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 #: 456268-01
LOT #: 29423@3
DESCRIPTION: Ticarcillin / Clavulanate 30:1
DATE RECEIVED: 03 / 15 / 2018
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Five 30 mL clear vials w / powder, Thirty 30 mL amber vials w / powder

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility (*Preliminary*)	Sterile / Not Sterile	No Growth at 7 Days	USP <71>	03 / 16 / 2018
Endotoxin	19.23 EU / mg	<0.10 EU / mg	USP <85>	03 / 21 / 2018
Fungal	Sterile / Not Sterile	No Growth at 7 Days	MBI-114	03 / 16 / 2018
Method Suitability-Sterility	Pass / Fail	Pass	USP <71>	03 / 23 / 2018
Method Suitability-Fungal	Pass / Fail	Pass	MBI-142	03 / 21 / 2018

Kerri Hirst

Kerri Hirst - Microbiologist II

03 / 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.

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 #: 456268-01
LOT #: 29423@3
DESCRIPTION: Ticarcillin / Clavulanate 30:1
DATE RECEIVED: 03 / 15 / 2018
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Five 30 mL clear vials w / powder, Thirty 30 mL amber vials w / powder

ANALYSIS	Limits	Results	Test Method	Date Tested

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

Kerri Hirst

Kerri Hirst - Microbiologist II

03 / 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.

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 #: 456268-01
LOT #: 29423@3
DESCRIPTION: Ticarcillin / Clavulanate 30:1
DATE RECEIVED: 03 / 15 / 2018
STORAGE: 20°C to 25°C (68°F to 77°F)
CONTAINER: Five 30 mL clear vials w / powder, Thirty 30 mL amber vials w / powder

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility	Sterile / Not Sterile	Sterile	USP <71>	03 / 16 / 2018
Fungal	Sterile / Not Sterile	Sterile	MBI-114	03 / 16 / 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

Kerri Hirst

Kerri Hirst - Microbiologist II

03 / 30 / 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.