DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CBER/OCBQ/Division of Manufacturing and Product Quality 10903 New Hampshire Avenue, Silver Spring, MD 20993 Lead Insp.: Carl Perez Telephone: 301-796-9102 Industry Information: www.fda.gov/oc/industry	May 27-30, 2025 FEI NUMBER 3021247180

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dr. Kristi Elliott, Chief Operating Officer

FIRM NAME	STREET ADDRESS
Capricor, Inc.	10865 Road to the Cure, Suite 150
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
San Diego, CA 92121	Drug substance and drug product 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. (b) (4) in the (b) (4) lacks adequate qualification. Specifically, (b) (4) performed in (b) (4) under dynamic conditions do not accurately reflect actual manufacturing conditions. The layout, amount of (b) (4) observed inside (b) (4) (b) (4) during Production (b) (4) formulation operations on (b) (4) were not replicated in the (b) (4) under dynamic conditions.

2. Written procedures are not followed. Specifically:

a. According to CORP-QA-SOP-0166, 'Deviations and CAPA Management SOP', the trending and analysis of deviations should be performed by the quality unit to identify recurrent issues; however, over a 2-year period, there have been 27 deviations related to missing (b) (4) data incidents observed on the (b) (4) (b) (4), which are used for (b) (4) in the (b) (4).

b. According to CORP-QA-SOP-0166, 'Deviations and CAPA Management SOP', nonconforming products (NCPs) must be (b) (4) or (b) (4) unless an extension is issued; however, there are outstanding NCPs without extension requests. Specifically, NCP-582, NCP-580, and NCP-86 were past due, with the oldest outstanding initiated on May 10, 2023, with no record of extension requests. NCP-535, initiated on June 03, 2024, had one extension request that was past due and no additional extension requests.

c. According to CORP-QA-SOP-0166, 'Deviations and CAPA Management SOP', corrective action reports (CARs) must be (b) (4) unless an extension is issued; however, CAR-212, CAR-244, CAR-246 were past due with no record of a requested extension.

d. According to CORP-QA-SOP-0109, 'Good Documentation Practices', individuals creating, correcting, and presenting data generated during GxP must comply with ALCOA+ principles; however, deficiencies in documentation were noted. Specifically, an entry on a (b) (4) was marked through and corrected

SEE REVERSE OF THIS PAGE

/s/

EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
Carl Perez, Consumer Safety Officer Ivey Choi, Consumer Safety Officer Malcolm Moos, Jr., Senior Science Advisor Kyung Sung, Supervisory Biologist	05/30/2025

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without initials, date, or footnote. In addition, two (b) (4) contained a missing entry for (b) (4) (b) (4) for a footnote.

3. Quality agreements are not established between (b) (4) facilities and (b) (4) to delineate the roles, operational activities and responsibilities of each party to ensure compliance with CGMP. Specifically, no quality agreements have been established with multiple (b) (4) including the (b) (4) for (b) (4) for (b) (4) at release, (b) (4) testing, (b) (4) testing, (b) (4), and (b) (4).

4. Procedures applicable to the quality control unit are not in writing. Specifically, procedures for the receiving, evaluating, and documenting complaints related to (b) (4) and for the handling, evaluation, and disposition of returned (b) (4) have not been established.

5. (b) (4) is not maintained in a state of good repair. Specifically, (b) (4) was observed on the (b) (4) inside the ISO (b) (4) Room (b) (4) manufacturing suite (Production (b) (4).

/s/

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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."