

Microbiology Report

CLIENT: BET Pharmacy-KY
Web Report

ARL #: 468470-01

LOT #: 29561@2

DESCRIPTION: Thyroxine Microparticles 50 mg

DATE RECEIVED: 05/16/2018

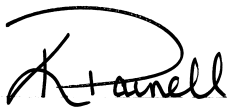
STORAGE: 2°C to 8°C (35.6°F to 46.4°F)

CONTAINER: Ten 5 mL amber vials w/ powder in a clear bag

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility (*Preliminary*)	Sterile / Not Sterile	No Growth at 5 Days	USP <71>	05/16/2018
Endotoxin	35.97 EU/mcg	<0.01 EU/mcg	USP <85>	05/21/2018
Fungal	Sterile / Not Sterile	No Growth at 5 Days	MBI-114	05/16/2018

Formulation ID: 04

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>.



05/22/2018

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
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Fungal	Sterile / Not Sterile	Sterile	MBI-114	05/16/2018

Formulation ID: 04

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05/30/2018

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.

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