DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781) 596-7700 Fax:(781) 596-7896 Industry Information: www.fda.gov/oc/industry	03/21/2012 FEI NUMBER 3006571100

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Dr. Charles R. Eck, Ph.D., President

FIRM NAME	STREET ADDRESS
Exemplar Pharmaceuticals LLC	927 Currant Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fall River, MA 02720-4712	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

The in process control procedures were deficient in that they did not include an examination of the adequacy of mixing to assure uniformity and homogeneity.

Your firm lacks in process controls on your pressurized filling system to assure content unformity from beginning to end of filling operations. Specifically, you do not prevent propellant loss due to evaporation and concomittant increase in drug substance concentration.

For example, the following total content results for two canisters sampled at beginning and end of batch were observed for (b) (4)

(Results above are expressed as % Drug Target based on theoretical concentratio(b) (4)

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.

A.) Specifically, your firm does not have a mechanism to assure that total content specifications are met when product flow and/or pressure is disturbed. For example, lo(b) (4)) had a catastophic failure perturbing product flow resulting in canisters meeting fill weight specification with total content below specification.

B.) Furthermore, Lo(b) (4) was run on Filling Station 2 only after Filling Station 1 failed, and you did not evaluate whether filling can be performed on one station only, without adverse product impact.

C.) Your firm does not have data to demonstrate that product at the end of fill is still within specification throughout the end of its stability lifecycle. For Lo(b) (4) , your firm changed the release specifications for total content fro(b) (4) to

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Edmund F. Mrak Jr., Investigator
Maya M. Davis, Investigator

DATE ISSUED
03/21/2012

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781) 596-7700 Fax:(781) 596-7896 Industry Information: www.fda.gov/oc/industry	03/21/2012 FEI NUMBER 3006571100

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Dr. Charles R. Eck, Ph.D., President

FIRM NAME	STREET ADDRESS
Exemplar Pharmaceuticals LLC	927 Currant Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Fall River, MA 02720-4712	Manufacturer

(b) (4) and did not initiate a change control to justify and determine impact of the change for criteria including but not limited to stability data.

Blank space EFM 03/21/2012

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Edmund F. Mrak Jr., Investigator Maya M. Davis, Investigator	03/21/2012