

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

DISTRICT ADDRESS AND PHONE NUMBER 8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913) 495-5100 Fax: (913) 495-5115	DATE(S) OF INSPECTION 3/16/2021-3/23/2021*
	FEI NUMBER 1910619

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Everett B. Hughes, President and CEO

FIRM NAME Sparhawk Laboratories Inc	STREET ADDRESS 12340 Santa Fe Trail Dr
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CITY, STATE, ZIP CODE, COUNTRY Lenexa, KS 66215-3587	TYPE ESTABLISHMENT INSPECTED Animal Drug Manufacturer
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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

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically,

- A. The data from your HPLC units # (b)(4) and # (b)(4) lacked controls and the HPLC runs could be deleted at the user level.
- B. Analysts utilize separate (b) (4) spreadsheet templates for calculations related to finished product release and stability results. The formulas for spreadsheet L436.01 for Lincomycin 300 mg/mL assay, are not protected to ensure the reported results are accurate.

Repeat Observation from 02/2020.

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic process.

Specifically, your primary speeds used on your media fills were not representative of actual run speeds used in production as seen in the examples below. In addition, each of your media fills included more than one fill speed during the batch.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Carl A Huffman, Investigator Wayne D Mcgrath, Investigator Torrey M Ward, Investigator	Carl A Huffman Investigator Signed By: Carl A. Huffman-S Date Signed: 03-23-2021 14 35 22 X	DATE ISSUED 3/23/2021

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Media fills from 2020

Date filled	Fill Room	Bottle size	Total run time	High speed (in CPM) for (b) (4)	Medium speed (in CPM) for (b) (4)	Low speed (in CPM) for (b) (4)
02/11/2020	(b) (4)	500	(b) (4)	(b) (4)	(b) (4)	(b) (4)
06/01/2020	(b) (4)	50	(b) (4)	(b) (4)	(b) (4)	(b) (4)
08/04/2020	(b) (4)	50	(b) (4)	(b) (4)	(b) (4)	(b) (4)
11/03/2020	(b) (4)	500	(b) (4)	(b) (4)	(b) (4)	(b) (4)

Actual Product Runs

Date filled	Fill Room	Bottle size	Fill speed (in CPM)	Drug name and MF number	Batch number
01/08/2021	(b) (4)	50 ml	(b) (4)	Ivermectin Injection, MF (b) (4)	(b) (4)
01/08/2021	(b) (4)	500 ml	(b) (4)	High potency multi B complex, MF (b) (4)	(b) (4)
02/09/2021	(b) (4)	100 ml	(b) (4)	Lidocaine HCl 2%, MF (b) (4)	(b) (4)
03/08/2021	(b) (4)	50 ml	(b) (4)	Ivermectin Injection, MF (b) (4)	(b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Carl A Huffman, Investigator Wayne D Mcgrath, Investigator Torrey M Ward, Investigator	DATE ISSUED 3/23/2021
	Carl A Huffman Investigator Signed By: Carl A. Huffman-S Date Signed: 03-23-2021 14:35:22 X	

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OBSERVATION 3

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

Specifically, your firm lacks procedures for the qualification of employees working in the aseptic processing areas. In addition, there is no documentation showing employees conducting operations in the aseptic processing areas, including aseptic connections, have been qualified to conduct such operations.

***DATES OF INSPECTION**

3/16/2021(Tue), 3/17/2021(Wed), 3/18/2021(Thu), 3/19/2021(Fri), 3/22/2021(Mon), 3/23/2021(Tue)

X Torrey M Ward
Investigator
Signed By: Torrey M. Ward -S4
Date Signed: 03-23-2021 14:35:43

X Wayne D Mcgrath
Investigator
Signed By: 2001897192
Date Signed: 03-23-2021 14:36:14

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Carl A Huffman, Investigator Wayne D Mcgrath, Investigator Torrey M Ward, Investigator	<small>Carl A Huffman Investigator Signed By: Carl A. Huffman -S Date Signed 03-23-2021 14 35 22</small> X _____	DATE ISSUED 3/23/2021

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."