

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER Atlanta District Office 60, 8 th St NE, Atlanta, GA 30309; 404-253-1160; ORAPHARM2_RESPONSES@fda.hhs.gov	DATE(S) OF INSPECTION 9/20/2021 – 9/29/2021
	FEI NUMBER 3009127876

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Andy Stoker, Pharmacist in Charge

FIRM NAME The Compounding Pharmacy	STREET ADDRESS 750 4th St SW
---------------------------------------	---------------------------------

CITY, STATE AND ZIP CODE Hickory, NC 28602-3401	TYPE OF ESTABLISHMENT INSPECTED Manufacturer – Sterile/non-Sterile Compounding Pharmacy
--	--

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 facility design allowed the influx of poorer quality air into a higher classified area.

Specifically,

a) (b) (4) cleanroom (b) (4) and (b) (4) (classified ISO 7) contain a mini-split type of air conditioning (AC) unit. The presence of this equipment, containing a condenser and fan, within or in close enough proximity to the ISO 5 area could compromise the air in the ISO 5 area as they are particle generating equipment that cannot be sufficiently cleaned inside and do not provide for HEPA filtration of air moving into the classified space.

b) the hole for the drain tube removing condensation from the mini-split air conditioning (AC) unit in cleanroom (b) (4) had air movement from the hole. This shows a connection between the open back of the AC unit in the ISO 7 area surrounding the ISO 5 hood, and the unclassified space in which the hole terminates. There is a gap between the top edge of the AC unit in cleanroom (b) (4) and the wall which may further indicate an unsealed connection on the back of the AC unit.

c) I observed the drain tube for the unit in cleanroom (b) (4), containing stagnant water on the unclassified side of the hole which has black deposition (particles) and a symmetrical, circular white spot inside of the drain tube.

d) all of your sterile products are compounded within approximately three feet, in the case of cleanroom (b) (4), and within approximately eight feet, in the case of cleanroom (b) (4), of these AC units. Furthermore, these units are placed parallel to the face of the ISO 5 aseptic processing area with maneuverable vents positioned such that they could potentially blow directly into the hood where sterile product including intrathecal, intravitreal, intravenous, and intramuscular products are compounded.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Adam R. Cooke -55 <small>Digitally signed by Adam R. Cooke: SS DN: cn=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, email=Adam.R.Cooke.55@FDA.HHS.gov, c=US Date: 2021.09.29 12:17:03 -0400</small>	EMPLOYEE(S) NAME AND TITLE (Print or Type) Adam R. Cooke, Investigator	DATE ISSUED 9/29/2021
-----------------------------------	---	---	--------------------------

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER Atlanta District Office 60, 8 th St NE, Atlanta, GA 30309; 404-253-1160; ORAPHARM2_RESPONSES@fda.hhs.gov	DATE(S) OF INSPECTION 9/20/2021 – 9/29/2021
	FEI NUMBER 3009127876

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Andy Stoker, Pharmacist in Charge

FIRM NAME The Compounding Pharmacy	STREET ADDRESS 750 4th St SW
---------------------------------------	---------------------------------

CITY, STATE AND ZIP CODE Hickory, NC 28602-3401	TYPE OF ESTABLISHMENT INSPECTED Manufacturer – Sterile/non-Sterile Compounding Pharmacy
--	--

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 2

The classified aseptic processing areas had difficult to clean and/or visibly dirty equipment or surface.

Specifically,

- a) the AC units in cleanrooms (b) (4) and (b) (4) (classified ISO 7) are surrounded on three sides with foil tape that contains adhesive to the edge. This tape is not cleanroom grade and the adhesive presents its own hazard by its non-cleanable nature. The edge of the tape appears to be darker than the tape itself, and there is evidence of water leakage from under the tape potentially providing an ideal environment for microbial growth.
- b) your environmental monitoring process does not sample the AC units or the surrounding tape, and your procedures do not specifically call out that the units are cleaned.
- c) (b) (4) cleanroom (b) (4) and (b) (4) contain a mini-split type of air conditioning (AC) unit. The equipment, containing a condenser and fan inside the units, are not cleanable without disassembly and therefore are difficult to clean.
- d) the gap at the back of the AC unit in cleanroom (b) (4) (approximately 0.5 – 1 cm) does not allow for cleaning of the wall via a smooth easily cleanable surface.

OBSERVATION 3

Non-depyrogenated equipment was used in sterile drug production.

Specifically, glassware used in the compounding of product intended to be sterile (including (b) (4) products) was placed in a (b) (4) for depyrogenation. There is no assurance that that glassware was depyrogenated due to the lack of endotoxin indicators used in the batch of glassware. This affects all products compounded in the pre-sterile room.

Furthermore, your report of values from 8/30/2021 on the (b) (4) used to depyrogenate glassware for compounding sterile product shows (b) (4) of test points as being (b) (4) with an average of (b) (4).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Adam R. Cooke -S <small>Digitally signed by Adam R. Cooke, SS DN: cn=US, ou=U.S. Government, ou=HHS, ou=FDA, ou=People cn=Adam R. Cooke, SS, o=9 2342 19200300 100 1 1=2001332542 Date: 2021.09.29 12:17:50 -0400</small>	EMPLOYEE(S) NAME AND TITLE (Print or Type) Adam R. Cooke, Investigator	DATE ISSUED 9/29/2021
-----------------------------------	---	---	--------------------------

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 unsanitary 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."