DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	1/28/2019-2/5/2019*
	FEI NUMBER 3002957541

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Pankaj Shitole, Senior General Manager - Operation

FIRM NAME	STREET ADDRESS
Sun Pharmaceutical Medicare Limited	Survey No. 22 & 24, Ujeti, Baska, Panchmahal
CITY, STATE, ZIP CODE, COUNTRY Halol, Gujarat, 389350 India	TYPE ESTABLISHMENT INSPECTED Pharmaceutical 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 OBSERVED:

OBSERVATION 1

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

Your firm has invalidated Out-of-Specification (OOS) results obtained during re-dispersibility tests attributing to human error as summarized below:

a) Investigation, PR ID 141361 was initiated on 12-OCT-2018 when OOS results for re-dispersibility were obtained during the testing of (b) (4) (b) (4) mg/mL, (b) (4) mL bottle (Lot# (b) (4) at 12M CRT stability sample (on-the-side orientation). The following OOS results were obtained (Specification: (b) (4) % – (b) (4) % of label claim):
Bottle-1: (b) (4) %
Bottle-2: %
Bottle-3: %

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Tamil Arasu, Investigator X Tamil Arasu Investigator Signed By 2001563486 Date Signed 02-05-2019 04 29 11	2/5/2019

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	1/28/2019-2/5/2019* FEI NUMBER 3002957541

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Pankaj Shitole, Senior General Manager - Operation

FIRM NAME	STREET ADDRESS
Sun Pharmaceutical Medicare Limited	Survey No. 22 & 24, Ujeti, Baska, Panchmahal
CITY, STATE, ZIP CODE, COUNTRY Halol, Gujarat, 389350 India	TYPE ESTABLISHMENT INSPECTED Pharmaceutical Manufacturer

OOS results on all the three bottles were attributed to the failure of analyst not shaking the samples adequately during sample preparation, without additional supporting evidence. Passing average results of (b) (4) %, (b) (4) %, and (b) (4) % were reported after a re-test with second analyst.

b) Similarly, additional OOS results on redispersibility test were invalidated for (b) (4) (b) (4) after root causes were attributed to human error during sample preparation without substantiating with adequate evidence. However, retested passing results were reported. Such investigations include:

PR ID#	LOT#	Stability Test / Orientation	Specification	Initial Results (3 bottles)	Reported Results (3 bottles)
214835	(b) (4)	3M CRT / (b) (4)	(b) (4) % – (b) (4) %	(b) (4) % % %	(b) (4) % % %
216619	(b) (4)	3M CRT / (b) (4)	(b) (4) % – (b) (4) %	(b) (4) % % %	(b) (4) % %
216619	(b) (4)	3M CRT / (b) (4)	(b) (4) % – (b) (4) %	(b) (4) % %	(b) (4) % %
216248	(b) (4)	3M CRT / (b) (4)	(b) (4) % – (b) (4) %	(b) (4) %	(b) (4) % %
216248	(b) (4)	3M CRT / (b) (4)	(b) (4) % – (b) (4) %	(b) (4) % %	(b) (4) % % %

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Tamil Arasu, Investigator

X Tamil Arasu
Investigator
Signed By: 2001563486
Date Signed: 02-05-2019 04:29:11

DATE ISSUED
2/5/2019

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	1/28/2019-2/5/2019*
	FEI NUMBER 3002957541

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Pankaj Shitole, Senior General Manager - Operation

FIRM NAME	STREET ADDRESS
Sun Pharmaceutical Medicare Limited	Survey No. 22 & 24, Ujeti, Baska, Panchmahal
CITY, STATE, ZIP CODE, COUNTRY Halol, Gujarat, 389350 India	TYPE ESTABLISHMENT INSPECTED Pharmaceutical Manufacturer

These tests have been performed by different analysts and all have been trained in sample preparation.

***DATES OF INSPECTION**

1/28/2019(Mon), 1/29/2019(Tue), 1/30/2019(Wed), 1/31/2019(Thu), 2/01/2019(Fri), 2/04/2019(Mon), 2/05/2019(Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Tamil Arasu, Investigator	X Tamil Arasu Investigator Signed By 2001563486 Date Signed 02-05-2019 04 29 11	2/5/2019