OBSERVATION 1

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.

***THIS IS A REPEAT OBSERVATION***

Specifically, on 16-17 January 2018, during the inspection of your firm which were used in the manufacturing process for __________ from __________ - July 2017 in Unit (4) and Unit (4)

Unit (4) (Location of equipment used in the production of __________ from __________ - July 2017)

A. I observed what appears to be discoloration resembling __________ inside the __________ (Equipment ID: __________-25) in areas that come into direct contact with drug product. The status of this non-dedicated equipment was identified as cleaned.

Unit (4) (Location of equipment proposed for use in the production of __________ on or about __________)

B. I observed what appears to be discoloration resembling __________ inside the __________ (Equipment ID: __________-12 & __________-12) in areas that come into direct contact with drug product. The status of this non-dedicated equipment was identified as cleaned. In addition, I observed visible signs of what appeared to be residue alongside the __________. Your firm did not initiate any investigations to ensure drug products manufactured in this __________ was not contaminated.

C. In the __________, I observed the __________ was torn, exposing what appears to be rust or corrosion. In addition, I noticed the gasket used to protect the __________ and the __________ was wrapped in
Teflon tape. I observed missing pieces of the Teflon tape alongside the inside of the [exhibit]. Your firm did not initiate any investigations to ensure the missing Teflon pieces did not contaminate drug products manufactured in this non-dedicated [room].


D. In the [location] of [room] and [room], I observed the gaskets, wrapped in Teflon tape, were beginning to unravel. In addition, I observed residue on the [surfaces] of [equipment]. Your firm did not initiate any investigations to ensure drug products manufactured in these non-dedicated [areas] were not contaminated.


E. Your VP of Quality and Regulatory Affairs and I observed residue in the [area]. The status of this non-dedicated equipment was identified as cleaned. Your firm did not initiate any investigations to ensure drug products manufactured in these non-dedicated [areas] were not contaminated.

OBSERVATION 2
Your firm's environmental monitoring sampling plan is not clearly defined and does not represent worst-case activities and conditions.

Specifically, sample locations taken in the [area] which is used in the [stages] of [product] API production for:

A. Non-viable air samples are not performed under dynamic conditions.

B. Surface samples are not representative of the most critical locations.

OBSERVATION 3
Extractable and leachable studies for the [material] bags [used in the packaging] have not been completed.
Specifically, your firm packages (b)(4) API into (b)(4) bags, which are subsequently placed in a (b)(4) Drum. However, the USP Monograph for this product references packaging and storage should be preserve in (b)(4) container.