DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
ORA OPQO HQ Room #2032 12420 Parklawn Drive Rockville, MD 20857 Industry Information: www.fda.gov/oc/industry	1/21/2019-1/25/2019
	FEI NUMBER 3003279188

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Mitsuo Sugiyama, Vice President, General Plant Manager

FIRM NAME	STREET ADDRESS
Daiichi Sankyo Chemical Pharma Co., Ltd.	477, Takada
CITY, STATE AND ZIP CODE Odawara, Kanagawa 250-0216, Japan	TYPE OF ESTABLISHMENT INSPECTED API Manufacturer

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

OBSERVATION 1

Appropriate documentation of testing performed to fully establish the identity and purity of the in-house primary reference standard was not retained.

Specifically,

Your firm does not have complete documentation to verify the GMP status of the Sankyo Investigational Medicinal Product GMP laboratory equipment used to conduct the full characterization of the primary reference standard for (b) (4) lot (b) (4) (b) (4) in-house reference standard is used to conduct finished product release testing of (b) (4) drug substance.

OBSERVATION 2

Suitability of each batch of in-house secondary reference standard is not determined by comparison against a primary reference standard.

Specifically,

Since 2004, (b) (4) in-house reference standard lots have not been fully characterized or compared against a fully characterized primary reference standard. (b) (4) in-house reference standard is used to conduct finished product release testing of (b) (4) drug substance.

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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Zachary L. Stamm -S	Zachary L. Stamm, Investigator	01/25/2019

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OBSERVATION 3

The written stability program does not assure testing of the drug substance intermediate in the same container closure system as that in which it is marketed.

Specifically,

Stability testing of the drug substance intermediate, (b) (4) is not conducted in the same container closure system as that in which it is marketed.

OBSERVATION 4

Written records of investigations into unexplained discrepancies are not always fully investigated.

Specifically,

Deviation investigations do not always extend to other processes that may have been associated with the specific failure or discrepancy and contain a conclusion and follow-up.

Examples:

1) Deviation Number TPACD2017-001 - A glass (b) (4) fragment was collected in a strainer of a liquid delivery pipe in the (b) (4) production process. The investigation did not include analytical methods to identify or verify the identity of the material as glass and the investigation did not evaluate possible sources of contamination other than the production equipment. The investigation was closed without identifying a root cause and it was determined there was no impact to product quality.

2) Deviation Number COMD2018-007 - The (b) (4) (W26) in the F-10 Freezer, was not appropriately recorded. The investigation did not identify that a previous deviation, COMD2017-002, had documented a similar event that occurred within the last year and that corrective actions had been deemed effective in preventing further occurrences.

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		Zachary L. Stamm, Investigator	01/25/2019