DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900	5/18/2026-5/22/2026
	FEI NUMBER 3011136472

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Sanjay Bhargav, Chief Operating Officer

FIRM NAME	STREET ADDRESS
Apnar Pharma LLP	10 Lake Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
East Windsor, NJ 08520-5321	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:

OBSERVATION 1

The responsibilities and procedures applicable to the quality control unit are not in writing and fully followed.

Specifically,

Your firm has not established, documented, or implemented effective current good manufacturing practice (cGMP) that involves the GMP refresher training and audit trail reviews for laboratory instruments.

For example,

A. Your firm fails to provide cGMP annual refresher training to employees involved in cGMP manufacturing. Additionally, your firm has not established a standard operating procedure (SOP) for employee training which requires ongoing cGMP annual refresher training.

B. Your firm fails to conduct routine, periodic instrument audit trail reviews for analyses of drugs run on your HPLC systems (i.e. instrument ID #'s (b) (4) (b) (4)) which are utilized for the analysis of drug raw materials and finished drug products, for batch release purposes. Furthermore, your firm has not established an SOP which requires that your firm conduct periodic audit trail reviews for raw data generating GMP laboratory instruments.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Ankur C Patel, Investigator X Ankur C Patel Investigator Signed By: 2003087186 Date Signed: 05-22-2026 14:53:43	5/22/2026

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The following are examples of commercial drug products tested with the aforementioned HPLC systems:

1 (b) (4) USP (b) (4) tablets,
2. (b) (4) USP (b) (4) tablets,
3. (b) (4) USP (b) (4) capsules.

OBSERVATION 2

Records are not maintained so that data therein can be reviewed at least annually to evaluate the quality standards of each drug product to determine the need for changes in specifications or manufacturing or control procedures.

Specifically,

Your firm failed to conduct annual product reviews for the following drug products you manufactured in 2024, in a timely manner. All following products' 2024 APRs were completed until 4/2026 (16 months after the end of the review period):

A. (b) (4) USP (b) (4) tablets,
B. (b) (4) USP (b) (4) tablets,
C. (b) (4) USP (b) (4) capsules.

Your SOP # QA098, entitled, "Preparation of Annual Product Review", version # 00, effective date: 03/20/2024, doesn't define specific APR completion due dates after completion of the 12 month review period in order to ensure that APR's are completed in a timely manner.

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."