DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702	7/12/2021-7/23/2021*
	FEI NUMBER 3015131327

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Dylan A. Herr, Vice President Quality and Compliance

FIRM NAME	STREET ADDRESS
Integrated Health Concepts Inc.	720 Aerovista Pl Ste D
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
San Luis Obispo, CA 93401-8726	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 WE OBSERVED:

OBSERVATION 1

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, on 07/14/21 we observed the operator fail to sanitize their gloves after touching equipment located on the ISO 7 mixing room table and before returning their gloves to handle materials within the ISO 5 Biological Safety Cabinet (BSC) during (b) (4) of compounded inhalation drug product, Albuterol/Ipratropium Bromide 2.5 mg/0.75 mg Solution for Nebulizer, Lot 071421-1, BUD 01/10/2022.

OBSERVATION 2

Personnel in an area that blocked the movement of first pass air around an open unit, either before or after it was filled with sterile product.

Specifically, on 7/14/21 we observed the operator place an IV bag containing (b) (4) drug product over the ISO 5 BSC air return vents, blocking downward airflow for approximately ten (10) seconds following (b) (4) of compounded inhalation drug product, Albuterol/Ipratropium Bromide 2.5 mg/0.75 mg Solution for Nebulizer, Lot 071421-1, BUD 01/10/2022.

*DATES OF INSPECTION

7/12/2021(Mon), 7/13/2021(Tue), 7/14/2021(Wed), 7/15/2021(Thu), 7/16/2021(Fri), 7/19/2021(Mon), 7/21/2021(Wed), 7/22/2021(Thu), 7/23/2021(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jolanna A Norton, Investigator Gunneet Kaur, Investigator	X Jolanna A Norton Investigator Signed By: Jolanna A. Norton -S Date Signed: 07-23-2021 12:16:54	7/23/2021

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EMPLOYEE(S) SIGNATURE

Jolanna A Norton, Investigator
Gunneet Kaur, Investigator

X Jolanna A Norton
Investigator
Signed By: Jolanna A. Norton -S
Date Signed: 07-23-2021
12:16:54

DATE ISSUED
7/23/2021

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."