

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

<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 300 River Place, Suite 5900 Detroit, MI 48207 (313) 393-8100 Fax: (313) 393-8139 Industry Information: www.fda.gov/oc/industry	<small>DATE(S) OF INSPECTION</small> 05/21/2013 - 05/30/2013*
	<small>FEI NUMBER</small> 1833173

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Rajesh (NMI) Kapoor, Ph.D., Vice President, Quality

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

Container closure systems do not provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product.

Specifically,

Labels for Carvedilol Tablets, USP contain the following statements, "Pharmacist Information: Dispense in a tight, light-resistant container as described in the USP" and "Protect from moisture". The following lots of Carvedilol Tablets, USP were packaged and distributed in a container closure system which did not meet the USP specification for a tight container closure, and data was not provided to support that such was adequate to protect the drug product from external factors including moisture:

- Carvedilol Tablets, USP, 3.125 mg - batch #CA120004A
- Carvedilol Tablets, USP, 3.125 mg - batch #CA120006A
- Carvedilol Tablets, USP, 6.25 mg - batch #CA120032A
- Carvedilol Tablets, USP, 12.5 mg - batch #CA120027A

*** DATES OF INSPECTION:**

05/21/2013(Tue), 05/22/2013(Wed), 05/23/2013(Thu), 05/24/2013(Fri), 05/28/2013(Tue), 05/30/2013(Thu)

SEE REVERSE OF THIS PAGE	<small>EMPLOYEE(S) SIGNATURE</small> Emily J Orban, Investigator Andrew J. Idzior, Investigator Sarah M. Napier, Investigator Aurora-Miha Trifanov, Investigator	<small>DATE ISSUED</small> 05/30/2013
		