

SCIENTECH LABORATORIES, INC.

107-G Corporate Blvd., Middlesex Business Center
South Plainfield, NJ 07080

FDA Reg No. 22-43843
DEA # R50384317
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CERTIFICATE OF ANALYSIS

SAMPLE SUBMITTED BY

ADVANCED PHARMACEUTICAL
TECHNICAL CO.
132 SOUTH CENTRAL AVENUE
ELMSFORD, NY 10523

LAB CONTROL NO: 97909

SAMPLE: TESTO 100

LOT_NO: P-14-3

SUBMISSION DATE: 8/5/2015

CODE_1: 10 AMPOULES

CODE:NO: PELLETT

COMPLETION DATE: 8/6/2015

CODE_2: 100mg TESTOSTERONE USP/
103mg PELLETT

PO:NO: 8315

REPORT DATE: 8/6/2015

CODE_3:

TEST	CLAIM	ACTUAL	METHOD
TESTOSTERONE	100 mg TESTOSTERONE USP/103 mg PELLETT	100.1 mg/PELLET	1770C

Meena Gunna

Meena Gunna
Deputy Laboratory Director



CONFIDENTIAL
REPORT

PEOPLE > SCIENCE > SOLUTIONS

Test Facility
6750 Wales Road
Northwood, OH 43619
419.666.9455

STUDY TITLE

Test of Sterility

TEST ARTICLE NAME

Geobacillus stearothermophilus

TEST ARTICLE IDENTIFICATION

P-14-3A

SPONSOR

Marco Persichillo
Advanced Pharmaceutical Technology
132 South Central Avenue
Elmsford, NY 10523

TEST ARTICLE PHYSICAL DESCRIPTION

See test specification.

TEST ARTICLE RECEIVED

August 4, 2015

SUMMARY

This qualitative test was performed according to a NAMSA specification to determine if the biological indicators were sterile.

RESULTS

Bioindicator: *Geobacillus stearothermophilus* BI Lot Number: 259

Article Tested	Number of Articles Tested	Type of Medium	Incubation Temperature (Degrees C)	Number of Hours Minutes Incubated	Number of Positive Articles
Self Contained Biological Indicator	6	mSCDB – 1 mL	55-60	48 hours	0
Self Contained Biological Indicator Positive Control	1	mSCDB – 1 mL	55-60	20 hours 48 minutes	1

mSCDB = modified Soybean Casein Digest Broth

Test Start Date: August 4, 2015 (3:12 pm)

Test Termination Date: August 6, 2015 (3:12 pm)

Positive Control Start Date: August 4, 2015 (3:12 pm)

Positive Control Termination Date: August 5, 2015 (12:00 pm)

METHOD

See the attached sterility test specification T0000742-03.

APPROVAL

Lisa A. Schwalenberg
Lisa A. Schwalenberg, BS
Laboratory Supervisor, Sterility Assurance

8-6-15
Date

Results apply only to the test article tested. Any extrapolation of these data to other articles is the sponsor's responsibility. This test was performed under an ISO 13485:2003 certified Quality System, with the test method accredited to the ISO 17025:2005 Standard.