DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
United States Food and Drug Administration/ CDER- Office of Compliance HFD-325 10903 New Hampshire, W051, Room 4225 Silver Spring, MD 20993 Attn: Foreign Inspection Team Phone: (301) 847-8738 Industry Information: www.fda.gov/oc/industry	July 20, 2015-July 24, 2015
	FEI NUMBER 3008565058

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Rahul Awasthi, Executive Vice President Operations

FIRM NAME	STREET ADDRESS
Glenmark Pharmaceuticals Ltd	Plot No. 2, Phase II, Sector III Pharma Zone, Indore SEZ
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Pithampur, District Dhar 454 775 Madhya Pradesh, India	Solid Oral Dosage Manufacturing Facility

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) (WE) OBSERVED:

1. Buildings used in the manufacturing, processing, and packing of a drug product are not maintained in a good state of repair. Specifically, On July 20, 2015, rain water was observed leaking through the walls and windows and causing some puddles on the floor of the (b) (4) level (b) (4) production area (b) (4) corridor used for solid oral dosage manufacturing. Approximately six (6) different locations were identified with water seepage from the walls and windows on the (b) (4) level inside the production area corridor. In addition, rain water was also observed seeping through the exterior walls and windows of the (b) (4) floor inside the (b) (4) packaging area (b) (4) corridor at four (4) different locations. Furthermore, rain water seepage through the exterior walls was also observed on the (b) (4) level service floor area containing the Heating, Ventilation and Air Conditioning (HVAC) units as well as the (b) (4) floor utility equipment area.

2. Written procedures are not followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product. Specifically, On July 20, 2015, I observed (b) (4) discoloration on the walls of the Vibra HT IEWH002 dispensing area analytical balance scale during a walk-through of the (b) (4) solid oral dosage weighing and dispensing manufacturing area. The analytical balance scale was previously cleaned on July 17, 2015 and was designated as clean. The (b) (4) solid oral dosage manufacturing area is used for the manufacture of (b) (4) Capsules (b) (4) mg, (b) (4) mg and (b) (4) mg as well as (b) (4) Tablets (b) (4) mg and (b) (4) mg.

3. Samples taken of drug products for determination of conformance to written specifications are not properly identified. Specifically, On July 22, 2015, sample reconciliation did not exist in the quality control testing laboratories. For example, routine reconciliation does not exist to identify discrepancies in the amount of quality test samples received, used and remaining for on-test/in-progress as well as completed drug product samples that are analyzed in the quality control laboratory.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Daniel J. Roberts, Investigator	07/24/2015