DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661 ORAPHARM1_RESPONSES@fda.hhs.gov	5/25/2022-6/15/2022* FEI NUMBER 2431950

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Daniel R. Akeson, Director

FIRM NAME	STREET ADDRESS
Jerome Stevens Pharmaceuticals, Inc.	60 Davinci Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Bohemia, NY 11716-2633	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

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

Specifically,

The equipment cleaning validation studies for the equipment utilized in the manufacturing of Levothyroxine Sodium tablets, Digoxin Tablets, and Butalbital, Aspirin, Caffeine, Codeine Phosphate (BACC) Capsules are deficient in that:

A) No Maximum Allowable Carryover (MACO) of the product residue from the preceding batch was defined in the cleaning validation studies for equipment. The following are some examples:

1. Equipment cleaning validation study for the shared equipmen (b) (4) Blender (b) (4) , Protocol # JSP2012-003.01, using BACC Capsules blend, lot # 012612.

2. Equipment cleaning validation study for the shared equipment (b) (4) Mill (b) (4), Protocol # JSP-2020-006.01, using Levothyroxine Tablets blend, 0.025mg, lot # IB-100120.

3. Equipment cleaning validation study for the shared equipment (b) (4) Filler, Protocol #

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Brandy N Lepage, Investigator Bijoy Panicker, Investigator	X Brandy N Lepage Investigator Signed By: Brandy N. Lepage -S Date Signed: 06-15-2022 16:22:44	6/15/2022

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661 ORAPHARM1_RESPONSES@fda.hhs.gov	5/25/2022-6/15/2022* FEI NUMBER 2431950

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Daniel R. Akeson, Director	
FIRM NAME Jerome Stevens Pharmaceuticals, Inc.	STREET ADDRESS 60 Davinci Dr
CITY, STATE, ZIP CODE, COUNTRY Bohemia, NY 11716-2633	TYPE ESTABLISHMENT INSPECTED Manufacturer

JSP-2013-001, using Digoxin Tablets blend, 0.125mg, lot # 027912.

B) Equipment cleaning validation studies (e.g.: Protocol #s JSP2012-003.01, JSP-2020-006.01, and JSP-2013-001) were performed by manufacturing (b) (4) of drug product followed by cleaning of the equipment, however; the firm routinely performs full cleaning after (b) (4) manufacturing campaigns with no full cleanings in between. The following are some examples:

1. Shared equipment:
   a) (b) (4) Blender ((b) (4)) was cleaned after manufacturing of (b) batches of Levothyroxine Sodium Tablets, 0.100mg (lot #s: (b) (4), (b) (4)).

   b) (b) (4) Mill (b) (4) was cleaned after manufacturing of (b) batches of Levothyroxine Sodium Tablets, 0.100mg (lot #s: (b) (4).

   c) Packaging Line (b) (4) was cleaned after manufacturing of (b) batches of Digoxin Tablets, 0.250mg (lot #s: (b) (4)).

2. Dedicated equipment:
   a) (b) (4) Mixer ((b) (4) was cleaned after manufacturing of (b) (4) batches of Levothyroxine Sodium Tablets blend (lot #s (b) (4))

   b) Tablet Compressor (b) (4) was cleaned after manufacturing of (b) batches of Levothyroxine Sodium Tablets (lot #s (b) (4))

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Brandy N Lepage, Investigator Bijoy Panicker, Investigator	X Brandy N Lepage Investigator Signed By: Brandy N. Lepage -S Date Signed: 06-15-2022 16:22:44	6/15/2022

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661 ORAPHARM1_RESPONSES@fda.hhs.gov	5/25/2022-6/15/2022* FEI NUMBER 2431950

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Daniel R. Akeson, Director	
FIRM NAME Jerome Stevens Pharmaceuticals, Inc.	STREET ADDRESS 60 Davinci Dr
CITY, STATE, ZIP CODE, COUNTRY Bohemia, NY 11716-2633	TYPE ESTABLISHMENT INSPECTED Manufacturer

C) Equipment cleaning validation studies (e.g.: Protocol #s JSP2012-003.01, JSP-2020-006.01, JSP-2013-001, and JSP-2014-002-01) were performed by manufacturing (b) (4) of drug product followed by cleaning of the equipment immediately, and they do not include evaluation of the worst case maximum dirty hold time. However, the firm holds the equipment in dirty condition routinely for a number of days before performing full cleaning. The following are some examples:

1. Tablet Compressor ((b) (4)) was held in dirty condition for 22 days before performing full cleaning after the manufacture of Levothyroxine Sodium Tablets, 0.175mg, lot # 007522.

2. Packaging Line (b) (4) was held in dirty condition for 7 days before performing full cleaning after the manufacture of Levothyroxine Sodium Tablets, 0.150mg, lot # 027321.

3. (b) (4) Mill (b) (4) was held in dirty condition for 6 days before performing full cleaning after the manufacture of Levothyroxine Sodium Tablets, 0.088mg, lot # 024320.

4. (b) (4) Blender (b) (4)) was held in dirty condition for 5 days before performing full cleaning after the manufacture of Levothyroxine Sodium Tablets, 0.050mg, lot # 013922.

D) No cleaning validation study was performed for (b) (4) encapsulator dedicated for the manufacture of Butalbital, Aspirin, Caffeine, Codeine Phosphate (BACC) capsules.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Brandy N Lepage, Investigator Bijoy Panicker, Investigator	X Brandy N Lepage Investigator Signed By: Brandy N. Lepage -S Date Signed: 06-15-2022 16:22:44	6/15/2022

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661 ORAPHARM1_RESPONSES@fda.hhs.gov	5/25/2022-6/15/2022* FEI NUMBER 2431950

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Daniel R. Akeson, Director	
FIRM NAME Jerome Stevens Pharmaceuticals, Inc.	STREET ADDRESS 60 Davinci Dr
CITY, STATE, ZIP CODE, COUNTRY Bohemia, NY 11716-2633	TYPE ESTABLISHMENT INSPECTED Manufacturer

OBSERVATION 2

Verification of the suitability of the testing methods is deficient in that they are not documented on the laboratory records.

Specifically,

A) The firm did not have any analytical method verification study documents for the following:

1. Assay and dissolution test methods for Digoxin tablets, USP.

2. Free salicylic acid and dissolution test methods for Butalbital, Aspirin, Caffeine, Codeine Phosphate (BACC) capsules, USP.

B) The firm failed to perform adequate analytical method verification or validation studies for the following:

1. Method verification of assay and limit of liothyronine test methods, and method validation of impurities test method for Levothyroxine Tablets, USP did not include evaluation of accuracy, linearity, detection limit or quantitation limit.

2. Method validation for impurities test method for Digoxin tablets, USP included only (b) (4) study for specificity and no other method parameters were validated.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Brandy N Lepage, Investigator Bijoy Panicker, Investigator	X Brandy N Lepage Investigator Signed By: Brandy N. Lepage -S Date Signed: 06-15-2022 16:22:44	6/15/2022

3. Method validation for impurities test method for BACC capsules, USP included only (b) (4) study for specificity and no other method parameters were validated.

OBSERVATION 3

There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

Specifically,

A. The mapping study for the (b) (4) performed by (b) (4) (Report # 209740-3, dated 11/16/2015) was executed for only (b) (4) and this short duration was not justified in an appropriate risk assessment. Additionally, this study used (b) (4), and the firm did not have the humidity data obtained over the various time intervals during this (b) (4) study.

B. According to Ms. T. D., Head of Quality, the firm unofficially uses (b) (4) ' software system to manage warehouse operations including generating status labels for the raw materials. According to SOP NO.: 02.00, "Receiving Department," a 'Released' sticker shall be placed on each raw material and packaging component pallet after a shipment is successfully tested. however, several pallets and individual units of raw of materials were observed in the 40 Davinci Drive warehouse with a 'Released' sticker from (b) (4) system in lieu of the official release label The following are examples of raw materials observed to have only (b) (4) System generated release stickers and no official release stickers:

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661 ORAPHARM1_RESPONSES@fda.hhs.gov	5/25/2022-6/15/2022* FEI NUMBER 2431950

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Daniel R. Akeson, Director	
FIRM NAME Jerome Stevens Pharmaceuticals, Inc.	STREET ADDRESS 60 Davinci Dr
CITY, STATE, ZIP CODE, COUNTRY Bohemia, NY 11716-2633	TYPE ESTABLISHMENT INSPECTED Manufacturer

a. Aspirin, USP (batch number (b) (4))
b. Purified water, USP (batch number (b) (4)
c. Colloidal Silicon Dioxide, NF (batch number (b) (4)
d. Acacia Gum Arabic Premium (batch number (b) (4))

In addition, data from (b) (4) system is used for investigations by Quality Assurance unit (e.g.: Investigation # QA-2019-010-DDI). However, this (b) (4) software system is not validated.

OBSERVATION 4
In-process materials are not tested for and approved or rejected by the quality control unit.

Specifically,

The bulk hold studies for Levothyroxine Sodium ((b) (4)), Digoxin ((b) (4)), and B.A.C.C. ((b) (4)) associated with Protocols: JSP-2014-004 and JSP-2017-005, do not include finished product stability studies to assess the long-term impact of these hold times on the drug product's stability performance throughout their entire shelf life; nor has your firm documented a scientifically sound justification explaining why excessive bulks hold times are unlikely to adversely impact the stability performance of these finished product batches.

OBSERVATION 5
Drug products are not stored under appropriate conditions of so that their identity, strength, quality, and purity are not affected.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Brandy N Lepage, Investigator Bijoy Panicker, Investigator X Brandy N Lepage Investigator Signed By: Brandy N. Lepage -S Date Signed: 06-15-2022 16:22:44	6/15/2022

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661 ORAPHARM1_RESPONSES@fda.hhs.gov	5/25/2022-6/15/2022* FEI NUMBER 2431950

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Daniel R. Akeson, Director	
FIRM NAME Jerome Stevens Pharmaceuticals, Inc.	STREET ADDRESS 60 Davinci Dr
CITY, STATE, ZIP CODE, COUNTRY Bohemia, NY 11716-2633	TYPE ESTABLISHMENT INSPECTED Manufacturer

Specifically,

Warehouses located at 40 Davinci Dr and 100 Davinci Dr, (b) (4) were not qualified using temperature mapping studies. APIs that require labeled storage conditions are stored at the 40 Davinci Drive warehouse, and bulk drug products and finished drug products are stored at the 100 Davinci Drive warehouse.

OBSERVATION 6

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,

According to the Ms. T. D., Head of Quality, the firm's Quality Control laboratory reviews only the printout of data generated from the High-Performance Liquid Chromatography (HPLC) systems. The original electronic data and the related audit trails are not reviewed by the Quality Control laboratory prior to the release and distribution of each batch of drug product. The firm uses HPLCs for ID, assay, impurities, and dissolution testing of drug products and raw materials. Additionally, the firm's Quality Assurance does not perform periodic audit trail reviews of the laboratory instrument software which generates and stores raw analytical data.

OBSERVATION 7

Each container of component dispensed to manufacturing is not examined by a second person to assure that the weight or measure is correct as stated in the batch records.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Brandy N Lepage, Investigator Bijoy Panicker, Investigator	X Brandy N Lepage Investigator Signed By: Brandy N. Lepage -S Date Signed: 06-15-2022 16:22:44	6/15/2022

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661 ORAPHARM1_RESPONSES@fda.hhs.gov	5/25/2022-6/15/2022* FEI NUMBER 2431950

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Daniel R. Akeson, Director	
FIRM NAME Jerome Stevens Pharmaceuticals, Inc.	STREET ADDRESS 60 Davinci Dr
CITY, STATE, ZIP CODE, COUNTRY Bohemia, NY 11716-2633	TYPE ESTABLISHMENT INSPECTED Manufacturer

Specifically,

SOP # 05.08, "Cleaning Procedure for Pharmacies" states the following: "8.1 Following the execution of a pharmacy weighing operation, per the Batch Production Record, materials are to be verified by a member of Department Supervision, Quality, and/or Designee. 8.2 When verifying, the individual executing the verification shall ensure the following: Section 8.2.A Place all materials on a scale and verify GTN calculations". However according to Compounding Supervisor, R.R., who is responsible for verifying the weighing operations, he does not verify the actual weight of the materials yet signs the verification column in the batch record page after checking only for the "completeness of the entries". The following are some of the deviation investigations due to weighing errors: QA-2019-010-DDI and QA-2021-002-DDI.

***DATES OF INSPECTION**

5/25/2022(Wed), 5/26/2022(Thu), 5/31/2022(Tue), 6/01/2022(Wed), 6/02/2022(Thu), 6/13/2022(Mon), 6/14/2022(Tue), 6/15/2022(Wed)

X Bijoy Panicker
Investigator
Signed By: 2001996716
Date Signed: 06-15-2022 16:23:33

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Brandy N Lepage, Investigator Bijoy Panicker, Investigator X Brandy N Lepage Investigator Signed By: Brandy N. Lepage -S Date Signed: 06-15-2022 16:22:44	6/15/2022

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."