

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER US Food and Drug Administration, ORA, NYK-DO 158-15 Liberty Avenue, Jamaica, NY 11433, USA Phone: 718-340-7000 Fax: 301-662-5651 Email: ORANYKFirmResponses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 01/17 thru 20, 23 and 30/17
	FEI NUMBER 3005734706

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Mr. Stephen S. Laddy, CEO

FIRM NAME MasterPharm LLC	STREET ADDRESS 115-02 Liberty Avenue
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CITY, STATE AND ZIP CODE Richmond Hill, NY 11419	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile and Non-sterile Drug Products
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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:

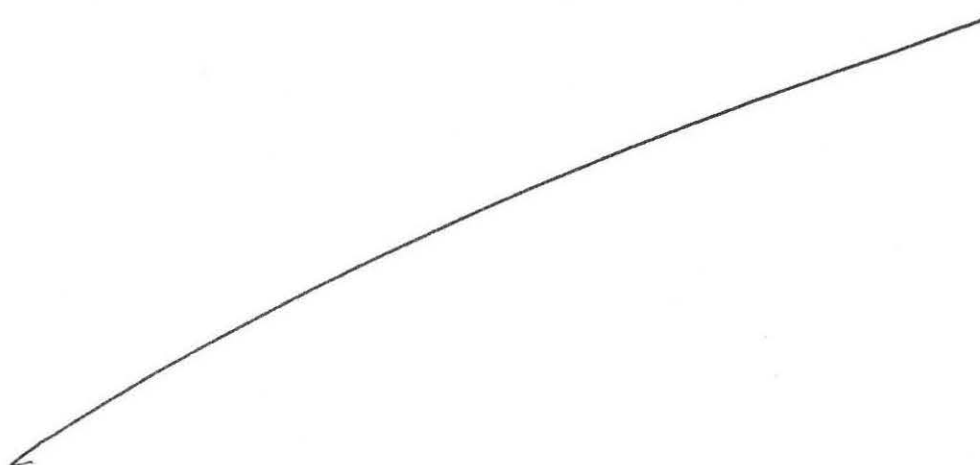
Observation 1

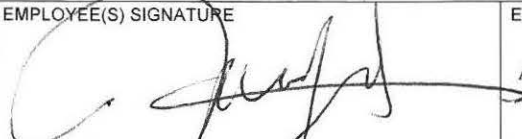
Failure to conduct adequate aseptic process stimulation (APS). Specifically,

- (A) failure to submit the vials produced from the APS for sterility testing in a timely manner.
- (B) failure to submit all vials produced from the APS for sterility testing.

Observation 2

Failure to depyrogenate stoppers used in the production of sterile compounding products.



SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Alice S. Tsao, CSO	DATE ISSUED 01/30/2017
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