DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CDER/International Compliance Team 10903 New Hampshire Ave., Bldg. 51, Rm. 4225 Silver Spring, MD 20993 U.S. Tel: 001-301-796-3334 Fax: 001-301-847-8738 Email: cderict@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	November 17 - December 01, 2016
	FEI NUMBER 3002809586

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Madhukar Ramdin, Senior Vice President of Operations and Halol Site Head

FIRM NAME	STREET ADDRESS
Sun Pharmaceutical Industries Limited	Halol-Baroda Highway
CITY, STATE AND ZIP CODE Halol, Gujarat 389350, India	TYPE OF ESTABLISHMENT INSPECTED Sterile and Non-Sterile Drug Product Manufacturer

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1

Field Alert Reports were not submitted within three working days of receipt of information concerning bacteriological contamination and significant chemical, physical, or other change or deterioration in a distributed drug product.

Specifically,
1) Investigation IN-JK-2015-0271 was initiated 05MAY2015 for dissolution failure of 18M long-term stability samples of Buproprion HCl extended release tablets, 200mg, Batch JKM4152A. An initial Field Alert Report (FAR) for batch JKM4152A was submitted to the agency 07MAY2015. Product impact assessment of the investigation included dissolution testing of reserve samples of Batch #'s JKM4737A and JKM5270A of Buproprion HCl extended release tablets, 200mg, completed 30-31MAY2015 with out-of-specification and borderline L3 results, respectively, recorded on 01JUN2015.
However, no separate Field Alerts were submitted for the dissolution failure/borderline results of Batch #'s JKM4737A and JKM5270A, and no notice of their failing/borderline results were submitted to the agency until notification of their recall on 08JUL2015. No follow-up Field Alert was submitted for failing/borderline dissolution results of Batch #'s JKM4737A and JKM5270A, until final FAR submission for Batch JKM4152A on 31JUL2015.

2) OS-JK-2016-0749 was initiated 09OCT2016 for L3 dissolution failures of 23M control samples of Buproprion HCl extended release tablets, 150mg Batch #'s JKN5125A and JKN5232A, and the L1 failure of 23M control samples of Batch JKN5275A. 23M sample L1 failures were identified 07OCT2016, L2 failures were identified 11OCT2016, and L3 failures (high individual tablet and mean values at 2 and 4hrs.) were identified 13OCT2016. A sufficient quantity of control samples of Batch JKN5275A was not available to perform L2 and L3 testing to confirm dissolution failure.

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An initial Field Alert for the 3 batches was submitted 24OCT2016. Incident IN-JK-2016-1378 was raised for the delayed FAR submission citing human error and referencing low risk as each of the batches were nearing their expiry of (b) (4)

3) OS-JK-2016-0275 was initiated 21APR2016 for L3 dissolution failure of 22M long-term stability samples of Buproprion HCl extended release tablets, 150mg Batch JKN0236A. 22M sample L1 failures were identified 07JAN2016, L2 failures were identified 13JAN2016, and L3 failures (5 high individual tablet values at 2hrs. and high mean values at 2 and 4hrs.) were not identified until (b) (4)

A deviation for the excessive hold time between 22M stability sample withdrawal on 07DEC2015 and the start of analysis was documented in an "Analysis Time Deviation Register". The entry states "Analysis not performed within timeline due to analyst busy with other priority work." Incident IN-JK-2016-0461 was initiated 15APR2016 for the excessive delay of L3 testing of Batch JKN0236A. The analyst performing the 22M testing failed to identify the failing L2 results; a secondary review on 14FEB2016 by a Quality Control Supervisor failed to identify the failing L2 results; and the failure to progress to L3 testing was identified during Quality Assurance review on 13APR2016. No stability samples for Batch JKN0236A remained and control samples were used for L3 dissolution testing for 22M stability studies.

No individual FAR was submitted for Batch JKN0236A and the 15APR2016 dissolution failure of Batch JKN0236A was not communicated to the agency until submission of a follow-up FAR for Batch JKN3477A on 13JUN2016. As Batch JKN0236A was expired at the time of the OOS L3 testing, no immediate corrective action was taken.

4) OS-JK-2016-0546 was initiated 28JUL2016 for out-of-trend L2 dissolution results of 21M control samples of Buproprion HCl extended release tabs, 150mg Batch JKN5124A, at 2hrs. L3 failures (high individual tablet and high average values at 2 and 4hrs.) were then identified 31JUL2016 (at 21M shelf-life). Notice of the failure was not communicated to the agency until follow-up FAR submission for Batch JKN3477A on 12AUG2016.

5) OS-JK-2016-0533 was initiated 01AUG2016 for L3 dissolution fail of 21M control samples of Burproprion HCl extended release tabs, 150mg Batch JKN5229A, at 2 and 4hrs. L3 failure (average high value at 4hrs.) was identified 31JUL2016 (at 21M shelf-life). Notice of the failure was not communicated to the agency until follow-

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up FAR submission for Batch JKN3477A on 12AUG2016.

6) [(b) (4)]-14/060 was initiated 09DEC2014 for identification of 1 turbid vial from Population-1 (normally filled, processed units) and 1 turbid vial from Population-2 (normally rejected units due to interventions) of Media Fill Batch [(b) (4)] following 14 days incubation.

Media Fill Batch [(b) (4)] executed 03NOV2014 as a post-inspectional commitment to the September 2014 U.S. FDA inspection, simulated filling of [(b) (4)] units total on the [(b) (4)] Line [(b) (4)] and [(b) (4)] in the firm's [(b) (4)]. Annexure-I of [(b) (4)]-14/060, "Interim Report", states that probable root cause of the turbid vial in Population-1 was identified as the failure to [(b) (4)] forceps following the simulated [(b) (4)] of the stopper [(b) (4)] chute and [(b) (4)] the clearance of [(b) (4)] stopper jams, a routine operation during commercial production. Probable root cause of the turbid vial in Population-2 was identified as poor aseptic technique prior to and during the simulated removal of [(b) (4)] broken vials.

Prior to the 22NOV2014 execution of Media Fill Batch [(b) (4)], the most-recent successful media fill on Line [(b) (4)] was performed in April 2014 (Batch [(b) (4)]. No Field Alert was submitted for the bacteriological contamination identified in Media Fill Batch [(b) (4)] potentially affecting the sterility assurance of batches of sterile [(b) (4)] products filled on Line [(b) (4)] from 14APR-03NOV2014.

OBSERVATION 2

Drug products do not bear an expiration date determined by appropriate stability data to assure they meet applicable standards of identity, strength, quality and purity at the time of use.

Specifically, the [(b) (4)] proposed expiries of Buproprion HCl extended release tablets of 150mg and 200mg strengths were based on 3M accelerated data for exhibit batches at the time of [(b) (4)] [(b) (4)] filing. 24M of long-term data to support the proposed expiries were generated for exhibit batches as of 08AUG2008 and confirmed dissolution failures of samples at time points of 18-24M have been identified by (but not limited to) the following:

150mg
• L2/314/2014, initiated 23SEP2014 for 24M long-term stability samples of Batch JKL4403A

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- OS-JK-2016-0275, initiated 21APR2016 for 22M long-term stability samples of Batch JKN0236A
- OS-JK-2016-0311, initiated 10MAY2016 for 21M control samples of Batch JKN3477A
- OS-JK-2016-0546, initiated 28JUL2016 for 21M control samples of Batch JKN5124A
- OS-JK-2016-0533, initiated 01AUG2016 for 21M control samples of Batch JKN5229A
- OS-JK-2016-0749, initiated 09OCT2016 for 23M control samples of Batch #'s JKN5125A, JKN5232A, and JKN5275A
- OS-JK-2016-0809, initiated 09NOV2016 for 24M control samples of Batch JKN5228A

200mg
- L2/122/2015, initiated 05MAY2015 for 18M long-term stability samples of Batch JKM4152A
- OS-JK-2016-0319, initiated 13MAY2015 for 23M control samples of Batch JKN2114A

Investigation OS-JK-2016-0524 was initiated 26MAY2015 to include dissolution analysis of all live market batches of 150mg to be carried out at 15/18/21/24M of shelf life according to Protocol SUN/NS-SP/300/01, yet no revision of the (b) (4) assigned expiry period of Buproprion HCl extended release tablets has been submitted to the agency to date.

OBSERVATION 3

Testing programs are not adequately designed to assess the stability characteristics of drug products.

Specifically, test schedules established by stability protocols are not adhered to so as to characterize the degradation of products over their actual shelf-lives. For example:

- 24M stability samples of Buproprion HCl 150mg Batch JKL4403A (expiry (b) (4)) were not analyzed until (b) (4) (b) (4) of shelf-life) at which time dissolution failure was documented by OOS L2/314/2014. No FAR was submitted for the 24M failure of Batch JKL4403A as it was expired at the time of analysis.
- 22M stability samples of Buproprion HCl 150mg Batch JKN0236A (expiry (b) (4)) were not analyzed until (b) (4) (b) (4) of shelf-life) at which time dissolution failure was documented by OS-JK-2016-0275. No FAR was submitted for the 22M failure of Batch JKN0236A as it was expired at the time of analysis.
- 18M stability samples of Buproprion HCl 200mg Batch JKM4152A (expiry (b) (4)) were not analyzed until

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04MAY2015 (20M of shelf-life) at which time dissolution failure was documented by L2/122/2015. An initial FAR was submitted for the 18M failure of Batch JKM4152A on 07MAY2015 and initial notice of its recall was submitted 08JUL2015 (22M of shelf-life).

• 23M control samples of Buproprion HCl 200mg batch JKN2114A (expiry (b) (4)) were not analyzed until (b) (4) (b) (4) of shelf-life) at which time dissolution failure was documented by OS-JK-2016-0319. No FAR was submitted for the 23M failure of Batch JKN2114A as it was expired at the time of analysis.

OBSERVATION 4

The establishment of test procedures, including any changes thereto, are not adequately reviewed and approved by the quality control unit.

Specifically, OS-JK-2016-0078 was initiated 02FEB2016 for (b) (4)2 dissolution failure of finished product samples of (b) (4) (b) (4) tablets, (b) (4) (b) (4) mg Batch (b) (4). No root cause was identified during the laboratory investigation and the failure was referred to Production for investigation under IN-JK-2016-0151; IN-JK-2016-0151 identified no root cause of failure in production activities. A 21MAY2016 addendum to the OOS investigations for Batch #'s (b) (4), (b) (4), and (b) (4) of (b) (4) (b) (4) mg (b) (4) tablets references dissolution studies conducted by the (b) (4) in (b) (4) under Protocol MVT/244/2015 which identified the de-aeration of dissolution medium as the root cause of the failure of each batch. Data generated by (b) (4) under Protocol MVT/244/2015 indicated an ~10% increased value of mean drug release when dissolution medium was not degassed. Analytical Test Procedures for (b) (4) (b) (4) mg, (b) (4) (b) (4) mg, and (b) (4) (b) (4) mg for (b) (4) (b) (4) tablets were updated per Change Control CC-JK-2016-1335 on 10MAY2016 to preclude the de-aeration of dissolution medium .

Re-analysis of each failing batch was performed according to a revised test method without de-aeration of dissolution medium with results for (b) (4) active ingredients passing (b) (4)1 + (b) (4)2 criterion, and the batches were approved for release with the MAY2016 closure of their respective investigations. However,

1) No assessment of the accuracy of dissolution data generated for batches tested and released under previous revisions of ATPs for (b) (4) dosage strength (requiring de-gassing of dissolution medium) was performed upon implementation of CC-JK-2016-1335. For example, although original, failing dissolution data sets for Batch #'s

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(b) (4), (b) (4) and (b) (4) (generated according to Revision 05 of ATP0011144) were invalidated and each batch was re-tested and released under Revision 06 of ATP 0011144. there has been no re-evaluation of the accuracy of dissolution testing results generated for (b) (4) (b) (4) mg batches of (b) (4) generated and released under Revisions 00-05 of ATP 0011144.

2) Although classified as a Level 2 "moderate" change, CC-JK-2016-1335 identifies no significant impact to quality or regulatory filing. It further states that notice of the method's revision was to be submitted in the next Annual Product Report for (b) (4) tabs.

The analytical test procedure for dissolution submitted in (b) (4) (b) (4) for (b) (4) tablets, is silent on the requirement for de-aeration of dissolution medium, and no specific requirement to not de-aerate dissolution medium is noted in the USP monograph for (b) (4) tablets. The change to the method approved in (b) (4) (b) (4) for dissolution testing of (b) (4) (b) (4) tablets without de-aeration of dissolution medium was implemented with no prior notice to or conference with the applicable CDER Reviewing Division, nor with the submission of any (b) (4)

OBSERVATION 5

The accuracy of test methods has not been established.

Specifically, validation the dissolution test method for (b) (4) tablets was performed according to Report MJ/ANAR/210 (eff. 24SEP2005). It includes studies of specificity/selectivity, precision, intermediate precision, linearity and range. No specific evaluation of method accuracy was performed.

Section 7 of Report MJ/ANAR/210 contains no requirement to avoid de-aeration of dissolution medium as implemented with the 10MAY2016 revision of Analytical Test Procedures for (b) (4) (b) (4) mg, (b) (4) (b) (4) mg, and (b) (4) (b) (4) mg strengths of (b) (4) tablets under CC-JK-2016-1335. No re-validation was performed to assess the effect of the change on method accuracy prior to its implementation for testing of commercial and stability batches of (b) (4) tablets.

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OBSERVATION 6

Scientifically sound and appropriate laboratory control mechanisms are not established to assure that components, drug product containers, closures, in-process materials, or drug products conform to appropriate standards of identity, strength, quality and purity.

Specifically,

1) Upon visual inspection following (b) (4) incubation of Media Fill Batch (b) (4), a (b) (4) (b) (4) fill on (b) (4) (b) (4) Line (b) (4) and simulated (b) (4) of (b) (4) mL vials using the (b) (4) the entirety of Population-1 and -2 were suspected for turbidity and Incident IN-JK-2015-0137 was initiated (b) (4). A (b) (4) unit from (b) (4) Run of Population-1 ((b) (4) vials total) and a (b) (4) unit from Population-2 were sent to the Microbiology Laboratory for evaluation. The notebook of Analyst (b) (6), 568/2014, documents loading of the samples at (b) (4) (b) (4) °C into Incubator QCC1090 from (b) (4) on (b) (4) until visual inspection at (b) (4) on (b) (4) a repeat visual inspection of the samples was performed following additional incubation at (b) (4) (b) (4) °C at (b) (4) on (b) (4) and third re-inspection of the samples was performed following additional incubation at (b) (4) (b) (4) °C at (b) (4) on (b) (4) each of which identified no turbidity. The vials were then returned back to QA for reunion with Batch (b) (4) on (b) (4) The remainder of Population-1 and -2 of Batch (b) (4) were immediately incubated at (b) (4) (b) (4) °C for an additional (b) (4) as normal.

No standard operating procedure for the assessment of turbid containers was in effect prior to 22JUL2015, and no cultivation of the contents of the suspected turbid vials of Media Fill Batch (b) (4) was performed to confirm and identify (or disprove) contamination either prior to or following incubation at (b) (4) (b) (4) °C.

2) Re-validation of disinfectant efficacy failed to include an evaluation of a specific organism isolated from various means of sampling throughout ISO classified clean areas, namely Staphylococcus cohnii. For example, OOS #OS-JK-2015 (Trackwise PR No. 49522) was created on 02OCT2015 due to a case of disinfectant efficacy studies failing to achieve a (b) (4) log reduction of test organisms. Instead, less than 1 log reduction was achieved during the in process step of (b) (4) for (b) (4) capsule, (b) (4) mg Batch (b) (4) The isolated organism recovered during the incident was Staphylococcus cohnii. Re-validation of disinfectant efficacy included an evaluation of ATCC test organisms specified by USP plus in-house isolates, but failed to include an evaluation of efficacy against Staphylococcus cohnii.

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3) Trend data for Personnel Monitoring of the [redacted] (b) (4) for the months of September and October 2016, identifies the following:

a. On 26OCT2016, chest samples from operator "[redacted] (b) (6) (b) (4)" in an ISO Grade B area of [redacted] (b) (4) resulted in over-action limit (OAL) recovery of 15cfu/plate (investigation referred to Trackwise PR 128627, not yet completed);
b. On 25OCT2016, right hand glove samples from operator "[redacted] (b) (6) (b) (4)" in an ISO Grade B area of [redacted] (b) (4) resulted in OAL recovery of 7cfu/plate (investigation referred to PR 128627, not yet completed);
c. On 18OCT2016, right hand glove samples from operator "[redacted] (b) (6)" in an ISO Grade B area of [redacted] (b) (4) resulted in OAL recovery of 7cfu /plate (investigation referred to PR 127171);
d. On 14SEP2016, right and left hand glove samples from operator "[redacted] (b) (6) (b) (4)" in an ISO Grade B area of [redacted] (b) (4) resulted in OAL recoveries of f 12cfu/plate and 6cfu/plate, respectively (referred to PR 120333);
e. On 17SEP2016, right hand glove samples from operator "[redacted] (b) (6) (b) (4)" in an ISO Grade B area of [redacted] (b) (4) resulted in OAL recovery of 7cfu/plate (referred to PR 120333);
f. On 17SEP2016, forearm and goggle samples from operator "[redacted] (b) (6) (b) (4)" in an ISO Grade B area of [redacted] (b) (4) resulted in OAL recoveries of [redacted] (b) (4) cfu /plate for each (referred to PR 120333);
g. On 14SEP2016, right and left hand glove samples from operator "[redacted] (b) (6) (b) (4)" in an ISO Grade A area of [redacted] (b) (4) resulted in OAL recoveries of [redacted] (b) (4) cfu/plate and 6cfu/plate, respectively (referred to PR 120333);
h. On 14SEP2016, right and left hand glove samples from operator "[redacted] (b) (6) (b) (4)" in an ISO Grade B area of [redacted] (b) (4) resulted in OAL recoveries of [redacted] (b) (4) cfu/plate and 6cfu/plate, respectively (referred to PR 120333).
Identification for each of these OAL recoveries determined isolates to consist of a variety of Gram-stain negative, Gram-stain positive, and fungal organisms to include Staphylococcus cohnii (recovered in both ISO Grade A and B areas).

In addition, a series of viable particle monitoring excursions occurring in [redacted] (b) (4) Block [redacted] (b) (4) from 23MAR-05MAY2016 are documented in Report SUNS/S-CSR/133/01R. 107 isolates of a total 233 contaminants failed to be identified, an additional 25 failed to be identified to the species level ("Micrococcus spp." genus level), and Staphylococcus cohnii was also isolated from various sampling locations.

Furthermore, the following Trackwise PR numbers identify the recovery of revealed Staphylococcus cohnii: 116212 ([redacted] (b) (4) ISO Grade A area), 86187 ([redacted] (b) (4) ISO Grade A & B areas), 44201 ([redacted] (b) (4) capsule production in-

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process area), 43983 ([(b) (4)] capsule [(b) (4)] mg 12M long-term stability sample microbial limit testing). However, Staphylococcus cohnii has not been used as a test organism in the evaluation or re-evaluation of the effectiveness of various sterility assurance controls.

4) Routine performance verification of [(b) (4)] used for various functions throughout the facility, performed [(b) (4)] [(b) (4)] fail to include calibration of the [(b) (4)] internal digital clocks. Accuracy of [(b) (4)] digital clocks have only been verified upon initial qualification of each unit. For example, upon review of the September 2016 routine performance verification of the microbiology department's [(b) (4)] a Micro-Lab-1 [(b) (4)] Sterilizer (Instrument ID QCC-788), documented by Qualification Report QUA/2124 (rev. 00), no calibration nor verification of the accuracy of the [(b) (4)] digital timer/clock was performed. Verification of the digital timer/clock of [(b) (4)] QCC-788 has only been performed upon initial validation. A similar failure to evaluate the performance of digital timers/clocks is documented for the [(b) (4)] [(b) (4)] used for terminal sterilization of drug products (Instrument ID D200) by the July 2016 Qualification Report QUA-S/0042 (rev. 00), Supplement 1.

5) No information for anaerobic jar and gas pack (to include lot number and expiry) was documented on a worksheet form F/QCM-042/014/02, "Report Format for Environmental Monitoring". For example, anaerobic testing and results data, documented on Form "Format for Environmental monitoring [(b) (4)] Filling Line)", fails to track or record the anaerobic jar and gas pack used on laboratory worksheets.

OBSERVATION 7

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically,
1) L1/476/2014 was initiated 04SEP2014 for [(b) (4)]3 dissolution failure of 3M long-term samples of [(b) (4)] [(b) (4)] [(b) (4)] tabs [(b) (4)] [(b) (4)] mg Batch [(b) (4)]. No assignable root cause was identified during the laboratory investigation, an initial Field Alert Report for Batch [(b) (4)] was submitted on 10SEP2014, the investigation was extended as ER-QCC-14/189, and no assignable root cause was identified in production. Upon release testing, Batch [(b) (4)] was passing at [(b) (4)]3 only. Review of dissolution result trend data for batches of similar age or older than the subject batch identified one additional batch released after meeting [(b) (4)]3

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criteria, [(b) (4)].

Although failing at 3M for low [(b) (4)] release and no assignable root cause could be identified, long-term stability test data for the 6M time point (28NOV2014) met acceptance criteria as of the time of investigation closure on 20JAN2015. SOP QA-014/08 specifies that product recall may need to be carried out for failure to meet regulatory specification/observation of quality defects, yet no market action was taken for Batch [(b) (4)] from SEP2014. Additionally, no market action was initiated for the other batch meeting [(b) (4)] criteria upon release, Batch [(b) (4)]. No Health Hazard Evaluations for Batch #'s [(b) (4)] and [(b) (4)] were performed.

2) [(b) (4)]-14/060 was reported 09DEC2014 for 1 turbid vial from Population-1 and 1 turbid vial from Population-2 of Media Fill Batch [(b) (4)] following 14 days incubation. Probable root cause of the turbid vial in Population-1 was identified as the failure to [(b) (4)] forceps following the simulated [(b) (4)] of the stopper [(b) (4)] chute and [(b) (4)] the clearance of [(b) (4)] stopper jams. Probable root cause of the turbid vial in Population-2 was identified as poor aseptic technique prior to and during the simulated removal of [(b) (4)] [(b) (4)] broken vials. Both interventions were performed by the same Production Operator who was properly trained in aseptic technique and fully qualified for aseptic operations at the time of contaminations.

Prior to the 22NOV2014 fill of Batch [(b) (4)], the most-recent successful media fill on Line [(b) (4)] was performed in April 2014 (Batch [(b) (4)]). The product impact assessment performed as part of Investigation [(b) (4)] [(b) (4)]-14/060 consists of a summary of the results for non-viable particulate count, surface examination, active air sampling, swab sampling, in-process [(b) (4)], and finished product sterility test data. The impact assessment fails to include a summary evaluation of personnel monitoring.

3) SOP QA-047 (rev. 07, eff. 14SEP2016) establishes general rules for personnel to follow good documentation practices during manufacturing activities. However, repeated failures to adhere to the requirements of SOP QA-047 include the following:

a) Manufacturing Investigation [(b) (4)]-14/061 was initiated 12DEC2014 for 1 turbid vial from Population-2 of Media Fill Batch [(b) (4)] following 14 days incubation. Media Fill Batch [(b) (4)] simulated sterile liquid filling on Line [(b) (4)] the firm's commitment to demonstrate [(b) (4)] successful process simulation on [(b) (4)] production line following the previous U.S. FDA inspection. Organisms from the turbid vial from Population-2 (Media Fill Run

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(b) (4) (b) (4) (b) (4) were identified as Staphylococcus cohnii. Contamination of the vial from (b) (4) (b) (4) was ascribed to the simulated removal of filled, fallen vials with forceps, a routine intervention. This intervention was performed by Operator "(b) (6)", and originally documented by Filling Supervisor "(b) (6)" during the filling of (b) (4) (b) (4) from (b) (4) (b) (4) on 26NOV2014.

An aborted overwrite and correction of the (b) (4) number filled during the simulated removal of fallen vials was corrected to "(b) (4) (b) (4)" with annotation by the correcting individual, a Production Officer "(b) (6)", on 12DEC2014. At least 1 additional review of the Batch Manufacturing Record (BMR) is identified by unrelated corrections made by "(b) (6)" on 06DEC2014. The BMR History Sheet references missing personnel monitoring data for an operator on 12DEC2014; a footnote on Page 70 of the BMR and an entry to the History Sheet by (b) (6) on 17DEC2014 identify 5 overwrites on Page 70 of the BMR (where six total are recorded); and no other changes to the BMR are noted on the History Sheet. Investigation (b) (4) 14/061 included interviews of both "(b) (6)" and "(b) (6)" on 02JAN2015 with no abnormal observations noted and provided no justification for failure to document the 12DEC2014 review and correction of the original 26NOV2014 entry by "(b) (6)".

b) OOS Investigation L2/380/2014 was initiated 06DEC2014 for (b) (4)2 dissolution failure of 18M long-term samples of (b) (4) (b) (4) tabs, (b) (4) (b) (4) mg Batch (b) (4) (b) (4) 1 failure was identified on 28NOV2014 and (b) (4)2 failure for individual low release of both (b) (4) (b) (4) active ingredients (units 1 and 6) + low mean release of (b) (4) was identified 06DEC2014. The OOS notes that upon interviewing the analyst on 08DEC2014, they observed baskets of each failing individual unit detach from the dissolution test apparatus shafts, fall to the bottom of their bowls, and not completely disintegrate into the dissolution media However, there is no analyst documentation of the baskets sinking or failure of units to disintegrate at the time of occurrence, no associated laboratory events, and no events noted during the initial (b) (4)2 analysis.

4) Appropriate measures are not taken to assure that batch control records include complete, original information relating to the production and control of each batch.

a) The issuance and handling of logbooks is described by SOP QCS-003/08 (eff. 01JAN2016. While controlled issuance and reconciliation of Quality Control Logbooks was in place since initial implementation of QC-S-003/01 on 01JUL2000 for a variety of equipment usage and analytical raw data test reports, including Bacterial Endotoxin Test Reports, Sterility Test Reports (Form F/QCM/036/004/01) were not included. Prior to

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12JUN2015, Sterility Test Report forms were issued as loose-leaf, uncontrolled sheets. Following a 12JUN2015 revision of Form F/QCM-036/004, controlled books consisting of sequentially numbered, perforated Sterility Test Reports in 3 different formats were issued for use. A 05OCT2015 revision of SOP QCS-003 to include Section 7.1.2 then formally required QC Section Heads to review for and invalidate any unnumbered pages in each controlled logbook upon issuance.

b) Prior to 17DEC2014, environmental monitoring test data sheets were issued as uncontrolled working copies. From 17DEC2014 – the 21SEP2016 implementation of the firm's Form Management System (FMS), original test data for environmental monitoring samples was documented in controlled, sequentially numbered logbooks

c) Prior to the 21SEP2016 implementation of FMS, Quality Assurance's issuance of microbial limit test (MLT) protocols was documented in a "Template/Protocol Issuance Register", Logbooks 911/2014, 001/2015, and 08300-2016-L1. Original test protocols were issued in loose-leaf form with the QA official's initials and date indicated on Page 1 only. The remainder of MLT protocols, including pages on which original test results were documented, contained no mechanisms to distinguishing between original issued and re-printed/copied versions.

d) Upon 21SEP2016 implementation, routine printing of controlled documents from the Form Management System is done in grayscale (black and white ink). However, the colored watermark designed to assure the integrity of controlled documents generated from FMS is compromised by printing original documents in grayscale. There is no means to distinguish between the original black & white printings of controlled documents with subsequent, uncontrolled black & white copies.

5) In response to observations cited during the September 2014 U.S. FDA inspection, a retrospective quality risk assessment of aseptic processes was performed (b) (4) according to Protocol SUN/S-QRM/004/02. According to SOP QA-059/05, failure modes assigned Risk Priority Numbers (RPNs) of > (b) (4) require adequate controlling measures to be taken. Line and product-specific Risk Assessments have not been updated to reflect the increased frequency of HEPA filter integrity testing performed, nor have the assigned RPN ratings been reevaluated, upon the identification and remediation of December 2014-May 2015 repeated HEPA filter failures. For example, FMEA-313 (eff. 15NOV2014) consists of the Quality Risk Assessment of aseptic processes performed in the (b) (4)

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• Investigation (b) (4) 14/055 was initiated 01DEC2014 following the observation of filter side leakage, media leakage, and out-of-limit air velocity during scheduled re-qualification for multiple HEPA filters throughout the (b) (4) aseptic production area on 29NOV2014. Management stated that as a partial corrective action, the existing (4) frequency of HEPA filter integrity testing was reduced to (b) (4) at that time.

• Investigation IN-JK-2015-0331 was initiated 23MAY2015 for HEPA filter media and side leakages and high air velocity during scheduled re-qualification for multiple HEPA filters throughout the (b) (4) aseptic production area on 20MAY2015. Management stated that as a partial corrective action, the existing (4) frequency of HEPA filter integrity testing was reduced to (b) (4) at that time.

Yet as of the time of the inspection, FMEA-313 consisted of a (b) (4) rating of "(b) (4)" assigned to Laminar Air Flow/Fan Filter (LAF/FFM) Module failures in (b) (4) based on the (b) (4) frequency of HEPA filter integrity testing. Laminar Air Flow/Fan Filter Module failures were assigned an overall RPN of "(b) (4)" ((b) (4)), thus requiring no additional mitigating factors.

OBSERVATION 8

Changes to written procedures are not drafted, reviewed and approved by the appropriate organizational units.

Specifically,

1) In response to Investigation (b) (4) 4/055, the (b) (4) frequency of HEPA filter integrity testing for LAF/FFM modules of (b) (4) was reduced to (b) (4). The change was not implemented according to a formal change control or pursuant to a Corrective Action Request. While implemented, the change was not formally reflected in the 20MAR2015 Revision 08 of SOP ENG-025.

2) In response to Investigation IN-JK-2015-0331, the (b) (4) frequency of HEPA filter integrity testing for LAF/FFM modules of (b) (4) was reduced to (b) (4). The change was not implemented according to a formal change control or pursuant to a Corrective Action Request. While implemented, the change had not been formalized as Section 7.3 of the current revision of SOP ENG-025/11 (eff. 19MAY2016) requires filter integrity and velocity tests to be completed (b) (4) (b) (4) with no exception noted for the current (b) (4) frequency applied to LAF/

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FFM modules in the [(b) (4)] or [(b) (4)] Areas.

OBSERVATION 9
Appropriate controls are not exercised to assure that changes to documents related to the manufacture of drug products are instituted only by authorized personnel.

Specifically, media fill BMRs include attachments of incubation room temperature graphs to verify the storage conditions of filled units. Raw data is transmitted to the M-947 Building Management System (BMS) unit in [(b) (4)] and compiled into [(b) (4)] data reports and graphs by G-Tek software. The data reports and graphs generated are retained in .pdf form by the [(b) (4)] department, but source electronic data for media fill incubation rooms acquired prior to July 2015 has not been retained. For example, data for the following specific events/time periods were not retained:

• Source data for temperature recording during 0-7D incubation of Media Fill Batch [(b) (4)] at [(b) (4)] - [(b) (4)] °C in ENG-002, identifying "communication errors" in which no data from sensor Channels [(b) (4)] appears in the firm's BMS system (approximately 1/2hr., around 15:00hrs. on 23MAR2015, 3hrs., 10:00-13:00hrs. on 24MAR2015, and 6hrs., 13:00-17:00hrs. on 24MAR2015).

Additionally, source data for high temperature excursion s of ENG-002 totaling 04:15hrs. are identified from 13:58-21:13hrs. on 20MAR2015.

• Source data and .pdf reports for temperature recording during the 0-7D incubation of Media Fill Batch [(b) (4)] at [(b) (4)] - [(b) (4)] °C in ENG-002 on 25MAR2015.

• Source data for temperature recording during 7-14D incubation of Media Fill Batch [(b) (4)] at [(b) (4)] - [(b) (4)] °C in ENG-001, identifying similar "communication errors" (approximately 1hr. each, 00:00-01:00 on 31MAR2015 and [(b) (4)], [(b) (4)] on 01APR2015).

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