

**CERTIFICATE
OF
ANALYSIS**

**BET PHARM
5/30/2017**

Description:	Altrenogest microparticle 500 mg IM injection	Lot Number:	28851@4
Sample Qty	20	Sample Number:	5/24/201728851@4 BET2290 0
Batch Size	1375	Test Ordered:	Sterility-Bioluminescence + Endotoxin

Results

<u>Test</u>	<u>Result</u>	<u>Sterility Comments</u>
Sterility	No Evidence of Growth	USP 71 COMPLIANT Based on batch & Sample size <u>Comments</u> Method Suitability on File: NO
Endotoxin	Quantitative Test Sample Value: < 20 EU/mL Endotoxin Limit: 45 EU/mL ADEQUATE	

This Certificate of Analysis is printable for your records.

Released By:

Heather R. Ealey

Pharmetric Laboratory, LLC testing services are performed only for the use that they are intended. It is the licensed practitioners' responsibility to apply professional judgment and experience with regard to the release of product for dispensing purposes. Pharmetric Laboratory, LLC, assumes no responsibility for the sampling, pooling, and transfer of samples that are out of its control. 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.

Pharmetric Laboratory Endotoxin testing is carried out using chromogenic technique based on the development of color after cleavage of synthetic peptide-chromogen complex. Testing is carried out following USP < 85 > Bacterial Endotoxins Test. Endotoxin Limits (EL) are calculated using the formula provided in USP < 85 > (EL=K/M). Adequacy of endotoxin result is determined by comparing the result to the EL. ELs determined by Pharmetric Laboratory are based on information provided. It is the responsibility of the Client to determine the ultimate adequacy of the endotoxin results.

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