

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

DISTRICT ADDRESS AND PHONE NUMBER 158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax: (718) 662-5661	DATE(S) OF INSPECTION 3/2/2026-3/6/2026
	FEI NUMBER 3012152381

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Polireddy Dondeti, Ph.D, President & CEO

FIRM NAME Saptalis Pharmaceuticals LLC	STREET ADDRESS 45 Davids Dr
CITY, STATE, ZIP CODE COUNTRY Hauppauge, NY 11788-2038	TYPE ESTABLISHMENT INSPECTED Manufacturer of Drug Products

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

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design, of adequate size and suitably located to facilitate operations for its intended use and cleaning and maintenance.

Specifically,

The transfer hoses used to transfer bulk drug products to the filling lines are cleaned and reused without an established replacement interval or life cycle management program

(A) Your firm has not conducted tubing leachable studies or tubing material compatibility studies for the transfer hoses used in the filling of the following drug products:

- (b) (4) Solution, (b) (4)
- (b) (4) Solution, USP ((b) (4))
- (b) (4) Solution, USP, (b) (4)

(B) Your firm has not established written procedures governing the use of transfer hoses that define the maximum number of uses or duration of use for (b) (4) solution/suspension and (b) (4) solution drug products.

**SEE REVERSE
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE
Emmanuel T Donyina, Investigator
Alice S Tsao, Investigator

Alice S Tsao
Investigator
Signed By: 1300423749
Date Signed: 03-05-2026
17:50:12
X

DATE ISSUED
3/6/2026

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CITY, STATE, ZIP CODE, COUNTRY Hauppauge, NY 11788-2038	TYPE ESTABLISHMENT INSPECTED Manufacturer of Drug Products

Emmanuel T Donyina
 Investigator
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 Date Signed: 03-16-2026 17:59:02

**SEE REVERSE
OF THIS PAGE**

EMPLOYEE(S) SIGNATURE
 Emmanuel T Donyina, Investigator
 Alice S Tsao, Investigator

Alice S Tsao
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DATE ISSUED
 3/6/2026