / 10 mL each

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility	Sterile / Not Sterile	Sterile	USP <71>	02 / 05 / 2018
Fungal	Sterile / Not Sterile	Sterile	MBI-114	01 / 30 / 2018

Formulation ID: 05
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>.
Potency results obtained by comparison to reference material provided by client.

Kerri Hirst - Microbiologist II

02 / 27 / 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.