DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900	5/13/2025-5/23/2025* FEI NUMBER 3002815949

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Michael Tursi, Owner/President

FIRM NAME	STREET ADDRESS
Stokes Healthcare Inc. dba Epicur Pharma	8000 Commerce Pkwy Ste 600
CITY, STATE, ZIP CODE, COUNTRY Mount Laurel, NJ 08054-2211	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-Sterile Drug Products

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 OBSERVED:

OBSERVATION 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written and followed.

This is a repeat observation.

Specifically,

A. Your firm released several batches of Tacrolimus AQ Ophthalmic Suspension (without labeling them for veterinary use) and other veterinary products intended to be sterile, despite the detection of microbial growth during personnel monitoring (PM) and environmental monitoring (EM) within the ISO 5 production area since October 2023. Your firm has identified positive microbial growth during the EM/PM activities associated with the production of Tacrolimus AQ Ophthalmic Suspension (without labeling them for veterinary use), described as follows:

- MIR-010-2023: Tacrolimus AQ 0.02% Ophthalmic Suspension, Lot# R230600 - 2 CFUs of Hansfordia sinuosae (a mold) were identified on the operator's right gloved hand. Date Occurred: 10/6/2023.
- MIR-005-2024: Tacrolimus AQ 0.03% Ophthalmic Suspension, Lot# R240103 - 1 CFU of Streptomyces tendae/tritolerans was identified on the left wall within the ISO 5 aseptic

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processing area. Date Occurred: 2/27/2024.

Although your firm conducted an investigation for each OOS result and concluded that the closed investigations presented a low risk to product quality, it was observed during aseptic processing that both operators repeatedly used their gloved hands to directly manipulate caps and eye dropper bottles. This practice poses a potential risk of product contamination due to possible microbial growth on the gloves.

B. Your firm has not established a hold time for vessels, measuring cylinders and utensils used in the manufacture of Tacrolimus AQ Ophthalmic Suspension (without labeling them for veterinary use) within the ISO 5 aseptic processing area following sterilization. For example, the hold time for a (b) (4) vessel used to hold bulk product intended to be sterile ranged from 11 to 51 days afte (b) (4) sterilization during the period from 3/19/2025 to 5/20/2025; however, your firm has not validated the maximum hold time for these vessels. These items are stored in the ISO 7 area prior to use.

C. Your firm has not established a hold time for Buffered HPMC and the Tacrolimus 3% concentrate which is combined from individual containers into a (b) (4) steril (b) (4) vessel during aseptic filling. Following sterilization, the 3% concentrate was held from 1 to 6 days in the ISO 7 area prior to use; however, your firm has not established a validated maximum hold time for it.

D. The media fill does not simulate the worst-case scenario of the actual production process. During the most recent media fill qualification for (b) (4) Filling and Capping Machine used for the manufacture of Tacrolimus Ophthalmic Suspension in Room 706 per Protocol # PR-23-201.01, the media was (b) (4) on 2/7/2024 and used for aseptic processing on 2/8/2024. However, during routine production of this product, the HPMC media and the media containing 3% condensed API could be held for 1 to 6 days post (b) (4) before being used for aseptic filling. Although (b) (4) media hold time was evaluated in a media fill for a different process

(b) (4) (b) (4) Filling Line), this hold time has not been incorporated into the routine media fill study for the manufacture of Tacrolimus Ophthalmic Suspension.

E. The certifications of cleaning room 706, dated (b) (4) show that (b) (4) testing of the HEPA filters located in the ceiling of the designated ISO 5 areas includes multiple test points outside of the (b) (4) range.

OBSERVATION 2

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the equipment to produce aseptic conditions.

This is a repeat observation.

Specifically,

A. The sporicidal agent used to clean the ISO 5 aseptic area did not meet the contact time specified in the cleaning SOP. According to SOP SC-SAN-1010 Cleaning and Maintenance of the Aseptic Manufacturing Area, Revision 2.00, Effective Date: 7/29/2024 (b) (4) surface contact time has been established fo (b) (4) however, camera footage dated 5/12/2025 shows that during the cleaning of the ISO 5 aseptic processing area immediately following the production of Tacrolimus AQ 0.5% (10 mL), Lot (b) (4) in Room 706, the operator applied (b) (4) at 10:16:59 and wiped it with a mop pre-saturated with (b) (4) at 10:21:41 - resulting in a contact time of less than 5 minutes.

B. The camera footage dated 5/12/2025 shows that the operator did not thoroughly disinfect racks containing wells used to hold caps and tips inside the ISO 5 aseptic processing area prior to use during the production of Tacrolimus AQ 0.5% (10 mL), Lot# (b) (4).

C. The camera footage dated 5/12/2025 shows that the operator did not clean the entire right wall and

hard-to-reach areas within the ISO 5 aseptic processing zone, such as the surfaces beneath the filling and capping equipment, and the gaps between the equipment following the production of following the production of Tacrolimus AQ 0.5% (10 mL), Lot# (b) (4) . A shared aseptic processing area is used for manufacturing both sterile veterinary drugs and human ophthalmic drugs.

D. The disinfectant efficacy study is inadequate. Efficacy testing o (b) (4) , conducted by a third-party laboratory, dated 7/16/2024, demonstrated that the product failed to achieve the minimum required (b) (4) against Aspergillus brasiliensis ATCC 16404.

OBSERVATION 3

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.

This is a repeat observation.

Specifically,

The process validation for the Tacrolimus eye drops has not established critical control parameters. During the aseptic filling of Tacrolimus eye drops, (b) (4) stir bar inside (b) (4) vesse (b) (4) stirs the bulk suspension product to maintain uniformity. However, the firm has not established an acceptable operating range for the stir bar speed. For example, the stir bar speed settings for two different batches of Tacrolimus AQ 1% Ophthalmic Suspension (Lot# 250197 and Lot# 250227) were (b) (4) and (b) (4) (b) (4), respectively without an established acceptable range. Since 2024, your firm has reported 19 out-of-specification (OOS) batches of Tacrolimus eye drops. Of those, 9 batches had confirmed OOS results and were rejected, but no definitive root causes have been identified during the manufacturing

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investigation. Your firm produced approximatel (b) (4) batches of Tacrolimus Ophthalmic Suspension per (b) (4) in Room 706.

OBSERVATION 4

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically,

Your stability study failed to test for impurities of Tacrolimus Ophthalmic Suspension including (b) (4) individual unspecified impurities and total impurities as specified in the finished product specifications. For example, your firm failed to test for any of these impurities during the (b) (4) stability study for Tacrolimus AQ 0.02% Ophthalmic Suspension, Lot# R230428 8/22/2023 and th (b) (4) stability study for Tacrolimus AQ 0.02% Ophthalmic Suspension, Lot# R230428, initiated on 8/22/2023. Impurities are tested at the time of product release; however, there is no assurance that impurity levels will remain within specification through the product's expiration date. Your firm manufactures approximately (b) (4) batches of Tacrolimus Ophthalmic Suspension pe (b) (4) in Room 706.

OBSERVATION 5

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that conform to appropriate standards of identity, strength, quality and purity.

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This is a repeat observation.

Specifically,

You firm has established an impurity specification for Tacrolimus AQ Ophthalmic Suspension; however, the method for impurity testing - Draft Test Method: Assay of Impurities in Tacrolimus AQ Ophthalmic Suspension by UPLC - has not yet been validated.

***DATES OF INSPECTION**
5/13/2025(Tue), 5/14/2025(Wed), 5/15/2025(Thu), 5/16/2025(Fri), 5/19/2025(Mon), 5/20/2025(Tue), 5/21/2025(Wed), 5/22/2025(Thu), 5/23/2025(Fri)

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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."