DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Avenue, Building 51, Room 4234 Silver Springs, MD 20993-0002 Phone: (301) 796-3334, Fax: (301) 847-8738 ORAPHARMInternational483responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	09, 11, 12, 13 March 2020 FEI NUMBER 3004956904

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Vinod Kamath, Head Technical Operations

FIRM NAME	STREET ADDRESS
Alembic Pharmaceutical Limited (Formulation 1)	Panelav, Post – Tajpura, Tal – Halol
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Dist – Panchmahal, Gujarat, 389 350 India	Finished Dosage 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/**WE** OBSERVED:

1. The responsibilities and procedures applicable to the quality control unit are not fully followed. Specifically,
   a) SOP # CQA/F/037, Handling of Product Recall was not followed when handling a mislabeling event. Five "critical" complaints from the U.S. were received in October & November 2019 regarding (b) (4) tablets (b) (4) mg, (b) (4) count, containing (b) (4) count (b) (4) tables (b) (4) mg. The complaints were confirmed and the firm conducted a "withdrawal". Withdrawal is defined as "removal or correction of a distributed product which involves a minor violation…". The procedures related to conducting a recall were not followed which would may have involved press releases and advertising campaigns to reach patients.

   b) Procedures describing the handling of written and oral complaints related to drug products are deficiently written or followed. Specifically,
      i. There is no assurance that acknowledgements are sent to the complainants.
      ii. There is no history of complaints in relation to the batch under complaint investigation.
      iii. There is no source documentation on the examination of samples returned from the complainants.
      iv. The source of photographs are not always maintained.

2. Access to the storage area for labels and labeling materials is not limited to authorized personnel. Specifically, on 09 March 2020, the label storage area was found unlocked and access not limited to authorized personnel only. The lock and key to lock were stored in an unsecure location.

3. Gowning procedures are not applied on a consistent basis:
   a) CSO Jim entered manufacturing area without being required to fully gown. When questioned about the differences in gowning, she was informed that it was not necessary for her to fully gown.
   b) Personnel were observed in manufacturing area (b) (4) (b) (4) with inconsistent gowning. Specifically, not all personnel were observed wearing goggles.
4. Camera equipment that has been implemented to check the (b) (4) ot number printing on the bottom of each bottle is not challenged in the way the camera is used. For example, only one bottle with incorrectly printed lot number is used to challenged the equipment prior to start of packaging operations. Whereas, during routine use, groups of (b) (4) bottles are checked at the same time.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Cynthia Jim Shirshendu Deb	**Cynthia Jim, CSO** **Shirshendu Deb, CSO**	**13 March 2020**