DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6th & Kipling St. (P.O. Box 25087) Denver, CO 80225-0087 (303)236-3000 Fax:(303)236-3100	7/9/2018-7/13/2018
	FEI NUMBER 3014453293

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Andrew D. West, Director of Quality

FIRM NAME	STREET ADDRESS
PolarityTE, Inc	1960 S 4250 W
CITY, STATE, ZIP CODE, COUNTRY Salt Lake City, UT 84104-4836	TYPE ESTABLISHMENT INSPECTED Biological Drug Establishment

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically, your firm has not performed and documented quantitative data that validates your process for SkinTE product to show consistent aseptic processing, aseptic tissue washing, and other relevant characteristics such tissue size, cell counts, or relevant skin cell type identification.

Your Director of Quality has stated the process "is more of an art than a science". Your firm has processed at least (b) (4) batches of product under batch instructions provided in the template "(b) (4) (b) (4)" since April 2018.

OBSERVATION 2

Buildings used in the manufacture, processing, packing, or holding of a drug product do not have the suitable construction to facilitate cleaning, maintenance, and proper operations.

Specifically, clean room (b) (4) is not adequately designed and built to maintain air quality and positive pressure in ISO 7 areas relative to surrounding areas of lower or no classification.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Travis S Bradley, Investigator Scott T Ballard, Investigator Kelly D Moore, Investigator	X Travis S Bradley Investigator Signed By: Travis S. Bradley -S Date Signed: 07-13-2018 15:53:34	7/13/2018

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On 10 July 2018, I observed processing of SkinTE product batch #(b) (4) " inside of a (b) (4) style hood inside the processing room classified as ISO 7. The processing room was in use without positive pressure as indicated by magnehelic gauge showing 0.0 inches of water.

On 12 July 2018, I observed the construction of the (b) (4) above the plenum space that serves the fan-filter units to the processing room. The air handlers controlling air temperature and humidity in the plenum are designed only for recirculation without fresh air intake to maintain pre-filtered air to the plenum as shown in the duct drawing dated 13 March 2018. This means positive flow of air is maintained by pulling air through construction gaps in the plenum.

OBSERVATION 3

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, your firm does not adequately monitor the ISO 7 environment used as a processing room that houses (b) (4) hoods for handling SkinTE product. On 12 July 2018, your Director of Manufacturing Operations stated that there is no growth promotion or positive controls executed for microbial growth plates used in environmental monitoring.

Also, your firm is not collecting air and surface samples within the ISO 7 processing room on a routine basis and there is no written procedure for routine monitoring of the processing room since the samples tested on 20 April 2018 documented in "(b) (4) Validation Plan".

OBSERVATION 4

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There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, the expiry of (b) (4) assigned to SkinTE products is not supported by adequately documented data. Your Director of Translational Medicine stated there is no data showing bio-burden at end of shelf life.

Additionally, data (without document identification or date) related to the viability of cells in SkinTE does not include the following documentation to establish as pertinent to commercial product:

- Specific preparation data pertaining to incoming human tissue
- Processing data such as batch record
- Final package presentation or specifications
- Specific dates of processing and storage
- Identity of analytical equipment
- Sample preparation such as reagents, stains, or storage
- Prospective protocol and acceptance criteria

OBSERVATION 5
The quality control unit lacks authority to fully investigate errors that have occurred.

Specifically, your firm does not have a written procedure to define or document an acceptable quantity, identity, or trend of bioburden within the SkinTE product, above/outside of which a deviation or investigation would be initiated.

Between 7 May and 22 June 2018, eight micro-organisms have been identified through SkinTE product cultures and (b) (4) .

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OBSERVATION 6

Established laboratory control mechanisms are not followed and documented at the time of performance.

Specifically, continuous or consistent temperature monitoring of microbial incubation samples for SkinTE product samples is not performed or documented. Between April 25th and July 9th, 2018, (b) (4) (b) (4) temperature readings were (b) (4) over the course of 75 days.

Additionally, your Director of Manufacturing Operations stated that differential pressures for the processing room where SkinTE product is handled inside (b) (4), is not documented and there is no written procedure for such record. (b) (4) batches have been produced since 25 April 2018.

OBSERVATION 7

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room to produce aseptic conditions.

Specifically, cleaning is not performed for (b) (4) processing SkinTE inside the ISO 7 room. SOP #(b) (4) "Manufacturing Facility Cleaning" states cleaning of the ISO 7 room floors should be performed "as needed" (p4, section 2d). Ceilings and floors are indicated to be cleaned "(b) (4)" (p4 section 2e).

The manufacturing cleaning log for (b) (4) processing room shows (b) (4) individual cleanings between 4 April and 9 July 2018 using (b) (4).

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OBSERVATION 8

Separate or defined areas to prevent contamination or mix-ups are deficient regarding the manufacturing and processing operations.

Specifically, on 11 July 2018, I observed an un-locked double door leading to the ISO 7 processing room in (b) (4) where SkinTE product is processed. This facility design allows for personnel to enter the ISO 7 environment directly from uncontrolled warehouse environment without standard "intake 1" controls or gowning controls.

X Kelly D Moore
Investigator
Signed By: 1300050990
Date Signed: 07-13-2018 15:54:12

X Scott T Ballard
Investigator
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