DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax:(313) 393-8139 Industry Information: www.fda.gov/oc/industry	01/07/2013 - 01/11/2013
	FEI NUMBER 1833173

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Rajesh Kapoor, Ph.D, Vice President Quality

FIRM NAME	STREET ADDRESS
Caraco Pharmaceutical Laboratories, Ltd.	1150 Elijah McCoy Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Detroit, MI 48202-3344	Manufacturer

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

Drug products are not stored under appropriate conditions of temperature and humidity so that their identity, strength, quality, and purity are not affected.

Specifically,

1. Temperature mapping of material storage rooms located in the production areas has not been performed. During a walk-through of your facility the following rooms were observed to be used for storage of both raw material and drug product:

a. (b) (4) Used for storage of Lactose Monohydrate AR No. 288RM91444.

b. (b) (4) Used for storage of Minocycline HCl 100mg filled capsules, Lot No. CA120068.

c. In-Process Storage Room (b) (4) Used for storage of Carvedilol Tablets, USP 12.5mg, Lot No. CA120080.

d. (b) (4) Used for storage of Colloidal Silicon Dioxide NF AR No. 288RIC0026.

e. (b) (4) Used for storage of Minocycline HCl (Final Blend) Lot No. CA120081

OBSERVATION 2

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically,

1. Your firm's long term CAPA two month minimum interim reporting requirement specified in Step 9.4.15 of procedure

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Robert M. Barbosa, Investigator Rebecca E. Dombrowski, Investigator Andrew J. Idzior, Investigator	01/11/2013

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SGP016 *Corrective Action and Preventative Action Program* was not consistently met as follows:

a. The first interim report issued for CAPA 12-011, initiated on 6/29/12, was not approved until 9/10/12.

b. The first interim report issued for CAPA 12-007, initiated on 6/13/12, was not approved until 9/10/12.

c. The first interim report issued for CAPA 12-009, initiated on 6/21/12, was not approved until 9/10/12.

d. The first interim report issued for CAPA 12-001 and approved on 2/28/12 did not receive an approved follow-up interim report until 5/15/12.

e. The first interim report issued for CAPA 12-013 and approved on 9/13/12 did not receive a follow-up interim report until its formal approved closure report on 1/9/13.

2. Written procedures detailed under Cleaning Validation Plan CVP-007-05, dated 8/27/2012, were not followed in that a formal assessment of a product not already included in the current cleaning matrix, had not been finalized until after the product was processed on common equipment. Specifically, the R&D manufacture of Ticlopidine Hydrochloride Tablets, USP, 250mg, lot RD-006-004 included coating in the (b) (4) [redacted] on 01/04/2013 before the documented assessment of this product into the cleaning validation matrix had occurred as specified under section 7.2.8 of the Cleaning Validation Plan. This same coating equipment is used in the production of Carvedilol Tablets, 3.125mg.

3. Mapping of (b) (4) [redacted] e outgoing storage space for finished product awaiting shipment, has not yet occurred over the "winter" months, as specified in the (b) (4) [redacted] Room Qualification Protocol, QP-11-075-00, signed 6/2011. Temperature requirements for room (b) (4) [redacted] re specified as "15° C to 30° C". Carvedilol Tablets, USP, 25mg, 100 ct, lot CA120077A was observed in this room on 01/07/2013, with tentative outgoing shipment scheduled for 1/08/2013. Labeled storage requirements for Carvedilol Tablets, USP, 25mg, are "USP Controlled Room Temperature".

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