DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Ave. Jamaica, NY 11433 718-662-5400 Industry Information: www.fda.gov/oc/industry	7/10-13/2018
	FEI NUMBER 3014454961

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Joseph Pierro, Owner and Pharmacist in Charge

FIRM NAME	STREET ADDRESS
Sharp Drugs, Inc.	8C Moniebogue Lane
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
West Hampton Beach, NY 11978-2613	Producer of Sterile and Non-sterile Drugs

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

Observation 1

The ISO 5 classified aseptic processing area was located within a non-classified room (segregated production area) Specifically,

the biological safety cabinet, which is used to make Deferoxamine 2.5gm IV, is located in a non-classified room, that lacks a HEPA filtration system. Additionally, the hood is powered off when not in use, exposed to unclassified air and is not re-cleaned before starting production. The unclassified room is separated from the rest of the pharmacy by a wooden door which has a hole where a doorknob would be placed.

Observation 2

Disinfecting agents, cleaning pads, and cleaning wipes used in the ISO 5 classified aseptic processing area were not sterile
Specifically,

the only disinfecting agent used to clean the biological safety cabinet is (b) (4) which is applied with non-sterile, disposable paper towels. Non-sterile (b) (4) wipes are used on each vial and the ports of the IV bags within the processing area. Additionally, no sporicidal agent is used. The biological safety cabinet is used to make Deferoxamine 2.5gm IV.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Nancy F. Scheraga, Consumer Safety Officer	07/13/2018

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Observation 3
Personnel engaged in aseptic processing wear non-sterile gloves
Specifically,

the only personnel protective equipment worn by the owner, who performs all of the sterile processing, is non-sterile, nitrile gloves. This was verbally stated to me on 07/10/2018.

Observation 4
Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations
Specifically,

you have not performed any media fills.

Observation 5
Materials or supplies were not disinfected prior to entering the aseptic processing area
Specifically,

(b) (4) and
Deferoxamine 2gm vials are not disinfected prior to being brought into the aseptic processing area for production of Deferoxamine 2.5gm IV.

Observation 6
Environmental monitoring was not performed in your aseptic processing areas

Add Continuation Page

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Specifically,

you do not conduct environmental monitoring (i.e., viable and non-viable air sampling, personnel and surface monitoring, etc.) during the production of Deferoxamine 2.5gm IV to assure that the biological safety cabinet remains in a state of environmental control appropriate for aseptic processing.

Add Continuation Page

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	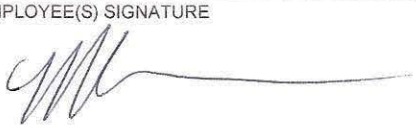	Nancy F. Scheraga, Consumer Safety Officer	07/13/2018