DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Use this check box to generate the required 483 statement on page 1 for medical device observations. ☐

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA/CDER/OMQ 12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483Response@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	02/25/2025 - 02/28/2025
	FEI NUMBER 3009336980

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Hemant D. Dholakia, Managing Director

FIRM NAME	STREET ADDRESS
Goran Pharma Private Limited	GIDC - 1 Bhavnagar Rajkot Road
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Dist. Sihor, Gujarat, 364240, India	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:

OBSERVATION 1

Suitable reader or photocopying equipment was not made readily available for component records maintained using reduction techniques.

Specifically,

Your current record-keeping process lacks a documented procedure for the electronic capture and retention of visual inspection records. Specifically:

1. Photographs of original retain sample visual inspection sheets are routinely taken before the originals are discarded. This process includes retain sample visual inspection sheets for [redacted] (b) (4) g, Lot [redacted] (b) (4)

2. There is no documented justification or control mechanism to ensure all required information is accurately transferred to the electronic format before disposing of the physical records.

3. A formal procedure has not been established to verify, retain, and protect digital copies against unauthorized modifications or deletions.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	CHAD W. RICE -S Digitally signed by CHAD W. RICE -S Date: 2025.02.28 01:22:51 -06'00'	Chad W. Rice, Investigator	02/28/2025

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA/CDER/OMQ 12420 Parklawn, Room 2032 Rockville, MD 20857 CDER-OC-OMQ-International483Response@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	02/25/2025 - 02/28/2025
	FEI NUMBER 3009336980

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Hemant D. Dholakia, Managing Director

FIRM NAME	STREET ADDRESS
Goran Pharma Private Limited	GIDC - 1 Bhavnagar Rajkot Road
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Dist. Sihor, Gujarat, 364240, India	Manufacturer

OBSERVATION 2

Procedures designed to prevent objectionable microorganisms in drug products not required to be sterile are not established.

Specifically,

You do not conduct (b) (4) testing on your (b) (4) used in (b) (4) of your (b) (4) products shipped to the USA, including (b) (4) g, Lot (b) (4) and (b) (4) g, Lot (b) (4)

OBSERVATION 3

Laboratory Records do not include the initials or signature of the person who performs each test.

Specifically,

1. The "Raw Material Retain Sample", tracking log, dated April 2024 to March 2025, does not document the signature of the individual entering information such as the raw material name, batch number, analytical record number manufacturing date, expiration date and storage location.

2. The "(b) (4) Incubator Usage Log Book (Micro Lab)", dated 02/21 - 02/24, does not document the signature and date of the individual entering information such as product name and batch number, media name, and lot number, incubation start date and time, incubation period, and incubated medium observation.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	CHAD W. RICE -S Digitally signed by CHAD W. RICE -S Date: 2025.02.28 01:22:26 -06'00'	Chad W. Rice, Investigator	02/28/2025