DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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	02/17/2025 - 02/21/2025
	FEI NUMBER 3010166683

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Asit Patel, President

FIRM NAME	STREET ADDRESS
TrueCare Biomedix	R.S. No. 2115 College Road
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Balisinor, Dist-Mahisagar, Gujarat 388255 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

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

Specifically, written procedures do no include sufficient details to ensure consistent implementation and written procedures are not always followed in that:

i) your procedure for good documentation practices, SOP No: QA-013-01, titled Procedure for Maintaining Good Documentation Practice, Effective January 1, 2024 states, "All documents should have the signature and date of the person who prepared the document, review of the documents and approve the document." However, during a review of your log books the following was found:

a) Logbook for 2023 Stability Sample Location Chart, Register Reference No: QC-042:A11, the date and signature of the employee performing the action is not documented.

b) Logbook for 2025 Entry Log Card for Sample Reconciliation, Register Reference No: QC-042, the date and signature of the employee performing the reconciliation is not documented.

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: 2025.02.21 00:16:12 -06'00'	Chad W Rice, Investigator	02/21/2025

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 judgement, 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."