

Microbiology Report

CLIENT: BET Pharmacy-KY
Web Report

ARL #: 449613-01

LOT #: 29318@2

DESCRIPTION: Ticarcillin/clavulanate

DATE RECEIVED: 02/06/2018

STORAGE: 20°C to 25°C (68°F to 77°F)

CONTAINER: 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 4 Days	MBI-144	02/15/2018
Endotoxin	19.23 EU/mg	<0.10 EU/mg	USP <85>	02/16/2018
Fungal	Sterile / Not Sterile	No Growth at 4 Days	MBI-114	02/15/2018

Formulation ID: 434107

MBI-144 is listed as the sterility test method due to sampling not being performed per USP <71> guidelines and/or method suitability cannot be traced to your specific formulation.



02/19/2018

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.



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Formulation ID: 434107

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03/01/2018

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.