

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615) 366-7801 Fax: (615) 366-7802 Industry Information: <a href="http://www.fda.gov/oc/industry">www.fda.gov/oc/industry</a>	<small>DATE(S) OF INSPECTION</small> 06/23/2014 - 06/27/2014
	<small>FEI NUMBER</small> 3010813678

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
**TO: Enrique DuBois, President**

<small>FIRM NAME</small> Transdermal Therapeutics Inc.	<small>STREET ADDRESS</small> 211 Summit Parkway Suite 124
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Birmingham, AL 35209	<small>TYPE ESTABLISHMENT INSPECTED</small> Drug Product Producer

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 I OBSERVED:**

**OBSERVATION 1**

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release.

Specifically, you do not test each lot/batch of drug product for potency for each active ingredient prior to release for distribution.

**OBSERVATION 2**

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, you have not validated your manufacturing process to demonstrate each batch of drug product meets the identity, strength, quality and purity it purports to be.

**OBSERVATION 3**

Reports of analysis from component suppliers are accepted in lieu of testing each component for conformity with all appropriate written specifications, without performing at least one specific identity test on each component and establishing the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.

Specifically, you do not conduct any additional testing of raw materials used to produce drug products.

In addition, you have not verified the Certificate of Analysis you receive with the raw material used to produce drug products.

<b>SEE REVERSE OF THIS PAGE</b>	<small>EMPLOYEE(S) SIGNATURE</small> Claire M Minden, Investigator <i>Claire M Minden</i>	<small>DATE ISSUED</small> 06/27/2014
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**OBSERVATION 4**

Written procedures describing the handling of complaints do not include provisions for review by the quality control unit of any complaint involving the possible failure of a drug product to meet any of its specifications, a determination as to the need for an investigation of any unexplained discrepancy, and explaining the reasons for the failure of the batch or any of its components to meet specifications.

Specifically, you do not fully investigate complaints to determine if the complaint extended to other batches of the same drug product and other drug products that may have been associated with the use of the same components.

In addition, complaint procedures are deficient in that they do not include provisions that allow for the review to determine if the complaints represent serious and unexpected adverse drug experiences which are required to be reported to FDA.

**OBSERVATION 5**

Written procedures are not established for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically, you have not performed cleaning validation of the (b) (4) to determine no residue remains from previous batches after cleaning.

**OBSERVATION 6**

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

Specifically, you have no scientific data to support the beyond use date you assign for drug products. In addition, you have not conducted any stability testing on any drug product you produce to determine an appropriate beyond use date.

In addition, you have not conducted any shelf life studies to determine drug products produced up to a month in advance have the same potency as produced on the initial date.

**OBSERVATION 7**

Reserve drug product samples are not retained and stored under conditions consistent with product labeling.

Specifically, you do not maintain reserve samples of drug products.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Claire M Minden, Investigator	DATE ISSUED 06/27/2014
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Birmingham, AL 35209	Drug Product Producer	

**OBSERVATION 8**

The calibration of recording devices is not done at suitable intervals in accordance with an established written program.

Specifically, you have not certified the calibration weights used (b) (4) to calibrate your scales that are used to weigh out the components for drug products.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Claire M Minden, Investigator <i>Claire M Minden</i>	06/27/2014

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."