DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
San Francisco District 1431 Harbor Bay Pkwy Alameda, CA 94502 (510) 337-6700 Industry Information: www.fda.gov/oc/industry	05/09/17 - 05/11/17
	FEI NUMBER 3012200488

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Michael B. Bitar, Pharmacist in Charge

FIRM NAME	STREET ADDRESS
Meditech Laboratories, Inc.	3200 Polaris Ave., #27
CITY, STATE AND ZIP CODE Las Vegas, NV 89102	TYPE OF ESTABLISHMENT INSPECTED Producer of non-sterile 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 (I) (WE) OBSERVED:

OBSERVATION 1

Drugs were produced without providing adequate containment and cleaning of utensils to prevent cross-contamination.

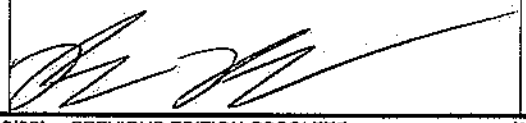
Specifically,

On 05/09/2017, a plastic scoop used to scoop out bulk drug substances for production was observed in the drawer in the production area containing visible white powder residue. Your firm's pharmacist in charge was unable to identify what the substances are and unable to determine when it was last cleaned. Your pharmacy technician confirmed this was the only scoop used for compounding in the entire facility. The most recent products were produced 4 days prior on 05/05/17 and include:

- Imperex Plus Lot 050517-IP produced on 05/05/17
- Imperex Lot 050517-I produced on 05/05/17
- Imperex Plus Lot 050117-IP produced on 05/01/17

The firm has also produced the following products this year in 2017:

- GCB – Gabapentin 10%, Cyclobenzaprine 6%, Bupivacaine 5% Cream
- FBD – Flurbip. 20%, Baclofen 5%, DMS 2%, Camphor 2%, Cap 0.025% Cream
- KBC - Ketoprofen 20% / Baclofen 2% / Cyclobenzaprine 2% Cream

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Rumany C. Penn, Investigator	05/11/2017