



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 #: 460334-01
 LOT #: 29474@2
 DESCRIPTION: Ticarcillin/Clavulanate 30:1 3.1 grams
 DATE RECEIVED: 04/04/2018
 STORAGE: 20°C to 25°C (68°F to 77°F)
 CONTAINER: Five 30 mL amber vials w/powder

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility (*Preliminary*)	Sterile / Not Sterile	No Growth at 4 Days	USP <71>	04/05/2018
Endotoxin	19.23 EU/mg	<0.10 EU/mg	USP <85>	04/06/2018
Fungal	Sterile / Not Sterile	No Growth at 4 Days	MBI-114	04/05/2018

Formulation ID: 1379

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>.

04/09/2018

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/m²/hour × 1.80 m²)/70 Kg.

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

Microbiology Report

CLIENT: BET Pharmacy-KY
 Web Report

ARL #: 460334-01
 LOT #: 29474@2
 DESCRIPTION: Ticarcillin/Clavulanate 30:1 3.1 grams
 DATE RECEIVED: 04/04/2018
 STORAGE: 20°C to 25°C (68°F to 77°F)
 CONTAINER: Five 30 mL amber vials w/powder

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility	Sterile / Not Sterile	Sterile	USP <71>	04/05/2018
Fungal	Sterile / Not Sterile	Sterile	MBI-114	04/05/2018

Formulation ID: 1379

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>.

04/19/2018

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.