DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave, Bldg 51, Rm 4225 Silver Springs, MD 20993 (301) 796 3334 Fax: (301) 847 8738 Industry Information: www.fda.gov/oc/industry	02/22/2016 - 02/26/2016
	FEI NUMBER 3008565058

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Dhananjay Wyawahare, VP Manufacturing

FIRM NAME	STREET ADDRESS
Glenmark Pharmaceuticals Ltd	Plot No. 2, Pharma Zone SEZ
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Pithampur, Dhar 454775, India	Finished drug product 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 I OBSERVED:

Production and Process Control

OBSERVATION 1

Control procedures fail to include tablet or capsule weight variation and adequacy of (b) (4) to assure uniformity and homogeneity.

Specifically, process validation completed in Oct. 2015 on (b) (4) batches [batch #s (b) (4)] is defficient.

a) Your firm failed to study the (b) (4) as a critical parameter as it was determined by the performance qualification on the (b) (4) (VP/PQ/PD/172) performed and completed in November 2014.
b) Youjr firm failed to study the (b) (4) for the (b) (4) and (b) (4) during the (b) (4) hold time.

Holding and Distribution

OBSERVATION 2

Procedures describing the warehousing of drug products are not established. Electronic records are used, but they do not meet systems validation, operational system check, employee accountability/responsibility policy, and systems documentation control requirements to ensure that they are trustworthy, reliable and generally equivalent to paper records.

Specifically, SAP system used by your firm to control the inventory of finished drug products and raw materials can not identify and locate the physical location of the drug products in the warehouse.

Equipment

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Yasamin Ameri, Investigator	02/26/2016

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OBSERVATION 3

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel. Electronic records are used, but they do not meet systems validation, system access limitation, audit trail, operational system check, employee accountability/responsibility policy, systems documentation control, and open systems control requirements to ensure that they are trustworthy, reliable and generally equivalent to paper records.

Specifically, qualification of the software (Empower 3) used for operation HPLC, UPLC, and GC is difficient. For example, all users can modify default settings and save or delete the settings under the preference.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Yasamin Ameri, Investigator 	02/26/2016