

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900 Fax:(973)331-4969 ORAPHARM1_RESPONSES@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 1/27/2022, 1/31/2022, 2/01-02/2022, 2/04/2022, 02/08/2022
	FEI NUMBER 2434223

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Mr. Michael Tranmer, Chief Operating Officer

FIRM NAME Strides Pharma, Inc.	STREET ADDRESS 1 Ram Ridge Rd
CITY, STATE AND ZIP CODE Chestnut Ridge, NY 10977-6714	TYPE OF ESTABLISHMENT INSPECTED Drug Manufacturer

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:

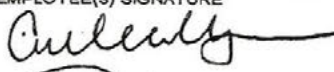

Laboratory Control System

OBSERVATION 1

Established laboratory control mechanisms are not followed and documented at the time of performance.

Specifically,

- 1) (b) (4) Date: 01/25/2022, Time: (b) (4) and (b) (4), Date: 01/25/2022, Time: (b) (4) were displayed in the previous analysis list screen of (b) (4). However, such analyses were not recorded in the Equipment and Usage Logbook for (b) (4).
- 2) There is no indication of QC review and verification for laboratory (b) (4) recorded in Laboratory (b) (4), Pages (b) (4), Project No. (b) (4) for assay testing of Valganciclovir Tablets, (b) (4) # (b) (4).
- 3) On 02/02/2022, we observed Amlodipine/Valsartan/HCTZ tablets, 5/160/12.5 mg, Lot #TO-15-001-001(C), Sample Date: 02/25/2015, being stored in the laboratory raw material sample storage area. However, there was no logged record of the sample receipt and documented reason as to why the finished drug product sample was being stored in the laboratory raw material sample storage area.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Guerlain Ulysse, Investigator	DATE ISSUED 02/08/2022
		Janet Rajan, Investigator	

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Packaging and Labeling System

OBSERVATION 2

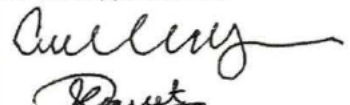
Inspection of the packaging and labeling facilities is (b) (4) to assure that materials not suitable for subsequent operations have been removed.

Specifically,

Labeled (b) (4) material issued during the previous drug product batch run remained on the primary packaging line, despite (b) (4) cleaning being performed and the packaging rooms' status being labeled as cleaned. For example:

1) On 1/27/2022, we observed foil slice material labeled: "Testosterone Gel 1%, 2.5 grams packet" that remained on the (b) (4), Room (b) (4). This is despite (b) (4) cleanings performed on (b) (4) and (b) (4) respectively. According to the Packaging Manager, the (b) (4) remained from the packaging of Testosterone Gel 1%, 2.5 grams, Lot #14855601, on 10/26/2021. A major re-cleaning of the room was performed on (b) (4) since (b) (4) had passed after the last cleaning performed on (b) (4).

2) On 01/27/2022, we observed (b) (4) material labeled: "(b) (4)" that remained on the (b) (4) Room (b) (4). This is despite (b) (4) clean performed on (b) (4) after the packaging of (b) (4) Lot (b) (4) on (b) (4).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Guerlain Ulysse, Investigator Janet Rajan, Investigator	DATE ISSUED 02/08/2022
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