CERTIFICATE OF ANALYSIS

BET PHARM
5/30/2017

Description:	Thyroxine microparticle 50 mg IM injection	Lot Number:	28857@8
		Sample Number:	5/24/201728857@8 BET22901
Sample Qty	10		
Batch Size	100	Test Ordered:	Sterility-Bioluminescence + Endotoxin

Results

Test	Result	Sterility Comments
Sterility	**No Evidence of Growth**	**USP 71 COMPLIANT**
Endotoxin	**Quantitative Test**	**Based on batch & Sample size**
Sample Value:	< 20 EU/mL	Comments
Endotoxin Limit:	250 EU/mL ADEQUATE	**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.

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