

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER USFDA CDER Office of Surveillance, Inspection Assessment Branch 10903 New Hampshire Avenue Bldg. 51, Room 4135 Silver Spring, MD 20993 Phone: 301-796-3334 E-mail: CDEROSIAB@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 02/05/2018 - 02/15/2018
	FEI NUMBER 1000623515

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Mr. Venkat Jasti, Chairman and CEO

FIRM NAME Suven Life Sciences Limited	STREET ADDRESS Plot Nos. 262-271 IDA, Pashamylaram Sangareddy District
CITY, STATE AND ZIP CODE Telangana, India 502307	TYPE OF ESTABLISHMENT INSPECTED Intermediate, API, and Finished Dosage 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:

OBSERVATION 1

Appropriate controls are not exercised over computer or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically,

A. Your firm has a total of (b) (4) HPLCs and (b) (4) UPLCs used to analyze raw material, finished product, and related substances for products marketed and distributed to the US. The HPLCs and UPLCs use either Empower 3 or EZ CHROM ELITE, which have audit trail capabilities. However, your firm could not provide documentation these audit trails have been electronically reviewed by quality personnel.

B. Your firm's Manager of Quality Assurance and Deputy Manager of QC verified your firm did not conduct electronic data review for any analysis performed in the QC Formulations Laboratory prior to August 2017.

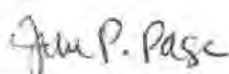
OBSERVATION 2

Equipment and utensils are not cleaned and maintained to prevent contamination that would alter the safety, identity, strength, quality or purity of the Intermediates and APIs manufactured.

Specifically, on 05 February 2018 and 08 February 2018, during the inspection of your (b) (4) which are used in the manufacturing process for varied APIs in Production Block-(b) (4) Area. Your firm failed to adequately clean and visually inspect the following (b) (4)

A. (b) (4) - 3109 is used in the production of (b) (4) API/Intermediate: I observed what appears to be discoloration resembling (b) (4) inside the (b) (4) -3109 in areas that come into direct contact with drug product. The status of this non-dedicated (b) (4) was identified as cleaned.

B. (b) (4) - 3139: I observed the gasket used to protect the (b) (4) and the (b) (4) of (b) (4) 3139 was

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wrapped in Teflon tape and starting to unravel. I observed what appeared to be missing pieces of the Teflon tape at the bottom of the (b)(4). In addition, I observed what appeared to be a white, powdery residue along the inside of the (b)(4). The status of this equipment was identified as cleaned and a visual inspection was documented in the Equipment Use Logbook.

C. (b)(4)-3137: I observed what appears to be (b)(4) residue and black residue alongside the sides of this (b)(4). In addition, I observed the (b)(4) bolts located on the bottom of the (b)(4) that comes in direct contact with drug products to have a (b)(4) discoloration. I observed a hole at the bottom of the (b)(4) indicating this (b)(4) is damaged. The Equipment Use Logbook documents the equipment qualifications were completed on 29 December 2017 and the status of this non-dedicated equipment was identified as cleaned.

OBSERVATION 3
 Manufacturing Batch Records are deficient.


Specifically,
 A. On 13 February 2018, your firm failed to document in-process checks during the manufacturing of the drug product, (b)(4) Tablets, Batch # (b)(4) on Form, F/CQO-F/320, as outlined in Step (b)(4) of the Batch Manufacturing Record. However, this step was verified by your firm's Quality Assurance.

B. Recorded weights are not verified by a second verifier.

OBSERVATION 4
 Procedures for sampling of raw materials were not followed.

Specifically, on 05 February 2018, I observed the raw material, (b)(4) (Batch # (b)(4)) did not contain the appropriate number of sampled containers as written in your firm's written procedures for raw material sampling (SOP/CQO/3024).

OBSERVATION 5
 Label access is not controlled.

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THIS IS A REPEAT OBSERVATION

Specifically, the label storage room that contains printed packaging materials for (b)(4) Capsules and (b)(4) Tablets was observed to be unlocked by your firm's Corporate Quality Manager during a walkthrough of production on 12 February 2018.

OBSERVATION 6

Employees engaged in the manufacture, processing, packing, and holding of a drug product lack the training required to perform their assigned functions.

THIS IS A REPEAT OBSERVATION

Specifically, your firm failed to conduct cGMP training for (b)(4) % of (b)(4) selected employees performing Quality related functions, such as, production, quality control, and quality assurance in 2016.

OBSERVATION 7


Your firm's Product Quality Reviews (PQRs) are deficient.

Specifically,

A. 2017 PQR for (b)(4) Capsules (review period January 2016 – December 2017):

- Does not address corrective and preventative actions implemented for out of specification (OOS16-005) for (b)(4) content for (b)(4) Capsules (b)(4) mg, Batch # (b)(4)
- Is missing change control (EN/CCP/17/5036) for the installation of new equipment in the packing line (b)(4) Inserting Machine, (b)(4) Machine, (b)(4) Labeling Machine, (b)(4) Overprinting, Leaflet in Outserter Machine, and Torque Machine), which were qualified and installed in 2017.
- In addition, your firm's written procedures for Product Quality Review (SOP/CQO/3021), defines the product review period as a calendar year from January to December. However, the 2017 PQR for (b)(4) covers a review period of January 2016 – December 2017. A Deviation was not provided.

B. Your firm's PQR for (b)(4) Tablets does not address corrective and preventative actions

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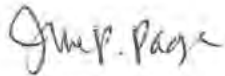
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implemented for an out of specification (OOS) for the following:

- OOS 17-002: Unknown impurity peaks were found in ^{(b) (4)} Tablets, Batch # ^{(b) (4)}, dated 7 March 2017.
- OOS 17-003: Sub-potent assay results for ^{(b) (4)} tablets, Batch # ^{(b) (4)} and Batch # ^{(b) (4)} dated 17 March 2017.

C. Your firm's APQR for ^{(b) (4)} Capsules does not address corrective and preventative actions implemented for an out of specification (OOS) for the following:

- OOS 17-002: Unknown impurity peaks were found in ^{(b) (4)} Capsules, Batch # ^{(b) (4)} dated 7 March 2017.

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