DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 W. Jackson Blvd., Suite 800 Chicago, IL 60661-4716 (312)353-5863 Fax:(312)596-4187	4/22/2026-5/7/2026* FEI NUMBER 3005402103

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Marzena Savas, President

FIRM NAME	STREET ADDRESS
Topical Pharmaceuticals, Inc.	1470 W Bernard Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Addison, IL 60101-4330	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 WE OBSERVED:

OBSERVATION 1

The quality control unit lacks responsibility to approve and reject all procedures or specifications impacting on the identity, strength, quality and purity of drug products.

Specifically,

1. Key personnel responsible for drug product batch release decisions, including those performing quality functions, are contractors. Your firm has not established quality agreements with these contractors. During the inspection, your firm was unable to provide documentation defining the authority and responsibilities of these individuals for quality oversight functions at this facility.
2. Your firm was unable to provide written procedures for the following:

   - Actions to be taken related to drug product out-of-specification (OOS) results **(Repeat observation, 2022, Observation 1,1 (a))**.
   - Actions to be taken related to (b) (4) out-of-specification results **(Repeat observation, 2022, Observation 1, (b))**.

3. Your firm has failed to establish and follow procedures for the qualification of third-party laboratories used in the testing of drug products manufactured at this facility.

   - Your firm's qualification process for third-party laboratories relies solely on a self-reported checklist completed by the third-party laboratory. Your firm was unable to provide documentation of independent verification of the information on these checklists.

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4. An expired drug ingredient was used in the manufacture of drug products. Your firm was unable to provide scientific justification or retest data supporting the use of this ingredient beyond its expiration date.

   - Your firm used (b) (4), lot number (b) (4), to produce (b) (4) batch (b) (4), which was distributed on (b) (4)
   - (b) (4), lot number (b) (4), expired on (b) (4) per manufacturer's certificate of analysis.

5. Lot (b) (4), (b) (4) for (b) (4). (expiration (b) (4)), was manufactured on (b) (4) and released for distribution on (b) (4) At the time of release, out-of-specification results existed for assay and finished product testing. Additionally, batch records for this lot indicate the product was mixed for approximately (b) (4) while the batch record specifies a mixing time of (b) (4).

OBSERVATION 2

Your firm failed to establish adequate written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically,

1. Your firm's (b) (4) system validation did not include an assessment of baseline (b) (4) Your firm uses this (b) (4) to manufacture drug products intended for the treatment of (b) (4) (b) (4) and (b) (4) **(Repeat observation, 2022 Observation 1, 2 (a)(1)**.

2. Your firm has not validated the sanitation process for the (b) (4) system. There is no

documented evidence demonstrating that the sanitation procedure consistently reduces and controls microbial contamination within the (b) (4) system to acceptable levels.

3. In 2019, your firm performed a process validation for the manufacture of (b) (4). The process validation documentation references new equipment, including (b) (4) drums (IDs: (b) (4) a mixer (model (b) (4)), and a (b) (4) filler. The mixer and (b) (4) filler are not identified by equipment ID in the process validation. Your firm was unable to provide a documented assessment of whether the new equipment was equivalent to the replaced equipment for purposes of the existing process validation. Additionally, the drums designated exclusively for the manufacture of (b) (4) are not the drums identified in the process validation. Your firm has multiple (b) (4) fillers and mixers of the same model number at this facility, and the process validation does not specify which unit was validated.

OBSERVATION 3

Written procedures are not established for evaluations done at least annually and including provisions for a review of complaints, recalls, returned or salvaged drug products and investigations conducted for each drug product.

Specifically,

Firm management was unable to provide annual product reviews for each of the firm's drug products. Management stated that no internal procedure exists requiring laboratory out-of-specification results to be tracked, trended, and reviewed, or requiring deviations and CAPAs to be reviewed on a regular basis.

OBSERVATION 4

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CITY, STATE, ZIP CODE, COUNTRY Addison, IL 60101-4330	TYPE ESTABLISHMENT INSPECTED Manufacturer

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use.

Specifically,

Your firm's (b) (4) system has been operating with an expired (b) (4) for 49 days as of the date of inspection and has not been validated to consistently produce (b) (4) meeting the requirements of the (b) (4) monograph. The firm continued to manufacture topical OTC drug products using (b) (4) generated by your system.

Your quality unit approved the release of (b) (4) batch (b) (4), which used (b) (4) (b) (4) at a time when your (b) (4) system was not fully validated or operational. This batch also presented multiple out-of-specification (OOS) results during finished product testing and OOS assay results for its active ingredient (b) (4) lot number (b) (4) prior to production.

OBSERVATION 5

There is a failure to thoroughly review the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

1. Your firm was unable to provide evidence that your firm initiated, conducted, or completed investigations into out-of-specification (OOS) results to determine root cause, assess product impact, or implement corrective and preventive actions (CAPAs). Batches with uninvestigated OOS results include, but are not limited to:
   - Batch (b) (4) (b) (4) Bulk Product, an email from third party laboratory dated 10/22/2025 found in the batch record indicates (b) (4) was tested twice with a low result: .0708% and .0739%. There was no documented investigation into the earlier OOS results.

- Batch (b) (4) for (b) (4) spray, Certificate of Analysis, reported on March 24, 2026 by third party laboratory showed potency of (b) (4) across (b) (4) samples ranging from .116 w/v% to .183 w/v%. The firm used an (b) (4) of results, including (b) (4) results below the established specification limit of (b) (4) (b) (4) to determine release approval on 04/21/2026. There was no documented investigation into the OOS results or assessment on the impact to product quality.

OBSERVATION 6

Buildings used in the manufacture, processing, packing, or holding of a drug product do not have the suitable construction to facilitate cleaning, maintenance, and proper operations.

Specifically,

A. Your firm has not established environmental controls in storage areas where active pharmaceutical ingredients (APIs) and drug components are held.

1. Temperature monitoring devices are not positioned in the locations where APIs and components are stored. Furthermore, your firm has not conducted temperature mapping studies to characterize the temperature distribution within the warehouse and identify areas of temperature excursion.
2. Your firm has not established any humidity monitoring program for the warehouse where APIs and drug product components are stored.

B. The following conditions were noted in drug product manufacturing areas where drug products are compounded, including:

1. Hoses used in the production of drug products were observed stored uncovered and in direct contact with wall surfaces in the compounding area.
2. The ceiling above designated drug mixing tank (b) (4) in the compounding room was observed to

have a debris-covered cord suspended over the compounding tank.

C. Your firm has not established adequate physical segregation of materials of differing quality status within your warehouse and receiving area. Rejected materials are held in the same general dock space as incoming materials, without adequate physical separation or clear status designation to prevent mix-ups.

OBSERVATION 7

Component testing is deficient in that each component is not tested for conformity with all appropriate written specifications for purity, strength, and quality.

Specifically,

1. Your firm has not tested raw (b) (4) used in the production of (b) (4) for drug manufacturing for objectionable microorganisms, including, but not limited to (b) (4) and total coliform, to characterize baseline microbial (b) (4).
2. Your firm does not test the (b) (4) produced for use in the manufacture of drug products for objectionable microorganisms, including (b) (4) and total coliform.

OBSERVATION 8

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

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Your firm's finished drug product microbial specifications and associated test methods for (b) (4) and (b) (4) Spray are based on recommendations from a third-party laboratory and customer concurrence. During the inspection, your firm was unable to provide documentation of the scientific basis for these microbial specifications and test methods. Notably, testing of (b) (4)-based finished drug products, such as (b) (4) for objectionable organisms such as (b) (4) has not been performed.

OBSERVATION 9

Laboratory controls do not include the establishment of scientifically sound and appropriate sampling plans and test procedures designed to assure that components, in-process materials and drug products conform to appropriate standards of identity, strength, quality and purity.

Your firm's (b) (4) sampling plan (SOP No. 93, Revision Date: 08/01/22) does not include a risk-based rationale or scientific justification for the frequency of (b) (4) sampling at the point of use. Table 1 of SOP No. 93 establishes sampling frequencies (e.g., Aerobic Plate Count (b) (4) for (b) (4), Yeast and Mold (b) (4)) without documented justification demonstrating that these frequencies are adequate to ensure (b) (4) quality for the manufacture of topical over-the-counter (OTC) drug products.

OBSERVATION 10

Batch production and control records do not include complete information relating to the production and control of each batch.

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1. Batch production records for (b) (4) products contain references to, or incorporate, documents that have not been formally controlled, reviewed, or approved through your firm's quality system.
2. Batch records (b) (4) products were found to lack required information, including mixer speed settings, page numbers, and documentation of quality unit checks.
3. In-process check worksheets are included as part of the batch record for (b) (4) drug products and do not include a form number, page number, or revision number, and there is no procedural requirement for quality unit review of these worksheets.
4. Batch records were found to contain missing signatures required to document the performance and verification of critical manufacturing steps.
5. Batch records reviewed during this inspection lacked documented evidence that laboratory data, including test results used to support release, were independently reviewed and verified by a second qualified individual prior to batch disposition.

Examples of the deficiencies stated above were observed in batches including, but not limited to:

(b) (4)

OBSERVATION 11

Written procedures are not established and followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically,

1. Investigators observed new unused mixing drums bearing clean status designations that did not reflect the true condition of the equipment at the time of inspection.

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2. Investigators observed (b) (4) filler, serial number (b) (4), used for (b) (4) drug products bearing cleaned and sanitized status designations that had visible black residue present on equipment surfaces.

***DATES OF INSPECTION**

4/22/2026(Wed), 4/23/2026(Thu), 4/24/2026(Fri), 4/27/2026(Mon), 4/28/2026(Tue), 4/29/2026(Wed), 4/30/2026(Thu), 5/06/2026(Wed), 5/07/2026(Thu)

X Angela C Welker
Investigator
Signed By: ANGELA C. WELKER -S
Date Signed: 05-07-2026 15:08:21

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
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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."