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	1/28/2021-2/6/2021*
	FEI NUMBER 3015685305

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Srinivas Avirneni , Head-Site Operations

FIRM NAME	STREET ADDRESS
Alembic Pharmaceuticals Limited	Formulation Division III, Plot No. 779P/790P, Village - Karakhadi, Taluka - Padra
CITY, STATE, ZIP CODE, COUNTRY Vadodara, Gujarat, 391450 India	TYPE ESTABLISHMENT INSPECTED Sterile 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 WE OBSERVED:

OBSERVATION 1

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, you failed to provide scientific justification demonstrating that samples collected for environmental monitoring represent the greatest risk of product contamination. For Example;

A) "Area Qualification Protocol for Line (b) (4) SD/PD/AQ-003-00 was conducted in March 2019. During area qualification you failed to conduct surface monitoring of (b) (4) (Grade B) (b) (4) During production simulation on 02/02/21, we observed the (b) (4) and the (b) (4) in the Grade B area. The (b) (4) end was protected by (b) (4) While performing environmental sampling in the Grade A area near the (b) (4) on (b) (4) your microbiologist bumped into the (b) (4) and knocked (b) (4) end on the Grade B floor. (b) (4) was picked up from the floor by your Production Operator and placed back on the (b) (4) Our observation was communicated with Assistant Production Manager and Production Head, we were informed the (b) (4) will protect (b) (4) production simulation continued. The (b) (4) was removed in the Grade B area using (b) (4) located near (b) (4) (b) (4) was exposed to Grade B area before connecting to (b) (4) which is connected to the filling "Buffer Tank". (b) (4) into the buffer tank. You failed to provide a scientific justification why surface sampling is not conducted for your Grade B (b) (4) Specifically, the area where (b) (4) fell. In addition, you placed the (b) (4) used to remove the (b) (4) from (b) (4) back on the stand containing (b) (4) used on th (b) (4) after

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Rita K Kabaso, Investigator Dipesh K Shah, Office of International Programs Employee	X Rita K Kabaso Investigator Signed By: 2001767329 Date Signed: 02-06-2021 20:46:18	2/6/2021

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	1/28/2021-2/6/2021*
	FEI NUMBER 3015685305

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mr. Srinivas Avirneni , Head-Site Operations	
FIRM NAME Alembic Pharmaceuticals Limited	STREET ADDRESS Formulation Division III, Plot No. 779P/790P, Village - Karakhadi, Taluka - Padra
CITY, STATE, ZIP CODE, COUNTRY Vadodara, Gujarat, 391450 India	TYPE ESTABLISHMENT INSPECTED Sterile Pharmaceutical Manufacturer

intervention and (b) (4) wipes used in the Grade A area.

B) You failed to perform (b) (4) integrity testing for your (b) (4) utilized in your Grade A and Grade B area. You failed to provide a scientific justification explaining why (b) (4) integrity testing is not conducted.

C) Your current sampling locations identified in "Viable monitoring in Manufacturing Area", SD/QM/SOP038 do not represent the greatest risk for product contamination. During production simulation conducted on Line (b) (4) on 02/02/21, Aseptic Operator contact surfaces observed in the Grade A and Grade B included, but were not limited to:

- During (b) (4) wipe down, Aseptic Filling Operator was observed touching the (b) (4) (b) (4) (Filling Machine) (b) (4) You do not conduct sampling at this location. Surface sampling is conducted on the (b) (4) You failed to provide a justification why the (b) (4) is not sampled for surface monitoring.
- Your current personnel monitoring program does not include testing of aseptic filling operators' shoulders. During equipment setup, operators were observed reaching in the filling machine and shoulders contacting areas in the Grade A area. You provided no rationale why the shoulders are not sampled nor why the Grade A contact part is not sampled.
- (b) (4) (Grade B) is equipped with a (b) (4) which is moved from the (b) (4) (b) (4) of the room to th (b) (4) of the room via (b) (4) (Grade A). You failed to provide a scientific justification why the (b) (4) used to move the (b) (4) are not sampled.

D) On February 2, 2021, we witnessed two employees improperly gowned in the aseptic, Lin (b) (4) manufacturing area during the assembly of the line. Employee (b) (6) and employee (b) (6) were

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Rita K Kabaso, Investigator Dipesh K Shah, Office of International Programs Employee	X Rita K Kabaso Investigator Signed By: 2001767329 Date Signed: 02-06-2021 20:48:18	DATE ISSUED 2/6/2021

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	1/28/2021-2/6/2021*
	FEI NUMBER 3015685305

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mr. Srinivas Avirneni , Head-Site Operations	
FIRM NAME Alembic Pharmaceuticals Limited	STREET ADDRESS Formulation Division III, Plot No. 779P/790P, Village - Karakhadi, Taluka - Padra
CITY, STATE, ZIP CODE, COUNTRY Vadodara, Gujarat, 391450 India	TYPE ESTABLISHMENT INSPECTED Sterile Pharmaceutical Manufacturer

observed with approximately a ¼ inch gap between the bottom of the goggles and headdress of the aseptic gown.

Employee (b) (6) was observed to be conducting support activities such as transporting sterile equipment on a cart from the entrance of the manufacturing area to (b) (4) area. Employe (b) (6) was observed taking Environmental Monitoring sample plates from Grade "A" area.

OBSERVATION 2

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic and sterilization process.

Specifically, validation and control processes for "Line (b) (4) used in the manufacturing of (b) (4) Injection USP, (b) (4) are lacking. Example;

E) (b) (4) Performance Qualification (SD/PD/PQ/029-00) for (b) (4) (Equipment ID (b) (4) fails to contain scientific evidence demonstrating that (b) (4) njection USP, (b) (4) (b) (4) prior to product filling. Your Senior Executive-Validation and Assistant Production Manager for "Line (b) (4) indicated that the (b) (4) Prior to (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Rita K Kabaso, Investigator Dipesh K Shah, Office of International Programs Employee	X Rita K Kabaso Investigator Signed By: 2001767329 Date Signed: 02-06-2021 20:46:18	2/6/2021

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	1/28/2021-2/6/2021*
	FEI NUMBER 3015685305

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mr. Srinivas Avirneni , Head-Site Operations	
FIRM NAME Alembic Pharmaceuticals Limited	STREET ADDRESS Formulation Division III, Plot No. 779P/790P, Village - Karakhadi, Taluka - Padra
CITY, STATE, ZIP CODE, COUNTRY Vadodara, Gujarat, 391450 India	TYPE ESTABLISHMENT INSPECTED Sterile Pharmaceutical Manufacturer

(b) (4). Subsequently, the (b) (4) is closed during equipment unloading in Grade A. The (b) (4) (b) (4) is then op rea and attached to the (b) (4) ocated i (b) (4) Your performance qualification for Line (b) (4) fails to provide scientific evidence to demonstrate that (b) (4) is adequate to remove potential viable organisms. (b) (4) (b) (4) are product contact surfaces for sterile product (b) (4) (b) (4) njection USP.

In addition;

- You failed to provide a risk assessment documenting why the (b) (4) is close when placed on the line. Your Senior Executive- Validation, indicated that the (b) (4) with (b) (4) can withstand (b) (4)
- During production simulation on 02/02/21, we observed the (b) (4) attached to the (b) (4) and the (b) (4) placed on the (b) (4) in the Grade B area. The (b) (4) end was protected by (b) (4) While performing environmental sampling in the Grade A area near the turn table on (b) (4) your microbiologist bumped into the (b) (4) and knocked (b) (4) on the Grade B floor. (b) (4) was picked up from the floor by your Production Operator and placed back on the (b) (4) Our observation was communicated with Assistant production Manager and Production Head, we were informed the (b) (4) will protect (b) (4) production simulation continued. (b) (4) connects to (b) (4) to transfer sterile product from the (b) (4) to the filling line.

F) Engineers who perform interventions in Grade A area on Aseptic Fill Line (b) (4) are not adequately qualified to conduct interventions in the Grade A area. The following media fills have been conducted at the facility using protocols listed below:

Media Fill	Protocol and Report	Dated

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	1/28/2021-2/6/2021*
	FEI NUMBER 3015685305

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. Srinivas Avirneni , Head-Site Operations

FIRM NAME	STREET ADDRESS
Alembic Pharmaceuticals Limited	Formulation Division III, Plot No. 779P/790P, Village - Karakhadi, Taluka - Padra
CITY, STATE, ZIP CODE, COUNTRY Vadodara, Gujarat, 391450 India	TYPE ESTABLISHMENT INSPECTED Sterile Pharmaceutical Manufacturer

(b) (4) [redacted]

During media fill qualification you failed to demonstrate that intervention performed were wort-case activities. Your engineers are qualified to perform interventions in the Grade B area, using (b) (4) ABs (b) (4) (b) (4) and not Grade A area. Your Engineering Manager affirmed that when the engineer is qualified for Grade B area, they can perform interventions in the Grade A area by (b) (4) [redacted] You have (b) (4) engineers who you consider qualified to perform interventions during production in the Grade A area. Examples of interventions conducted in the Grade A area near empty vials and filling area include:

(b) (4) [redacted]

G) You failed to provide a rationale justification for the selection and placement of Non-Viable Particle Probs. Validation protocol, "Area Qualification Protocol for Line (b) (4) of open Restricted Access Barrier (b) (4) RABs) Equipment ID (b) (4) [redacted] and (b) (4) [redacted] Equipment ID (b) (4) [redacted] fails to account for equipment design during NVP plac [redacted] ection. Per your Quality Assurance Senior Executive, Validation; NVPs

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Rita K Kabaso, Investigator Dipesh K Shah, Office of International Programs Employee	X Rita K Kabaso Investigator Signed By: 2001767329 Date Signed: 02-06-2021 20:48:18	2/6/2021

selection during equipment qualification was based on the area of the equipment. There is no NVP monitoring in the Grade A (b) (4) area which are separated by a partition on Equipment ID (b) (4) The (b) (4) area not monitored is (b) (4) There is no NVP monitoring in the Grade A (b) (4) area for Equipment ID (b) (4) The (b) (4) area not monitored is (b) (4) Your Line (b) (4) Production Assistant Manager that interventions still occur in the areas where non-viable counts are not conducted. You failed to provide a rationale justification why the areas listed above are not monitored.

H) Qualification of your (b) (4) Equipment ID (b) (4) was conducted per protocol, SD/PD/PQR-021-00. Your Performance Qualification fails to provide a logical explanation for the Biological Indicator (BI) and Chemical Indicator (CI) placement. Your current placement of BI and CI do not represent the worst-case location for (b) (4) Specifically,

- Qualification of the "Filling machine parts (b) (4) you failed to place a BI in the groove of your (b) (4) (b) (4) guide Sr. No. (b) (4) The (b) (4) guide are on the (b) (4) (b) (4)
- Qualification of "Miscellaneous Load", you placed your BI and CI on the top of you (b) (4) (b) (4)

Your Assistance Manager-Validation indicated that (b) (4) is adequate as each corner of the (b) (4) is represented.

I) Your firm's Qualification for (b) (4) Testing Machine (SD/PD/CQ-010-00) with post approval date

January 23, 2018 is inadequate. In reviewing the records for (b) (4) Testing Machine for Lin (b) (4) dated January 9, 2021 to February 1, 2021, your firm has 15 recorded failures that were performed by your operators. The firm uses Standard Operating Procedure titled, 'Handling and Integrity Testing of Filters', SD/PD/SOP021 for testing filters.

On February 4, 2021, we asked Assistant Manager Production and Head Quality Assurance why the operators had 15 failures performing the (b) (4) test. They stated that the factors the operators are facing were not encountered during the validation and the firm only started seeing the failures when operators were actually conducting tests.

OBSERVATION 3

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design, of adequate size and suitably located to facilitate operations for its intended use and cleaning and maintenance.

Specifically, you failed to perform simultaneous qualification of you (b) (4) Equipment ID (b) (4) and (b) (4) (b) (4) (located in Line (b) (4) to ensure that your (b) (4) can efficiently supply (b) (4) (b) (4) to both equipment. (b) (4) Equipment ID (b) (4) is utilized in the manufacture of (b) (4) (b) (4) Injection USP, (b) (4) During (b) (4) conducted on August 4 , 2018, your (b) (4) failed to archive minimum (b) (4) of (b) (4) Non-conformance report SD/PD/OQ-035-00/AD-01/001 was initiated to investigate the non-conformance. The root cause identified was, your (b) (4) could not supply sufficient (b) (4)

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	1/28/2021-2/6/2021*
	FEI NUMBER 3015685305

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Srinivas Avirneni , Head-Site Operations

FIRM NAME	STREET ADDRESS
Alembic Pharmaceuticals Limited	Formulation Division III, Plot No. 779P/790P, Village - Karakhadi, Taluka - Padra
CITY, STATE, ZIP CODE, COUNTRY Vadodara, Gujarat, 391450 India	TYPE ESTABLISHMENT INSPECTED Sterile Pharmaceutical Manufacturer

Equipment ID PDX-031 and (b) (4) A new (b) (4) was purchased and connected to your (b) (4) quipment ID (b) (4) and (b) (4) (b) (4) Your Assistant Production Manager affirmed there is a possibility of (b) (4) Equipment ID (b) (4) and (b) (4) being run stimulatingly during routine production.

OBSERVATION 4

Equipment for adequate control over air pressure is not provided when appropriate for the manufacture, processing, packing or holding of a drug product.

Specifically, your airflow visualization studies for Line (b) (4) ail to demonstrate unidirectional airflow pattern under static and dynamic conditions. Per your protocol, SD/MIS/112-00, SD/MIS/360-00, and SD/PD/OQ-034-00/AD-03; airflow visualization studies are conducted to check unidirectional airflow with no eddy currents, or recirculation of air form less clean areas into critical areas. The Table below lists examples of instances where unidirectional airflow was not archived.

SD/MIS/112-00 Visualization conducted on (b) (4)

Intervention number	Approximate time	Brief Description
(b) (4)		Unable to assess aseptic activity (too much smoke)
		No smoke over personnel activity
		No smoke over personnel activity

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	1/28/2021-2/6/2021*
	FEI NUMBER 3015685305

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. Srinivas Avirneni , Head-Site Operations

FIRM NAME	STREET ADDRESS
Alembic Pharmaceuticals Limited	Formulation Division III, Plot No. 779P/790P, Village - Karakhadi, Taluka - Padra
CITY, STATE, ZIP CODE, COUNTRY Vadodara, Gujarat, 391450 India	TYPE ESTABLISHMENT INSPECTED Sterile Pharmaceutical Manufacturer

SD/PD/OQ 034/00-AD03 Visualization conducted on (b) (4)

Intervention number	Approximate time	Brief Description
(b) (4)		No smoke on operator's hands
		Cannot see airflow while employee is using (b) (4)
		Cannot see airflow while employee is putting away the (b) (4)
		Too much smoke
		Smoke is not on the employee so cannot see the airflow
		The (b) (4) is moving down really fast the smoke is not on the (b) (4) so you cannot see the airflow

A risk assessment evaluating the pressure of the smoke from the manifold was not conducted.

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Rita K Kabaso, Investigator
Dipesh K Shah, Office of International Programs Employee

X Rita K Kabaso Investigator Signed By: 2001767329 Date Signed: 02-06-2021 20:48:18

DATE ISSUED
2/6/2021

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	1/28/2021-2/6/2021* FEI NUMBER 3015685305

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. Srinivas Avirneni , Head-Site Operations

FIRM NAME	STREET ADDRESS
Alembic Pharmaceuticals Limited	Formulation Division III, Plot No. 779P/790P, Village - Karakhadi, Taluka - Padra
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Vadodara, Gujarat, 391450 India	Sterile Pharmaceutical Manufacturer

In addition, your firm failed to test for residue of (b) (4) to determine if further cleaning is deemed necessary after conducting (b) (4) smoke studies (b) (4)(b) (4) and (b) (4) All of the smoke studies were completed used (b) (4) According to document titled, 'Rational for Cleaning activity after Smoke study in Line (b) (4) states "the vendor declared that the smoke does not generate any residue. So, extensive area cleaning was not performed. However, routine cleaning of equipment & area has been performed (b) (4) as per SOP: Cleaning and Disinfection of Aseptic and Clean area' No. SD/PD/SOP053. So no risk/impact is involved in the area." The vendor's statement was not scientifically verified by your firm.

OBSERVATION 5

The quality control unit lacks authority to fully investigate errors that have occurred.

Specifically,

Your firm's Investigations ER/E/OAC/SD/19-005 and ER/E/OAC/SD/19-006 are inadequate because the firm do not address the testing of toxins in your (b) (4) njection USP (b) (4) mg/ml) (Batch Nos.: (b) (4) Microbiology found employees tested above the observed Microbiological count for Gram negative Isolate in the Grade "B" manufacturing sterile area.

Investigations ER/E/OAC/SD/19-005, with approved date June 12, 2019 states that employee (b) (6) was found to have a Personal Monitoring count of (b) (4) cfu (NMT (b) (4) cfu as per page 8 of SD/QM/SOP042, 'Gowning

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Rita K Kabaso, Investigator Dipesh K Shah, Office of International Programs Employee	X Rita K Kabaso Investigator Signed By: 2001767329 Date Signed: 02-06-2021 20:48:18	2/6/2021

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
12420 Parklawn Drive, Room 2032 Rockville, MD 20857	1/28/2021-2/6/2021*
	FEI NUMBER 3015685305

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Mr. Srinivas Avirneni , Head-Site Operations

FIRM NAME	STREET ADDRESS
Alembic Pharmaceuticals Limited	Formulation Division III, Plot No. 779P/790P, Village - Karakhadi, Taluka - Padra
CITY, STATE, ZIP CODE, COUNTRY Vadodara, Gujarat, 391450 India	TYPE ESTABLISHMENT INSPECTED Sterile Pharmaceutical Manufacturer

Qualification of Personnel Entering in Aseptic Area') on his right hand. The employee was working in the Grade "B", Line (b)(4) sterile manufacturing area on May 4, 2019 while Batch # (b)(4) was being manufactured and is responsible but not limited to all activities related to Filling, Solution filtration, component preparation and component receipt.

Investigations ER/E/OAC/SD/19-006, with approved date June 25, 2019 states that employee (b)(6) was found to have a Personal Monitoring count of (b)(4) cfu (NMT (b)(4) cfu as per page (b)(4) of SD/QM/SOP042, 'Gowning Qualification of Personnel Entering in Aseptic Area') on his chest. The employee was working in the Grade "B", Line (b)(4) sterile manufacturing area on May 14, 2019, while Batch (b)(4) was being manufactured and is responsible but not limited to all activities related to Filling, Solution filtration, component preparation and component receipt.

Investigation concluded with no root cause determined, however a CAPA # CAPA-19-096 was implemented on August 20, 2019. That CAPA stated to revise SOP, SD/PD/SOP124 and SD/PD/SOP (b)(4) On page 1 of the CAPA states "SOP to be revised for inclusion of cleaning provision, (b)(4) (b)(4) On February 3, 2021, we asked if increase testing or increased cleaning was done after both incidents in Line (b)(4) Sr. Manager-Quality Control Microbiology and Production Manager stated that the firm did not increase testing, nor did they increase environmental monitoring.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Rita K Kabaso, Investigator Dipesh K Shah, Office of International Programs Employee	X Rita K Kabaso Investigator Signed By: 2001767329 Date Signed: 02-06-2021 20:46:18	2/6/2021

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	1/28/2021-2/6/2021*
	FEI NUMBER 3015685305

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Srinivas Avirneni , Head-Site Operations

FIRM NAME	STREET ADDRESS
Alembic Pharmaceuticals Limited	Formulation Division III, Plot No. 779P/790P, Village - Karakhadi, Taluka - Padra
CITY, STATE, ZIP CODE, COUNTRY Vadodara, Gujarat, 391450 India	TYPE ESTABLISHMENT INSPECTED Sterile Pharmaceutical Manufacturer

According to section (b) (4) of Standard Operating Procedure titled, 'Procedure for Finished Product Sampling' states that for Bacterial Endo Toxin (BET) testing (b) (4) unit each from Top, middle and bottom racks are sampled. The firm's Reserve Sample Register states that the firm has (b) (4) units for each batch (b) (4) The firm has not conducted any Bacterial Endo Toxin (BET) testing on any of the reserve samples.

***DATES OF INSPECTION**
1/28/2021(Thu), 1/29/2021(Fri), 1/30/2021(Sat), 2/01/2021(Mon), 2/02/2021(Tue), 2/03/2021(Wed), 2/04/2021(Thu), 2/05/2021(Fri), 2/06/2021(Sat)

X Dipesh K Shah
Office of International Programs Employee
Signed By 1300184065
Date Signed 02-06-2021 20 49 50

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Rita K Kabaso, Investigator Dipesh K Shah, Office of International Programs Employee X Rita K Kabaso Investigator Signed By 2001767329 Date Signed 02-06-2021 20 48 18	2/6/2021