DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave, Bldg71, Rm 5054 Silver Spring, MD 20993-0002 (240)402-9160 orabioinspectionalcorrespondence@fda.hhs.gov	9/11/2023-9/19/2023* FEI NUMBER 3005559915

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Alex Scheepers, General Manager

FIRM NAME	STREET ADDRESS
Octapharma AB	Lars Forssells Gata 23
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Stockholm, Stockholms Lan, 112 15 Sweden	Plasma Derivatives Manufacurer

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

Deviations from written production and process control procedures are not recorded and justified.

Specifically, deviations from written procedures and corrective actions for deviations are not always documented and justified. For example:

a) Cleaning instructions 4025-(b) (4) and 4065-(b) (4) for the filling (b) (4) for (b) (4) and Octagam and filling room at the department (b) (4) were updated in response to deviation TW #106318 opened on 23 MAY 2019 but no training of operators on the updated instructions was documented.

b) Employees setting up and monitoring of temperature alarms in room (b) (4) updated settings after temperature excursions. This room is used for storage of Octagam bulk, (b) (4) bulk, and (b) (4) fill (b) (4). The human error identified in deviation TW #145329 opened 16 APR 2021 was not addressed with training.

c) Deviation TW #94014 is opened on 1 OCT 2018 for Octaplas (b) (4) machine operations not starting after (b) (4). Root cause was identified as incorrect assembly of the (b) (4) of the machine and inexperience of the (b) (4). Work instructions were established as part of the CAPA, but no evidence was apparent to demonstrate that firm personnel were trained on these instructions.

d) Deviation TW #100586 is opened on 6 FEB 2019 for incorrect amount of (b) (4)) being added in the (b) (4) for (b) (4) (used for Nuwiq operations). The root cause was identified as firm personnel not detecting that (b) (4) was used instead of its (b) (4) version, resulting in the incorrect

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Scott T Ballard, Investigator Alan L Truong, Investigator Ze Peng, FDA Center Employee Olga Simakova, FDA Center Employee X Scott T Ballard Investigator Signed By: Scott T. Ballard -S Date Signed: 09-19-2023 10:56:00	9/19/2023

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(b) (4). Training of firm personnel to correctly identify and approve (b) (4) was not documented.

e) On 12 SEP 2023, we observed a lack of (b) (4) on (b) (4) fraction area during batch manufacturing. The instructions for (b) (4) were initialed by the operator in (b) (4) batch record (b) (4). At this time no deviation to this effect is documented.

OBSERVATION 2

Equipment and (b) (4) are not maintained at appropriate intervals to prevent that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically, you do not always adequately maintain equipment in the manufacturing of plasma derivatives. For example:

A. On 12 SEP 2023, we observed tank (b) (4) showed visible (b) (4) on the (b) (4) the tank during (b) (4) fractionation batch (b) (4). This creates a (b) (4) for (b) (4).

B. On 12 SEP 2023, we observed (b) (4) showed (b) (4) on (b) (4) that creates (b) (4) in the basic fractionation area used for manufacturing of pooled plasma intermediates.

OBSERVATION 3

Written procedures are not established and followed that describe the in-process controls to be conducted on appropriate samples of in-process materials of each batch.

Specifically, there is no written procedure for directing recovered (b) (4) for (b) (4) or (b) (4) when batches of recovered (b) (4) fail testing to (b) (4) standards. Recovered (b) (4) is a processing aid for manufacturing (b) (4) and Octagam.

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On 23 APR 2023, recovered (b) (4) batch (b) (4) failed testing of relative (b) (4) according to the specification. In the past (b) (4) at least four batches of recovered (b) (4) have failed testing to specifications.

Additionally, there is not a specified document for recording (b) (4) or (b) (4) of rejected (b) (4) recovery batches.

***DATES OF INSPECTION**
9/11/2023(Mon), 9/12/2023(Tue), 9/13/2023(Wed), 9/14/2023(Thu), 9/15/2023(Fri), 9/18/2023(Mon), 9/19/2023(Tue)

X Ze Peng
FDA Center Employee
Signed By: 1300426454
Date Signed: 09-19-2023 10:56:40

X Alan L Truong
Investigator
Signed By: 2002619229
Date Signed: 09-19-2023 10:57:16

X Olga Simakova
FDA Center Employee
Signed By: 0014147366
Date Signed: 09-19-2023 10:58:10

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EMPLOYEE(S) SIGNATURE
Scott T Ballard, Investigator
Alan L Truong, Investigator
Ze Peng, FDA Center Employee
Olga Simakova, FDA Center Employee

X Scott T Ballard
Investigator
Signed By: Scott T. Ballard -S
Date Signed: 09-19-2023 10:56:00

DATE ISSUED
9/19/2023

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."