DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd, third floor Parsippany , New Jersey, 07054 973-331-4900 Industry Information: www.fda.gov/oc/industry	08/27-30/2018, 09/13/2018, 09/25/2018 & 09/27/2018
	FEI NUMBER 3011761882

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Mr. Mark Taylor, RPh, FACVP, Chief Executive Officer

FIRM NAME	STREET ADDRESS
Curexa	3007 Ocean Heights Ave.
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Egg Harbor, New Jersey 08234	Producer of sterile and non-sterile Prescription drugs

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:

Sterile, injectable liquid dosage form preparation

OBSERVATIONS 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written or followed.

Specifically,

Records to demonstrate the cleanroom meets the required grade suitable for sterile filling are inadequate.

For example.

a. Air changes reported by the contracted provider of service do not meet ISO 5 and ISO 6 standards.
b. Although the suite designated for sterile processing uses magnehelic gauges, there are no records to demonstrate the differential pressure conditions suitable for ISO 5, ISO 6 and ISO7 are maintained during sterile filling.
c. Environmental monitoring records do not include continual sampling of non-viable particles to show the rooms/ hoods classified as ISO 5, ISO 6 or ISO 7 maintain acceptable conditions for intended operations.

Inspection dates: 08/27/2018, 08/28/2018, 08/29/2018, 08/30/2018, 09/13/2018, 09/25/2018 & 09/27/2018

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Frederick Razzaghi, Investigator	09/27/2018