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MICROBIOLOGY CERTIFICATE OF ANALYSIS (COA)

COA RELEASE DATE:	04/02/2018
CLIENT:	BET Pharm
SAMPLE #:	3/28/201829452@2BET30998
DESCRIPTION:	Altrenogest 150 mg/mL
LOT #:	29452@2
METHOD SUITABILITY ON FILE:	Yes

SAMPLE QUANTITY	BATCH SIZE	Batch & Sample Size Compliance
11	540	USP 71 COMPLIANT

TEST	METHOD	LIMITS	RESULTS
Sterility	Bioluminescence	Growth / No Growth	No Evidence of Growth
Endotoxin	USP <85>	35 EU/ml	<20 EU/mL

QA BY:	<i>Wayne DeHaven</i> Wayne DeHaven, Ph.D. Director, Quality Assurance 4/2/2018 1:49:18 PM	RELEASED BY:	<i>Ruben C. Aponte</i> Ruben Aponte Laboratory Manager 4/2/2018 1:50:50 PM
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Samples accepted by Pharmetric Laboratory, LLC, are assumed to be prepared by the customer within the guidelines of USP <71> regarding sample size and number of units sampled. Pharmetric Laboratory, LLC conducts sterility testing using bioluminescence technology. Per USP <797> "A method not described in the USP may be used if verification results demonstrate that the alternative method is at least effective and reliable as the USP membrane filtration method as described in USP<71>." Sterility Testing performed by Pharmetric Laboratory using bioluminescence technology was validated as equal to compendial test by direct comparison. Validation documents are on file at Pharmetric Laboratory.