

SCIENTECH LABORATORIES, INC.

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

FDA Reg No. 22-43943
DEA # RS0384317
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CERTIFICATE OF ANALYSIS

SAMPLE SUBMITTED BY

ADVANCED PHARMACEUTICAL
132 SOUTH CENTRAL AVENUE
ELMSFORD, NY 10523

LAB CONTROL NO: 96340

SAMPLE: ESTRADIOL USP

LOT_NO: P-14-1

SUBMISSION DATE: 12/16/2014

CODE_1: 10 GLASS AMPOULES

CODE:NO: PELLETT IN AMPOULE

COMPLETION DATE: 12/23/2014

CODE_2: ESTRA-25 PELLETS

PO:NO: 121214

REPORT DATE: 12/23/2014

CODE_3: EACH 26 mgCONTAINS
25 mg ESTRADIOL USP

TEST	CLAIM	ACTUAL	METHOD
ESTRADIOL	25 mg/26 mg pellet	25.6 mg/ 26 mg PELLETT	USP-37



M.R. Bhambhani, Ph.D
Laboratory Director

STUDY TITLE

Test of Sterility

TEST ARTICLE NAME

Geobacillus Stearothermophilus

SPONSOR

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

TEST ARTICLE IDENTIFICATION

Estra-25 Lot ID: P-14-1A

TEST ARTICLE PHYSICAL DESCRIPTION

See test specification.

TEST ARTICLE RECEIVED

December 16, 2014

SUMMARY

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

RESULTS

Bioindicator: *Geobacillus stearothermophilus* @ 10⁶

BI Lot Number: MA-248

Article Tested	Number of Articles Tested	Type of Medium	Incubation Temperature (Degrees C)	Number of Hours Incubated	Number of Positive Articles
Self Contained Biological Indicator	6	mSCDB - 1 mL	55-60	48 hours	0
Self Contained Biological Indicator Postive Control	1	mSCDB- 1 mL	55-60	18 hours, 50 minutes	1

mSCDB = modified Soybean Casein Digest Broth

Test Start Date: December 17, 2014

Test Termination Date: December 19, 2014

METHOD

See the attached sterility test specification T0000742-03.

APPROVAL

Lisa A. Schwalenberg

12.22.14

Lisa A. Schwalenberg, BS
Laboratory Supervisor, Sterility Assurance

Date

Results apply only to the test article tested. Any extrapolation of these data to other articles is the sponsor's responsibility. All procedures were conducted in conformance with good manufacturing practices, certified to ISO 13485:2003 and accredited to ISO 17025:2005.