

## **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 #:	468474-01		
LOT #:	29576@3		
DESCRIPTION:		Ticarcillin/Clavulanate 30:1 3.1 grams	
DATE RECEIVED:		05/16/2018	
STORAGE:		20°C to 25°C (68°F to 77°F)	
CONTAI	NER:	Five 30 ml clear vials w/ powder in a clear bag	

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility (*Preliminary*)	Sterile / Not Sterile	No Growth at 7 Days	USP <71>	05/22/2018
Endotoxin	19.23 EU/mg	<0.10 EU/mg	USP <85>	05/24/2018
Fungal	Sterile / Not Sterile	No Growth at 7 Days	MBI-114	05/22/2018

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>. Formulation ID: 1379

Kern Hust

Kerri Hirst - Microbiologist II

05/29/2018

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.

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  $\times$  1.80 m2)/70 Kg.

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

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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ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility	Sterile / Not Sterile	Sterile	USP <71>	05/22/2018
Fungal	Sterile / Not Sterile	Sterile	MBI-114	05/22/2018

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>. Formulation ID: 1379

Kern Hust

06/05/2018

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.