

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 12420 Parklawn Drive, Room 2032 Rockville, MD 20857 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 11/05/19 - 11/12/19
	FEI NUMBER 1000171152

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Mr. Mikael Ericson, General Manager

FIRM NAME Recipharm Monts	STREET ADDRESS Site de Monts Sud, 18 rue de Montbazou
CITY, STATE AND ZIP CODE Monts, Indre Et Loire, 37260, France	TYPE OF ESTABLISHMENT INSPECTED Sterile Drug Manufacturer

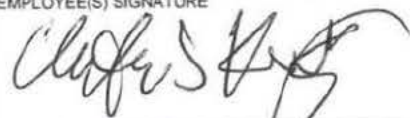
THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS, AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO 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:

1. Records of the inspections of automatic, mechanical or electronic equipment, including computers or related systems are not maintained.

Specifically,

- a) You have not installed the labeling and packaging line or performed any qualification for the labeling and packaging of (b) (4) injection.
- b) You did not adequately perform installation qualification of the (b) (4) filling line for (b) (4) as specified in the qualification protocol.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Christopher S. Keating, Investigator	DATE ISSUED 11/12/2019
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