

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 250 Marquette Ave, Ste. 600 Minneapolis, MN 55401 (612) 334-4100 Fax: (612) 334-4134		<small>DATE(S) OF INSPECTION</small> 7/21/2025-7/30/2025* <small>FEI NUMBER</small> 3002919848	
<small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> Amy R. Pralat, Senior Director, API Manufacturing			
<small>FIRM NAME</small> GenTrac, Inc.		<small>STREET ADDRESS</small> 2232 Pleasant View Rd	
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Middleton, WI 53562-5523		<small>TYPE ESTABLISHMENT INSPECTED</small> Drug Substance 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>			
<p>DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:</p> <p>Observation 1</p> <p>(b) (4) identified on equipment product contact surfaces is not characterized nor its potential impact to drug substance quality assessed. Specifically,</p> <p>Procedure SOP-105027 (“SOPQ: Visual Inspection of Process Equipment for Cleanliness”, Version 2.0, Effective on 02/14/2019, and Version 3.0, Effective on 02/01/2024) lists (b) (4) types of (b) (4) as Type (b) (4), and instructs for a work order initiation upon identification of surface quality and integrity issues, if a work order does not exist. In addition, the procedure the procedure states that “(b) (4) (b) (4) and to (b) (4)”. However, (b) (4) identified during (b) (4) cleaning audits performed for Prothrombin Area Equipment, and during (b) (4) cleaning audits performed on Bulk Thrombin Area Equipment, was not characterized to determine the type of (b) (4), nor was a risk/impact assessment for the identified (b) (4) performed. The (b) (4) for (b) (4) inspected as part to the (b) (4) visual inspection of process equipment on (b) (4) do not provide information about the type of (b) (4) identified nor about the size of (b) (4) or surface area covered to compare with (b) (4) from the previous years. (b) (4) inspection in (b) (4) found that (b) (4) exhibited (b) (4), including (b) (4) and (b) (4). (b) (4) inspection in (b) (4) found that (b) (4) exhibited (b) (4), including (b) (4) and (b) (4).</p>			
<p>Observation 2</p> <p>Microbiological recovery studies used to validate the swab testing method used in cleaning validation are inadequate. Specifically,</p>			
SEE REVERSE OF THIS PAGE		<small>EMPLOYEE(S) SIGNATURE</small> Lizaida Perez, Investigator Peng Zhou, Investigator <div style="text-align: right;"> <small>Lizaida Perez Investigator Signed By: 2004213019 Date Signed: 07-30-2025 14:58:46</small> X </div>	
		<small>DATE ISSUED</small> 7/30/2025	

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Amy R. Pralat, Senior Director, API Manufacturing

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The swab method validation for bioburden testing of equipment surfaces (b) (4) (b) (4) was conducted using an inadequate microbial challenge panel consisting of only (b) (4) microorganisms (b) (4). This limited panel is not representative of the microorganisms recovered from the manufacturing process (from in-process and bulk bioburden samples) or from (b) (4) used to clean equipment. For example, the validations failed to include Gram (b) (4) bacteria, such as (b) (4) which has been recovered from the (b) (4) used in the process (b) (4) (b) (4), process bioburden samples, and equipment surfaces.

Observation 3

Training and qualification related to laboratory operations are not adequately documented or implemented and associated corrective actions are not demonstrated to be effective. Specifically,

A. Your firm lacks formal written instructions and training provided to analysts on proper pipette usage. Specifically, an analyst (b) (6), (b) (7)(C) was observed on 07/23/2025 using improper pipetting technique (bubbles were observed in the pipette tip) during sample preparation for bioburden testing of batch (b) (4) of the PROTHROMBIN intermediate. On that same date, another analyst (b) (6), (b) (7)(C) was observed using improper pipetting technique (bubbles were observed in the pipette tips) during sample preparation for potency testing of batch (b) (4) of the PROTHROMBIN intermediate using the " (b) (4) " pipette with the (b) (4). This (b) (6), (b) (7)(C) had previously been the subject of CAPA-162998 initiated on 04/27/2025 as a result of deviation QE-173372 initiated due to an Out of Limit result for the potency test caused by inconsistent pipetting volumes. The CAPA required a senior analyst to observe (b) (6), (b) (7) use of the pipette (b) (4) and provide retraining if needed. The CAPA also restricted (b) (6), (b) (7) from the pipette (b) (4) for volumes of 1 mL or less with the (b) (4) until this evaluation was completed. There is no documentation demonstrating that (b) (6), (b) (7) has been observed, retrained, and reassessed by the senior

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<p>analyst.</p> <p>B. Your training program for electronic data management is inadequate. Deviation QE-141729 was opened on 10/3/2024 for the permanent loss of electronic data from 03/27/2024 to 09/25/2024 associated with the (b) (4). Per the investigation of this deviation, on 09/25/2024, a Quality Control Manager (QCM) performed (b) (4) electronic file backup transfer of (b) (4) data to (b) (4) for the (b) (4) derived from the vendor and SOP- (b) (4) Version 3. No performance-based training was delivered or documented prior to execution of the task, no direct supervision, coaching, or verification was provided during the execution of this task on 9/25/2024, and no performative-based retraining activities were provided to the QCM during the subsequent task executions.</p>							
<p>Observation 4</p> <p>Procedures regarding segregation of duties are inadequately defined or not always followed in the Quality Unit. Specifically,</p> <p>A. (b) (4) does not adequately define roles and responsibilities for individuals regarding use of accounts for individuals having dual system access privileges for (b) (4) used in potency testing. For example:</p> <p>i. On 5/20/2025, (b) (4)</p> <p>ii. On 5/12/2025, (b) (4)</p>							
SEE REVERSE OF THIS PAGE		<table border="0" style="width: 100%;"> <tr> <td style="width: 60%; vertical-align: top;"> <small>EMPLOYEE(S) SIGNATURE</small> Lizaida Perez, Investigator Peng Zhou, Investigator </td> <td style="width: 40%; vertical-align: top; text-align: center;"> <small>DATE ISSUED</small> 7/30/2025 </td> </tr> <tr> <td style="vertical-align: bottom;"> <div style="border: 1px solid black; padding: 2px; display: inline-block;"> X </div> </td> <td style="vertical-align: bottom; text-align: center;"> <small>Lizaida Perez Investigator Signed By: 2004213019 Date Signed: 07-30-2025 14:58:46</small> </td> </tr> </table>		<small>EMPLOYEE(S) SIGNATURE</small> Lizaida Perez, Investigator Peng Zhou, Investigator	<small>DATE ISSUED</small> 7/30/2025	<div style="border: 1px solid black; padding: 2px; display: inline-block;"> X </div>	<small>Lizaida Perez Investigator Signed By: 2004213019 Date Signed: 07-30-2025 14:58:46</small>
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FIRM NAME

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TYPE ESTABLISHMENT INSPECTED

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(b) (4)

B. Personnel responsibilities of SOP- 43561" Issuance, Review, and Use of Logbooks" are not defined. Multiple entries in Logbook (b) (4) (Appendix (b) (4) Logbook) from 5/13/2025 to 6/2/2025 documented the same individual serving as both author and reviewer of an entry.

***DATES OF INSPECTION**

7/21/2025(Mon), 7/22/2025(Tue), 7/23/2025(Wed), 7/24/2025(Thu), 7/25/2025(Fri), 7/28/2025(Mon), 7/29/2025(Tue), 7/30/2025(Wed)

X Peng Zhou
Investigator
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Date Signed: 07-30-2025 14:59:37

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OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Lizaida Perez, Investigator
Peng Zhou, Investigator

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Lizaida Perez
Investigator
Signed By: 2004213019
Date Signed: 07-30-2025
14:58:46

DATE ISSUED

7/30/2025

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 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."