

Customer:	BET Pharm(Lexington, KY 40511)	Storage:	Room Temperature
Received:	03/15/2018	Device/Amount:	vial(s) 6 x 30 ml
Compound:	ESTRADIOL 17 BETA IN BIORELEASE 50MG/ML INJECTABLE	Sample Number:	W-1-79
Lot Code:	29413@6	DEA:	No

RESULTS

Test	Active	Test Spec	Test Result	Test Date	Tech Review Date	Comment
Potency/Purity : HPLC ¹	Estradiol	90.0 - 110.0 %	65.8% (32.9 mg/mL)	03/16/2018	03/22/2018	
Endotoxin : USP <85> ²		≤ 116666.67 EU/mL	<1.00 EU/mL	03/16/2018	03/16/2018	
Sterility : USP <71> ³		Negative at 14 days	Negative at 14 days	03/30/2018	03/30/2018	

Compounded By: DePasquale, Seth
Date Compounded: 3/8/2018

1. Method has been validated to meet USP<1225> criteria of accuracy, recovery, linearity, range, robustness, precision, ruggedness, and stability indicating for non-customer specific formulations.
2. USP <85> Turbidimetric or Photometric Technique.
3. USP <71> Sterility Test. Includes tests for Aerobic and Anaerobic Bacteria, and Fungi (Mold and Yeasts).

Limited Warranty

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Final QA By:



Christine Geiger

Date: 04/03/2018