DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6751 Steger Drive Cincinnati, OH 45237-3097 (513)679-2700 Fax:(513)679-2772 Industry Information: www.fda.gov/oc/industry	09/09,10,14,21,23,27 &30 /2021
	FEI NUMBER 1530045

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Cindy Kryc Rph Director of Pharmacy

FIRM NAME	STREET ADDRESS
Crosbys Drugs Inc	2609 N High St
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Columbus, OH 43202-2555	Producer of Sterile Drugs

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) (WE) OBSERVED:

OBSERVATION 1

Your firm failed to conduct (b) (4) testing on (b) (4) used to sterilize drug products.

Specifically,

i. On 09/14/2021, I observed the operator use the (b) (4) during compounding but discarded the (b) (4) into trash receptacle without conducting a (b) (4) test. The operator stated (b) (6) did not know what (b) (4) test was. I observed the the Director of Pharmacy pick up the used (b) (4) from the trash stating that she will conduct the (b) (4) test later in the lab.

ii. You did not perform a (b) (4) testing for Papaverine/Phentolamine/Alprostadil 29.4mg/1mg/10mcg lot 09142021 @11 which was compounded on 09/14/2021.

iii. I observed lack of documentation on lots 09022021@7, 09102021@1, 08192021@10 as to whether the (b) (4) (b) (4) test was performed. There is an indication that this was not done.

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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE *(Print or Type)*	DATE ISSUED
	Ucheabuchi C. Chudi-nwankwor -S	Ucheabuchi C. Chudi-Nwankwor CSO	09/30/2021

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OSERVATION 2
Your firm failed to conduct media fills that closely simulate aseptic production operations under the worst-case, most-challenging and stressful conditions.

Specifically, Your media fill was not performed that closely simulate aseptic production operations, incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operation. You set aside a time and a day to perform media fill without taking into consideration your continuous compounding products successively in a day (Repeat)

OBSERVATION 3
Non sterilized, non-depyrogenated equipment used in sterile drug production

Specifically ,
i. I observed depyrogenated, foil wrapped beaker being unwrapped by the operator on the work bench outside the ISO 5 hood. The beaker was used in the weighing and mixing of your ingredients. The glassware was exposed to less than ISO5 quality air.

ii. There is no data to show that depyrogenation is followed as intended for the glasswares.

OBSERVATION 4
Disinfectant contact time (also known as "dwell time") and coverage of the item being disinfected were insufficient to achieve adequate level of disinfection.

Specifically, You are not waiting the required (b) (4) dwell time for the disinfectants used to sanitize your ISO 5 hood where sterile products are compounded. On 9/14/21, I observed the operator performing sterile processing clean and disinfect the ISO 5 hood. Disinfectant was used but immediately wiped down after application. You stated that the disinfectants direction specify waiting (b) (4) prior to wiping down.

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OBSERVATION 5
Personnel engaged in aseptic processing were observed leaving and re-entering the clean room without replacing the gowning apparel.

Specifically, On 09/14/2021, I observed the Operator engaged in aseptic processing leaving and re-entering the cleanroom from non-classified area without first replacing gowning apparel.
I observed when (b)(6) opened the door to the ante room to collect the Alprostadil stock solution which was brought in by the Director of Pharmacy after the operator had already set materials to begin compounding in the ISO 5 Hood. The operator did not disinfect (b)(6) gloves. (b)(6) did not replace (b)(6) gloves or sterile gown after exiting the ISO 7 cleanroom.

OBSERVATION 6
Personnel donned gowning apparel improperly, in a way that may have caused the gowning apparel to have been contaminated.
Specifically,
i. On 09/14/2021, I observed the operator touch the sleeves of the donned sterile gowns on the sink in the anteroom.
ii. I observed the operator who had donned the sterile coverall gown step one of (b)(6) foot over the line of demarcation to the "dirty side" side of the gowning area in the Anteroom. (b)(6) proceeded into the cleanroom and subsequently engaged in sterile compounding of drug products without replacing (b)(6) sterile coverall with integrated sterile shoe coverings or booties.

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OBSERVATION 7

Personnel touched equipment or other surfaces located outside of the ISO 5 classified aseptic processing area with gloved hands and then engaged in aseptic processing without changing or sanitizing gloves.

Specifically,

i. On 09/14/2019, I observed an operator engaged in aseptic processing touch other surfaces located outside the compounding hood which include but not limited to beakers, Particulate counter, weighing of ingredients on the weighing balance, and handling the doorknobs when exiting the clean room to the ante room without changing the or sanitizing the gloves.

ii. I observed the operator, touch the sterile wipe holding container outside the ISO 5 hood,then proceeded to the ISO 5 Hood and wipe down. (b)(6) later transferred and staged compounding materials in the ISO 5 hood without disinfecting or changing (b)(6) gloves rather wiped (b)(6) hands with the sterile wipes (b)(6) had already used for the ISO 5 hood wipe down.

OBSERVATION 8

Your facility was designed in a way that permits poor flow of personnel and materials.

Specifically, On 09/14/2021, I observed the operator justling between the door and the sink in the anteroom into the ISO 7 Clean room.

The space for donning of sterile gowns is a demarcated line in front of the door leading to the clean room from the anteroom. This compact nature has the operator touch non-sterile surfaces with (b)(6) already donned gown. Materials are staged on the cart in the anteroom and then I observed the operator transfer the compounding materials after (b) (4) with (b)(6) hands. The Pharmacy Director stated that the carts cannot be wheeled into the ISO 7 clean room, rather the operators exit in and out the cleanroom to pick up materials used in compounding drug products.

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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 judgement, 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."