CERTIFICATE OF ANALYSIS

BET PHARM 5/30/2017

Description:	Meloxicam 750 mg/mL Injection	Lot Number:	28863@11
		Sample Number:	5/24/201728863@11 BET22902
Sample Qty	5		
Batch Size	50	Test Ordered:	Sterility-Bioluminescence + Endotoxin

Results

Test	Result
Sterility	**No Evidence of Growth**
Endotoxin	**Quantitative Test**
Sample Value:	< 20 EU/mL
Endotoxin Limit:	250 EU/mL ADEQUATE

Sterility Comments

USP 71 COMPLIANT

Based on batch & Sample size

Comments

Method Suitability on File: NO

This Certificate of Analysis is printable for your records.

Released By: Heather R Early

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.

PASS

PHARMETRIC LABORATORY