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 ORAPHARMInternational483responses@fda.hhs.gov	10/18/2021-11/01/2021 FEI NUMBER 3007517881

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Hara Prasad Rath, Vice President - Operations Site Head

FIRM NAME	STREET ADDRESS
Macleods Pharmaceuticals Limited	Village Theda, Post Office Lodhimajra, Tehsil Baddi
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
District Solan, Himachal Pradesh, 174101, India	Drug Product 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 WE OBSERVED:

OBSERVATION 1

Equipment and utensils are not cleaned and maintained at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

1. Cleaning procedures do not include provisions for routine cleaning or inspection of the (b) (4) (b) (4) areas. During a facility walkthrough, layers of dark colored (b) (4) and black) (b) (4) drug products residue were observed on the inside surfaces of (b) (4) (b) (4) of multiple non-dedicated (b) (4) These (b) (4) were directly connected to the (b) (4)

   a. On October 18, 2021 in Manufacturing Block (b) (4) a layer of (b) (4) /black colored (b) (4) drug product residue was seen on the inside surface of (b) (4) of (b) (4) /01 (ID # EQI/N2 (b) (4) /01). The (b) (4) is an integral part of the drug manufacturing system that are directly connected to (b) (4) (ID # EQI/N2 (b) (4) /01).

   Your cleaning procedure SOP No. PG/012-11 Cleaning and Operation of (b) (4) (Effective date 9/17/2020) and preventive maintenance procedure SOP No. UG/013-07

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Preventive Maintenance of (b) (4) (Effective date 8/8/2020) do not have provision to clean the (b) (4) that are contaminated and are integral part of (b) (4) /01 (ID # EQI/N2/(b) (4) /01). Additionally, your General Manger Engineering confirmed that these (b) (4) are not cleaned as part of the equipment cleaning.

Your (b) (4) /01 (ID # EQI/N2/(b) (4) /01) is a non-dedicated equipment and has been used to manufacture and ship a number of drug products to US. A list of products manufactured and shipped to US during 2019-2021 include but not limited to; (b) (4) (b) (4) Tablets (b) (4) mg (b) (4) mg (b) (4) tablets), and (b) (4) Tablets (b) (4) ng (b) (4) tablets).

b. On October 18, 2021 in Manufacturing Block (b) (4) a layer of (b) (4) /black colored (b) (4) drug product residue was seen on the inside surface of (b) (4) of (b) (4) /02 (ID # EQI/N2/(b) (4) /02). The (b) (4) is an integral part of the drug manufacturing system that are directly connected to (b) (4) /02 (ID # EQI/N2/(b) (4) /02).

Your cleaning procedure SOP No. PG/013-08 Cleaning and Operation of (b) (4) (GM 30/45 HW) (Effective date 9/17/2020) and preventive maintenance procedure SOP No. UG/013-07 Preventive Maintenance of (b) (4) (Effective date 8/8/2020) do not have provision to clean the (b) (4) that are contaminated and are integral part of (b) (4) /02 (ID # EQI/N2/(b) (4) /02). Additionally, your General Manger Engineering confirmed that these (b) (4) are not cleaned as part of the equipment cleaning.

Your (b) (4) /02 (ID # EQI/N2/(b) (4) /02) is a non-dedicated equipment and has been used to manufacture and ship a number of drug products to US. A list of products manufactured and shipped to US in during 2019-2021 include but not limited to; (b) (4) Capsules (b) (4) mg (b) (4) (b) (4) tablets), and (b) (4) Tablets (b) (4) mg (b) (4) tablets).

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c. On October 18, 2021 in Manufacturing Block(b) (4) a layer of(b) (4) black colored (b) (4) drug product residue was seen on the inside surface of(b) (4) of (b) (4) '03 (ID # EQI/N2(b) (4) '03). The (b) (4) is an integral part of the drug manufacturing system that are directly connected to (b) (4) '03 (ID # EQI/N2(b) (4) 03).

Your cleaning procedure SOP No. PG/109-07 Cleaning and Operation of (b) (4) (b) (4) (Effective date 9/17/2020) and preventive maintenance procedure SOP No. UG/013-07 Preventive Maintenance of (b) (4) (Effective date 8/8/2020) do not have provision to clean the(b) (4) that are contaminated and are integral part of (b) (4) 03 (ID # EQI/N2/(b) (4) '03). Additionally, your General Manger Engineering confirmed that thesc(b) (4) are not cleaned as part of the equipment cleaning.

Your (b) (4) '03 (ID # EQI/N2/(b) (4) '03) is a non-dedicated equipment and has been used to manufacture and ship a number of drug products to US. A list of products manufactured and shipped to US during 2019-2021 include but not limited to:(b) (4) Tablets(b) (4) mg(b) (4) (b) (4) tablets), and(b) (4) Tablets(b) (4) mg (b) (4) tablets).

d. On October 18, 2021 in Manufacturing Block(b) (4) a layer of(b) (4) black colored (b) (4) drug product residue was seen on the inside surface of(b) (4) of (b) (4) '05 (ID # EQI/N2/(b) (4) '05). The(b) (4) is an integral part of the drug manufacturing system that are directly connected to(b) (4) '05 (ID # EQI/N2/(b) (4) '05).

Your cleaning procedure SOP No. PG/164-08 Cleaning and Operation of (b) (4) (b) (4) (Effective date 9/14/2020) and preventive maintenance procedure SOP No. UG/013-07 Preventive Maintenance of (b) (4) (Effective date 8/8/2020) do not have provision to clean the(b) (4) that are contaminated and are integral part of (b) (4) '05 (ID # EQI/N2/(b) (4) '05). Additionally, your General Manger Engineering confirmed that these(b) (4) are not cleaned as part of the equipment cleaning.

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Your (b) (4) '05 (ID # EQI/N2/(b) (4) 05) is a non-dedicated equipment and has been used to manufacture and ship a number of drug products to US. A list of products manufactured and shipped to US during 2019-2021 include but not limited to; (b) (4) Tablets (b) (4) mg (b) (4) tablets).

e. On October 18, 2021 in Manufacturing Block (b) (4) a layer of (b) (4) /black colored (b) (4) drug product residue was seen on the inside surface of (b) (4) of (b) (4) 06 (ID # EQI/N2/(b) (4) '06). The (b) (4) is an integral part of the drug manufacturing system that are directly connected to (b) (4) '06 (ID # EQI/N2(b) (4) '06).

Your cleaning procedure SOP No. PG/246-04 Cleaning and Operation of (b) (4) (b) (4) (Effective date 9/17/2020) and preventive maintenance procedure SOP No. UG/013-07 Preventive Maintenance of (b) (4) (Effective date 8/8/2020) do not have provision to clean the (b) (4) that are contaminated and are integral part of (b) (4) 06 (ID # EQI/N2(b) (4) '06). Additionally, your General Manger Engineering confirmed that these (b) (4) are not cleaned as part of the equipment cleaning.

Your (b) (4) 06 (ID # EQI/N2/(b) (4) 06) is a non-dedicated equipment and has been used to manufacture and ship a number of drug products to US. A list of products manufactured and shipped to US during 2019-2021 include but not limited to; (b) (4) Tablets (b) (4) mg (b) (4) tablets), and (b) (4) Tablets (b) (4) mg (b) (4) tablets).

f. On October 18, 2021 in Manufacturing Block (b) (4) a layer of (b) (4) black colored (b) (4) drug product residue was seen on the inside surface of (b) (4) of (b) (4) 09 (ID # EQI/N2/(b) (4) '09). The (b) (4) is an integral part of the drug manufacturing system that are directly connected to (b) (4) /09 (ID # EQI/N2(b) (4) '09).

Your cleaning procedure SOP No. PG/246-04 Cleaning and Operation of (b) (4)

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(b) (4) (Effective date 9/17/2020) and preventive maintenance procedure SOP No. UG/013-07 Preventive Maintenance of (b) (4) (Effective date 8/8/2020) do not have provision to clean the (b) (4) that are contaminated and are integral part of (b) (4) 09 (ID # EQI/N2/(b) (4) '09). Additionally, your General Manger Engineering confirmed that these (b) (4) are not cleaned as part of the equipment cleaning.

Your (b) (4) /09 (ID # EQI/N2/(b) (4) '09) is a non-dedicated equipment and has been used to manufacture and ship a number of drug products to US. A list of products manufactured and shipped to US during 2019-2021 include but not limited to; (b) (4) Tablets (b) (4) mg (b) (4) tablets), and (b) (4) Capsules (b) (4) mg (b) (4) tablets).

g. On October 18, 2021 in Manufacturing Block (b) (4) a layer of (b) (4) /black colored (b) (4) drug product residue was seen on the inside surface of (b) (4) of (b) (4) '11 (ID # EQI/N2(b) (4) /11). The (b) (4) is an integral part of the drug manufacturing system that are directly connected to (b) (4) '11 (ID # EQI/N2/(b) (4) /11).

Your cleaning procedure SOP No. PG/357-01 Cleaning and Operation of (b) (4) (b) (4) (Effective date 1/10/2021) and preventive maintenance procedure SOP No. UG/013-07 Preventive Maintenance of (b) (4) (Effective date 8/8/2020) do not have provision to clean the (b) (4) that are contaminated and are integral part of (b) (4) '11 (ID # EQI/N2/(b) (4) '11). Additionally, your General Manger Engineering confirmed that these (b) (4) are not cleaned as part of the equipment cleaning.

Your (b) (4) '11 (ID # EQI/N2(b) (4) '11) is a non-dedicated equipment and has been used to manufacture and ship a number of drug products to US. A list of products manufactured and shipped to US during 2019-2021 include but not limited to; (b) (4) Capsules (b) (4) mg (b) (4) tablets).

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h. On October 18, 2021 in Manufacturing Block (b) (4) a layer of (b) (4) /black colored (b) (4) drug product residue was seen on the inside surface of (b) (4) of (b) (4) '12 (ID # EQI/N2/(b) (4) '12). The (b) (4) is an integral part of the drug manufacturing system that are directly connected to (b) (4) /12 (ID # EQI/N2(b) (4) '12).

Your cleaning procedure SOP No. PG/359-00 Cleaning and Operation of (b) (4) (b) (4) (Effective date 12/8/2020) and preventive maintenance procedure SOP No. UG/013-07 Preventive Maintenance of (b) (4) (Effective date 8/8/2020) do not have provision to clean the (b) (4) that are contaminated and are integral part of (b) (4) '12 (ID # EQI/N2(b) (4) '12). Additionally, your General Manger Engineering confirmed that these (b) (4) are not cleaned as part of the equipment cleaning.

Your (b) (4) '12 (ID # EQI/N2(b) (4) '12) is a non-dedicated equipment and has been used to manufacture and ship a number of drug products to US. A list of products manufactured and shipped to US during 2019-2021 include but not limited to (b) (4) Capsules (b) (4) mg (b) (4) (b) (4) tablets), and (b) (4) Tablets (b) (4) mg (b) (4) tablets).

i. On October 18, 2021 in Manufacturing Block (b) (4) , a layer of (b) (4) 'black colored (b) (4) drug product residue was seen on the inside surface of (b) (4) of (b) (4) '01 (ID # EQI/N2/(b) (4) '01). The (b) (4) is an integral part of the drug manufacturing system that are directly connected to (b) (4) /01 (ID # EQI/N2(b) (4) /01).

Your cleaning procedure SOP No. PG/129-14 Cleaning and Operation of (b) (4) (b) (4) (Effective date 1/2/2021) and preventive maintenance procedure SOP No. UG/146-07 Preventive Maintenance of (b) (4) (Effective date 12/4/2019) do not have provision to clean the (b) (4) that are contaminated and are integral part of (b) (4) /01 (ID # EQI/N2/(b) (4) '01). Additionally, your General Manger Engineering confirmed that these (b) (4) are not cleaned as part of the equipment cleaning.

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Your (b) (4) '01 (ID # EQI/N2(b) (4) 01) is a non-dedicated equipment and has been used to manufacture and ship a number of drug products including for US. A list of products manufactured during 2019-2021 include but not limited to; (b) (4) (b) (4) Capsules USP (b) (4) mg) (b) (4) capsules) as potential registration batches for US, (b) (4) Capsules (b) (4) mg (b) (4) capsules) to Korea, and (b) (4) Capsules (b) (4) mg (b) (4) capsules) to (b) (4) Germany.

j. On October 18, 2021 in Manufacturing Block (b) (4) a layer of (b) (4) black colored (b) (4) drug product residue was seen on the inside surface (b) (4) of (b) (4) /02 (ID # EQI/N2/(b) (4) '02). The (b) (4) is an integral part of the drug manufacturing system that are directly connected to (b) (4) 02 (ID # EQI/N2(b) (4) '02).

Your cleaning procedure SOP No. PG/292-05 Cleaning and Operation of (b) (4) (b) (4) (Effective date 2/28/2020) and preventive maintenance procedure SOP No. UG/146-07 Preventive Maintenance of (b) (4) (Effective date 12/4/2019) do not have provision to clean the (b) (4) that are contaminated and are integral part of (b) (4) 02 (ID # EQI/N2(b) (4) 02). Additionally, General Manger Engineering confirmed that these (b) (4) are not cleaned as part of the equipment cleaning.

Your (b) (4) 02 (ID # EQI/N2/(b) (4) 02) is a non-dedicated equipment and has been used to manufacture and ship a number of drug products to US. A list of products manufactured and shipped to US in during 2019-2021 include but not limited to; (b) (4) Capsules (b) (4) mg (b) (4) tablets) and (b) (4) Capsule (b) (4) mg USP ((b) (4) capsules, yet to be shipped).

2. Layers of colored (b) (4) drug product residues were observed on the inside surfaces of (b) (4) of multiple tablet (b) (4) machines. These (b) (4) were directly connected to the tablet (b) (4) Your cleaning procedures do not include provisions

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for routine cleaning or inspection of the (b) (4) areas.

a. On October 21, 2021 layers of (b) (4) colored (b) (4) drug product residues were seen on the inside surface of (b) (4) of (b) (4) /01 (ID # EQI/N2/(b) (4) 01). The (b) (4) is an integral part of the drug manufacturing system that is directly connected to (b) (4) /01 (ID # EQI/N2(b) (4) /01).

Your SOP No. PG/029-08 Cleaning and Operation of (b) (4) (Effective date 8/12/2020) and preventive maintenance procedure SOP No. UG/020-06 Preventive Maintenance of (b) (4) (Effective date 8/2/2020) do not have provisions to clean the (b) (4) (b) (4) that are contaminated and are integral part of (b) (4) /01 (ID # EQI/N2/(b) (4) /01). Additionally, General Manger Engineering confirmed that these (b) (4) are not cleaned as part of the equipment cleaning.

Your (b) (4) /01 (ID # EQI/N2(b) (4) /01) is a non-dedicated equipment and has been used to manufacture and ship a number of drug products to India and ROW (excluding US). A list of products manufactured and shipped to India Market (via (b) (4) (b) (4) during 2019-2021 include but not limited to; (b) (4) mg Tablets (b) (4) tablets), and (b) (4) mg Tablets (b) (4) (b) (4) tablets).

During the inspection of the (b) (4) /01), I observed that the (b) (4) were connected via a (b) (4) I also verified this for (b) (4) /01 on page 16 of the cleaning procedure SOP No. PG/129-14 Cleaning and Operation of (b) (4) (Effective date 1/2/2021). On October 25, 2021, your General Manager, Engineering shared schematic diagrams for (b) (4) /01, (b) (4) 03, and (b) (4) 04 that confirmed that the (b) (4) were connected with a (b) (4) I noted that the (b) (4) further increases potential cross

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contamination and compromises the safety and efficacy of the drug products that are manufactured on (b) (4) Your GM Engineering also shared a CAPA 58909. I noted that the CAPA was initiated on 2/13/2021 against observation trigger by USFDA as per CIF/21/0001.

On October 21, your Executive Vice President Corporate QA stated that the firm was aware about the Agency's concerns with the similar issues and shared a document, Risk Assessment for Installation of (b) (4) Cleaning System in (b) (4) (EQI/N2/(b) (4) '12), Document No. MPL/RAS/PR#62370, Effective date 4/20/2021. I noted that the document was mainly around installing a (b) (4) system for one of the (b) (4) '12 (ID # EQI/N2(b) (4) '12). The outcome of the risk assessment (Summary) stated that, "***Available cleaning procedures are sufficient to clean the (b) (4) (b) (4) in order to mitigate the risk of contamination and cross contamination.***" However, I noted the current cleaning procedures has provisions to clean the (b) (4) only until the (b) (4) closest to the (b) (4) and does not extend to the (b) (4) (b) (4) extend beyond the (b) (4) The report did not extend to the potential cross contamination from the layers of dark colored (b) (4) and black) (b) (4) drug products residue were observed on the inside surfaces of (b) (4) of multiple non-dedicated (b) (4) (b) (4)

On October 25, 2021, the firm management shared Report No. MPL/N2/RMIS/PR#93773/01 that contain testing results for the samples collected from the inside of the (b) (4) (b) (4) This report confirmed the presence of at least previous three drug substances on the inside of the (b) (4) As of October 25, 2021, the firm continues with the manufacture of the drug products in the contaminated (b) (4)

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OBSERVATION 2

*****REPEAT OBSERVATION*****

Your Quality Unit invalidated several OOS investigations through deficient investigative procedures. The root cause for a number of OOS investigations were obtained without scientific rationale. Examples include, but are not limited to, the following OOS investigations.

a. OOS/19/016: On 10/20/2021, your Quality Assurance Manager reviewed OOS/19/016 that was initiated to probe an OOS result for (b) (4) stage) for (b) (4) Tablet USP (b) (4) mg Batch No. (b) (4) The OOS results were obtained for (b) (4) ((b) (4) %) and %RSD (b) (4) %) with the mean value (b) (4) (Specification %RSD NMT (b) (4) % and individual values within ± (b) (4) % of the mean, mean NLT (b) (4) % and NMT (b) (4) %). Even though, your Phase I and Phase IIA investigation did not reveal any discrepancies, yet you retested the sample and invalidated the initial OOS results. This batch was used in the manufacturing of (b) (4) Tablet USP (b) (4) mg (b) (4) Batch No. (b) (4) Manufacturing date 1/5/2019, Expiry date (b) (4) On (b) (4) the firm shipped (b) (4) units ((b) (4) tablets) to the US. According to your CAPA (CAPA/19/072), the root cause for the OOS results reads as, "***there might be a chance of error during withdrawing of sample or holding of sample which resulted into abrupt value of (b) (4) sample.***"

   The respective CAPA/19/072 appears to be irrelevant to the OOS results. This CAPA initiated a change request CCD/19/616 to update the procedure for sampling. The changes included in the sampling procedure include, "***(b) (4) (b) (4) It is not clear how this revised sampling procedure would have changed the outcome of the assay result.

b. OOS/19/134: On 10/20/2021, your Quality Assurance Manager reviewed OOS/19/134 that was initiated to probe an OOS result for (b) (4) stage) for (b) (4) Tablets

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	FEI NUMBER 3007517881

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Hara Prasad Rath, Vice President - Operations Site Head

FIRM NAME	STREET ADDRESS
Macleods Pharmaceuticals Limited	Village Theda, Post Office Lodhimajra, Tehsil Baddi
CITY, STATE, ZIP CODE, COUNTRY District Solan, Himachal Pradesh, 174101, India	TYPE ESTABLISHMENT INSPECTED Drug Product Manufacturer

USP(b)(4) mg(b)(4) mg Batch No. (b)(4) The OOS results were obtained for the sample mean (b)(4) % (Specification mean NLT(b)(4) % and NMT(b)(4) % of the label claim). Even though, your Phase I and Phase IIA investigation did not reveal any discrepancies, yet you retested the sample and invalidated the initial OOS results. This batch was used in the manufacturing of (b)(4) Tablet USP(b)(4) mg(b)(4) Batch No. (b)(4) Manufacturing date 3/22/2019, Expiry date (b)(4) On (b)(4) the firm shipped (b)(4) units (b)(4) tablets) to the US.

c. OOS/19/136: On 10/20/2021, your Quality Assurance Manager reviewed OOS/19/136 that was initiated to probe an OOS result for (b)(4) stage) for (b)(4) Tablets USP(b)(4) mg(b)(4) mg Batch No. (b)(4) The OOS results were obtained for the sample mean (b)(4) % (Specification mean NLT(b)(4) % and NMT (b)(4) % of the label claim). Even though, your Phase I and Phase IIA investigation did not reveal any discrepancies, yet you retested the sample and invalidated the initial OOS results. This batch was used in the manufacturing of (b)(4) Tablet USP(b)(4) mg(b)(4) Batch No (b)(4) Manufacturing date 3/28/2019, Expiry date (b)(4) On (b)(4) the firm shipped (b)(4) units (b)(4) tablets) to the US.

d. OOS # 54646: On 10/21/2021, your Quality Assurance Manager reviewed OOS # 54646 that was initiated to probe an OOS result for (b)(4) stage) for (b)(4) Tablets USP(b)(4) mg Batch No. (b)(4) The OOS results were obtained for the sample (b)(4) (b)(4) %) that is not within ±(b)(4) % of the sample mean (b)(4) %. According to your Phase IA laboratory investigation, weight of the (b)(4) empty vial was the root cause for higher assay for (b)(4) However, the investigation failed to rule out (b)(4) vial cap as the source of (b)(4) According to the test procedure, the (b)(4) sample containing vials are (b)(4) (b)(4) The investigation did not include (b)(4) cap as the source of (b)(4) empty vial. This batch (Batch No. (b)(4) was used in the manufacturing of Exhibit Batch (b)(4)

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e. OOS # 53444: On 10/20/2021, your Quality Assurance Manager reviewed OOS # 53444 that was initiated to probe an OOS result for assay for (b) (4) Tablets USP (b) (4) mg Batch No. (b) (4) at (b) (4) stage. The OOS results were obtained for the assay (b) (4) % (Specification NLT (b) (4) % and NMT (b) (4) % of the label claim) for the (b) (4) (b) (4) sample. Phase I and Phase IIA investigation did not reveal any discrepancies. In Phase IIB, you hypothesized (b) (4) sample during sample weighing as the probable root cause of the OOS. This hypothesis was developed by (b) (4) and testing (b) (4) (b) (4) You used this hypothesis to retest the sample and invalidated the initial OOS result. This batch (Batch No. (b) (4) was used in the manufacturing of (b) (4) (b) (4) Tablets USP (b) (4) mg (b) (4) Batch No. (b) (4) Manufacturing date 11/30/2020, Expiry date (b) (4) On (b) (4) the firm shipped (b) (4) units (b) (4) tablets) to the US.

f. OOS # 76396: On 10/21/2021, your Quality Assurance Manager reviewed OOS # 76396 that was initiated to probe an OOS result (for assay) for the stability sample of (b) (4) (b) (4) Tablets (b) (4) mg USP having batch numbers and results as in **Table 1**.

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Table 1. Assay test results for the stability sample

Entry	Batch No.	Failed at	(b) (4)	Expiry date	Date shipped to US	Total Tablets
1	(b) (4) (annual batch)	12 month*		3/31/2023	(b) (4)	(b) (4)
2	(b) (4) (commercial validation batch)	6 month*		9/30/2023	(b) (4)	(b) (4)

*Condition at 25 °C/60% RH, **Specification NLT (b) (4) %, NMT (b) (4) %

The Phase I hypothesis study did not identify root cause for initial OOS results. There is no explanation why refill vial analysis is (b) (4) % lower than the assay results for the same vial. Instead, you concluded laboratory error as the root cause based on the passing results obtained by re-diluting and extended sonification. You did not conduct Phase IIA manufacturing investigation and invalidated the initial OOS result by retesting (in triplicate in Phase IIB) both the batches. These batches of drug products were shipped to the US (**Table 1**).

g. OOS # 63305: On 10/21/2021, your Quality Assurance Manager reviewed OOS # 63305 that was initiated on March 15, 2021 to probe an OOS result observed in assay test for (b) (4) (b) (4) and (b) (4) Tablets (b) (4) mg Batch No. (b) (4) at 12 month for 30 °C/65% RH. The batch failed for (b) (4) part with OOS assay results (b) (4) % (Specification (b) (4) % (b) (4) %). Phase IA laboratory investigation did not reveal any anomalies. In

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Phase IB hypothesis, the OOS result was reproduced from the same vial (re-injection) but assay data from Re-filled vial, re-dilution vial (from same stock solution) gave higher assay value. Based on the passing results from the Re-filled vial, you concluded that the root cause for OOS result was "***Analyst not shake final dilution properly at the time of vial filling***". You did not verify the hypothesis experimentally and invalidated the OOS result by retesting the sample. The investigation did not extend to Phase IIA manufacturing processes. This batch is part of the registration batch for (b) (4) and located in (b) (4).

h. OOS # 13455: On 10/22/2021, your Quality Assurance Manager reviewed OOS # 13455 that was initiated to probe an OOS result for dissolution test for (b) (4) Tablets USP (b) (4) mg Batch No. (b) (4) at (b) (4) stage. The OOS results include: **D1** (b) (4) %, D2 (b) (4) %, D3 (b) (4) %, D4 (b) (4) %, **D5** (b) (4) D6 (b) (4) % (Specification NLT (b) (4) % (Q) of the labeled amount). No assignable cause was identified in Phase I. In Phase II investigation you identified root cause that reads, "***it is infer that analyst skip to attached that paddle with shaft in disso-01 & disso-05 sample***'. You invalidated the OOS results by retesting the sample.

I inspected the dissolution equipment, EQI/QC//DRT/10 Model No. EDT-14Lx that was used in the study and noted the equipment uses a (b) (4) rod with one end shaped as paddle and the second end is hooked to the equipment.

I also observed unknown peak at ~(b) (4) min in the initial (OOS) assay chromatograms that was not included in the investigation. This peak was not present in the retest samples.

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OBSERVATION 3

Written procedures are not established for the cleaning and maintenance of equipment used in the manufacture, processing, packing, or holding of a drug product.

Specifically,

You have not validated the cleaning process for a number of manufacturing equipment that have been used to manufacture and ship a number of drug products to US such as;

1. You have not validated the cleaning process for your (b) (4) 02 (ID # EQI/N2/(b) (4) 02). This is a non-dedicated equipment and has been used to manufacture and ship a number of drug products to US. A list of products manufactured and shipped to US in between 2019-2021 include but not limited to; (b) (4) Capsule USP (b) (4) mg (b) (4) capsules), (b) (4) (b) (4) Capsule USP (b) (4) mg (b) (4) capsules, to be shipped).
2. You have not validated the cleaning process for your (b) (4) 03 (ID # EQI/N2/(b) (4) 03). This is a non-dedicated equipment and has been used to manufacture and ship a number of drug products to US. A list of products manufactured and shipped to US in between 2019-2021 include but not limited to; (b) (4) Capsule USP (b) (4) mg (b) (4) capsules), (b) (4) (b) (4) Capsule USP (b) (4) mg (b) (4) capsules, to be shipped).
3. You have not validated the cleaning process for your (b) (4) 04 (ID # EQI/N2(b) (4) 04). This is a non-dedicated equipment and has been used to manufacture and ship a number of drug products to US. A list of products manufactured and shipped to US in between 2019-2021 include but not limited to: (b) (4) Capsule USP (b) (4) mg (b) (4) capsules).

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OBSERVATION 4

Investigations of any unexplained discrepancy, a failure of a batch or any of its components to meet any of its specifications did not extend to other drug products that may have been associated with the specific failure or discrepancy.

Specifically, your firm's assessments for risk for the manufacturing of (b) (4) USP, (b) (4) mg / (b) (4) mg and (b) (4) (b) (4) and (b) (4) tablets products:

A- Does not evaluate suppliers other than Macleods Pharmaceuticals Limited API facility located in Sarigam, Vapi, India. However, your firm sources API for the above products from other manufactures such as (b) (4)
For example,

1- According to page 12 of Assessment Report for (b) (4) Tablets USP (b) (4) mg (b) (4) mg and (b) (4) mg, document number CQA/RAR/2020/353-00 states, that Macleods Pharmaceuticals Ltd. is the approved vendor for (b) (4) drug substance and was evaluated for potential (b) (4) impurities. On page 19 states, (b) (4) impurities (b) (4) and (b) (4) are monitored at API stage, further monitoring at Drug product stage is not required". Additionally, the document states "it is concluded that (b) (4) Tablets USP manufactured by Macleods is free from (b) (4) impurities." On page 54 states that "No source of (b) (4) is used in the manufacturing process of key starting material, reagents, (b) (4) and drug substance – (b) (4) " from Macleods Pharmaceuticals Ltd.'s API facility located in Sarigam, Valsad District, Gujarat, India. The

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assessment does not evaluate (b) (4) API from (b) (4) (b) (4) suppliers.

2- According to page 17 of Assessment Report for (b) (4) Impurities of (b) (4) and (b) (4) Tablets, (b) (4) mg / (b) (4) mg, document number CQA/RAR/2020/376-00 states, that based on the assessment "it is concluded that (b) (4) and (b) (4) Tablets manufactured by Macleods is free from (b) (4) impurities." The assessment does not evaluate (b) (4) API from (b) (4)

(b) (4) vendors are used to manufacture products on nondedicated manufacturing equipment.

B- According to Executive Vice President, Corporate Quality Assurance and Vice President of Operations the firm does not test for (b) (4) impurities. The evaluation of (b) (4) impurities of incoming (b) (4) API's are dependent on the suppliers COAs. The firm transcribes the results from the suppliers supplied COA on to the firm's Active Pharmaceutical Ingredient Specification. For example, page 6 of Active Pharmaceutical Ingredient Specification, C/SPC/RM002505C/06, with effective date November 16, 2019 for (b) (4) states (b) (4) content are by LCMS, microgram/gram, "Results to be reproduced from vendors Certificate of Analysis."

According to Executive Vice President, Corporate Quality Assurance also stated that the firm does not test for (b) (4) impurities in (b) (4) tablet products. The firm is currently validating their methods in their Research and Development Department.

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OBSERVATION 5

Control procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

REPEAT OBSERVATION

Specifically, manufacturing process performance qualification Report No MPL/N2/PPQR/19/046/02 for (b) (4) tablets USP (b) (4) mg, with approved Quality Assurance date July 7, 2021, failed for (b) (4) during the (b) (4) stage of manufacturing. The (b) (4) was (b) (4) % with a specification limit of (b) (4) - (b) (4) %. Your firm has manufactured and shipped (b) (4) batches (total of (b) (4) tablets) of (b) (4) tablets USP (b) (4) mg to the United States of America since August 2021.

OBSERVATION 6

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

Specifically, on October 25, 2021, while in the (b) (4) area it was observed that individual passwords are not being used for (b) (4) machine (equipment # EQI/N2 (b) (4) /18). In reviewing the list of equipment and access control for manufacturing equipment, it was found that approximately 44 equipment had employees sharing operator, supervisor and / or manager passwords. For example, equipment such as (b) (4) (equipment # EQI/N2/ (b) (4) /01 and EQI/N2 (b) (4) 08)

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(b) (4) machines (equipment # EQI/N2(b) (4) 21 and EQI/N2(b) (4) 18), (b) (4) machines (equipment # EQI/N2(b) (4) 08 and EQI/N2(b) (4) 10), (b) (4) (equipment # EQI/N2(b) (4) 02 and EQI/N2/(b) (4) 04) and capsule filling machine (equipment # EQI/N2/CF/01 and EQI/N2/CF/04) employees' are sharing passwords and user names. Additionally, 44 out of(b) (4) manufacturing equipment used to manufacture product do not have data storage capability. The data that is created while product is manufactured from the equipment are not stored and cannot be recovered. Examples of these equipment are (b) (4) (equipment # EQI/N2(b) (4) /02 and EQI/N2/(b) (4) 08),(b) (4) (equipment # EQI/N2/(b) (4) 06 and EQI/N2(b) (4) 05), (b) (4) machine (equipment # EQI/N2(b) (4) 06) and(b) (4) (equipment # EQI/N2(b) (4) /01 and EQI/N2(b) (4) 08).

OBSERVATION 7

Building used in the manufacturing, processing, and packing of a drug product are not maintained in a good state of repair.

Specifically, on October 16, 2021 during walkthrough of Manufacturing Block(b) (4) I observed water spillage on the floor in the primary packing corridor in front of blister packing(b) (4) and blister packing(b) (4) I observed water leaking from the HEPA box on the ceiling. I noted you were packing(b) (4) mg Batch No(b) (4) in blister packing(b) (4) and(b) (4) mg Capsule Batch No. (b) (4) in blister packing-(b) (4) These drug products were for ROW (Chile). The firm management stated that a water spillage on the service floor caused the leakage in the packing area through the HEPA filter box.

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