

| <b>DEPARTMENT OF HEALTH AND HUMAN SERVICES</b><br><b>FOOD AND DRUG ADMINISTRATION</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                            |                                                                                                          |                                        |
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| <small>DISTRICT ADDRESS AND PHONE NUMBER</small><br>1201 Main Street, Suite 7200<br>Dallas, TX 75202<br>(214) 253-5200 Fax: (214) 253-5314                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                            | <small>DATE(S) OF INSPECTION</small><br>3/2/2026-3/5/2026<br><br><small>FEI NUMBER</small><br>3030456591 |                                        |
| <small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small><br>Byron G. Holm, VP of Manufacturing                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                            |                                                                                                          |                                        |
| <small>FIRM NAME</small><br>SURETEC INNOVATIONS LLC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                            | <small>STREET ADDRESS</small><br>190 S Mcqueen Rd Ste 102                                                |                                        |
| <small>CITY, STATE, ZIP CODE, COUNTRY</small><br>Gilbert, AZ 85233-3418                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                                                                                                            | <small>TYPE ESTABLISHMENT INSPECTED</small><br>Manufacturer                                              |                                        |
| <p>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.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                            |                                                                                                          |                                        |
| <b>DURING AN INSPECTION OF YOUR FIRM I OBSERVED:</b><br>Quality System                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                            |                                                                                                          |                                        |
| <b>OBSERVATION 1</b><br>There is no quality control unit.<br><br>Specifically,<br>Your quality control unit has not been effectively carrying out its duties to ensure that drug products are manufactured in accordance with current good manufacturing practices (cGMP). Since January 2025 your firm has released and distributed about (b) (4) batches of (b) (4), under the following conditions: <ul style="list-style-type: none"> <li>a. The Quality Control Manager performs and approves all laboratory tests without independent review. The testing and batch release approval executed by the same individual, which represents a lack of segregation of duties in the quality control process.</li> <li>b. Your firm has not qualified or validated its manufacturing equipment, including the (b) (4) system, the blending tank for finished product bulk blend, and the storage tank for product storage and transfer to packaging.</li> <li>c. The labels for the product (b) (4) are not reviewed by Quality Control. There is no inventory of drug labels used in production. Drug labels are used and returned without any type of accountability, documentation or record keeping. There is no oversight for potential discrepancies.</li> </ul> |                                                                                                                                                                                                                                                                                                            |                                                                                                          |                                        |
| <b>SEE REVERSE OF THIS PAGE</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <small>EMPLOYEE(S) SIGNATURE</small><br>Jeffrey T Prosterman, Investigator <div style="text-align: right; margin-top: 20px;"> <small>Jeffrey T Prosterman<br/>Investigator<br/>Signed By: JEFFREY T.<br/>PROSTERMAN-S<br/>Date Signed: 03-05-2026<br/>11:40:26</small><br/>             X           </div> |                                                                                                          | <small>DATE ISSUED</small><br>3/5/2026 |

**DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION**

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|-----------------------------------------------------------------------------------------------------------------------------|--------------------------------------------|
| DISTRICT ADDRESS AND PHONE NUMBER<br>1201 Main Street, Suite 7200<br>Dallas, TX 75202<br>(214) 253-5200 Fax: (214) 253-5314 | DATE(S) OF INSPECTION<br>3/2/2026-3/5/2026 |
|                                                                                                                             | FEI NUMBER<br>3030456591                   |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED  
Byron G. Holm, VP of Manufacturing

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| FIRM NAME<br>SURETEC INNOVATIONS LLC                     | STREET ADDRESS<br>190 S Mcqueen Rd Ste 102   |
| CITY, STATE, ZIP CODE, COUNTRY<br>Gilbert, AZ 85233-3418 | TYPE ESTABLISHMENT INSPECTED<br>Manufacturer |

d. Your firm did not have a method validation or method verification for its modified version of USP <61> and USP <62>. Additionally, positive and negative controls are not used during micro analysis of finished product.

e. Your firm does not have a method validation for the potency of (b) (4), the active ingredient of the (b) (4).

f. The instruments and equipment in the laboratory have not been officially calibrated to provide adequate testing of raw materials or finished product of (b) (4).

g. All standard operating procedures (SOPs) utilized in the laboratory are Word documents. These documents have not been approved as an official SOP by Quality Control and not retained in Document Control.

h. Your firm does not have a designated Quarantine area for rejected components, raw materials or finished products.

i. No supplier qualification exists for the active ingredient (b) (4) used in (b) (4).

**Quality System**

**OBSERVATION 2**

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

|                                     |                                                             |                                                                                                                               |                         |
|-------------------------------------|-------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|-------------------------|
| <b>SEE REVERSE<br/>OF THIS PAGE</b> | EMPLOYEE(S) SIGNATURE<br>Jeffrey T Prosterman, Investigator | Jeffrey T Prosterman<br>Investigator<br>Signed By: JEFFREY T.<br>PROSTERMAN-S<br>Date Signed: 03-05-2026<br>11:40:26<br><br>X | DATE ISSUED<br>3/5/2026 |
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| DEPARTMENT OF HEALTH AND HUMAN SERVICES<br>FOOD AND DRUG ADMINISTRATION                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  |                                                                            |                                        |
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| <small>CITY, STATE, ZIP CODE, COUNTRY</small><br>Gilbert, AZ 85233-3418                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                        | <small>TYPE ESTABLISHMENT INSPECTED</small><br>Manufacturer                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |  |                                                                            |                                        |
| <p>Specifically,</p> <p>The quality unit did not fulfill its oversight responsibilities, as evidenced by the identification of multiple cGMP deficiencies across various operational areas during the inspection</p> <p>Examples of this include, but may not be limited to:</p> <ul style="list-style-type: none"> <li>a. Finished product ((b) (4)), lot# ((b) (4)) was shipped on 09/03/2025, prior to completion of laboratory testing and Quality review and approval of test results and batch record, which occurred on 09/10/2025. This violation indicates a fundamental failure in the quality system's ability to prevent release of an untested product, which is a serious GMP deficiencies.</li> <li>b. Your firm does not have a Stability study for your product, ((b) (4)) to justify giving it a ((b) (4)) expiration from the date of manufacture.</li> <li>c. ((b) (4)) is over ((b) (4)) of the ((b) (4)) product, ((b) (4)). Since February 2024, there have been twelve out of specification results for total plate count for ((b) (4)) samples taken from the ((b) (4)) system. None of the results were investigated to determine whether the ((b) (4)) was adequate to be used in a finished product.</li> </ul> |                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  |                                                                            |                                        |
| Laboratory System                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  |                                                                            |                                        |
| <p><b>OBSERVATION 3</b></p> <p>Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity.</p> <p>Specifically,</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  |                                                                            |                                        |
| <b>SEE REVERSE OF THIS PAGE</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                        | <table border="0" style="width: 100%;"> <tr> <td style="width: 60%; vertical-align: top;"> <small>EMPLOYEE(S) SIGNATURE</small><br/>           Jeffrey T Prosterman, Investigator         </td> <td style="width: 40%; vertical-align: top; text-align: center;"> <small>DATE ISSUED</small><br/>           3/5/2026         </td> </tr> </table> <div style="text-align: center; margin-top: 10px;"> <small>Jeffrey T Prosterman<br/>Investigator<br/>Signed By: JEFFREY T.<br/>PROSTERMAN-S<br/>Date Signed: 03-05-2026<br/>11:40:26</small><br/>           X         </div> |  | <small>EMPLOYEE(S) SIGNATURE</small><br>Jeffrey T Prosterman, Investigator | <small>DATE ISSUED</small><br>3/5/2026 |
| <small>EMPLOYEE(S) SIGNATURE</small><br>Jeffrey T Prosterman, Investigator                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <small>DATE ISSUED</small><br>3/5/2026 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  |                                                                            |                                        |

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Your firm does not have validated methods for Microbiology and potency testing. All procedures are contained in Word documents that can be edited. The standard operating procedures and the test methods were not officially approved by your Quality department.

Quality System

**OBSERVATION 4**

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release.

Specifically,

- a. Potency is not performed on the finished product (b) (4). Potency is performed on the bulk blend before it is transferred into the (b) (4), packaged and distributed.
- b. Raw materials used in the manufacture of finished product are not tested for identification, and the active ingredient, (b) (4), is not tested for potency.

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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 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."