10903 New Hampshire Avenue; White Oak Building 51, Room 2269, Silver Spring, MD 20993 FEI NUMBER Bemail: OPMABLA.Inspection483Responses@fda.hhs.gov 3002617771 NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED 3002617771 TO: Ms. Lisbet Jensen Young, Site Lead FIRM NAME STREET ADDRESS AstraZeneca Pharmaceuticals LP Frederick Manufacturing Center G33 Research Court CITY, STATE AND ZIP CODE Impediate Composition of Your Represent To Substance Manufacturer THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATION (SOUR COMPLIANCE, IF YOU HAVE AN OBJECTION OF ACTION WITH THE FDA REPRESENTATION (SOUR COMPLIANCE, IF YOU HAVE AN OBJECTION OF ACTION WITH THE FDA REPRESENTATION FOR MATION TO FDA AT THE ONDER AND ADDRESS ABOVE. DURING AN INSPECTION OF YOUR FIRM OF (WE) OBSERVED: Observation 1: Drug substance upstream manufacturing systems have unmitigated risk in assura performance, product quality. Specifically, You provided evidence of eleven (11) contamination events in upstream manufacture, Building, 2022 to 29 February 2024. You also provided twelve (12) contamination events for Building, 2020 to 09 November 2023, with each manufacturing system used in the production of other products. You failed to identify and address system deficiencies in a timely manner. This is a repeat observation from the 03/02 - 19/2021 inspection. Observation 2: Procedures in support of manufacture and the QC test laboratory are deficient. S	FOOD AND DRUG	G ADMINISTRATION		
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Email: OPMABLAInspection483Responses@data.hbs.gov 3002617771 Industry Information: www.fda.gov/oc/industry 3002617771 WMME AND TITLE OF FNOMDOLLS OF NOT NOT SUBJECT 633 Research Court TO: Ms. Lisbet Jensen Young, Site Lead STREET ADDRESS FIRM NAME STREET ADDRESS AstraZeneca Pharmaceuticals LP Frederick Manufacturing Center 633 Research Court TY: STATE AND 2P CODE Drug Substance Manufacturer THIS DOCUMENT USTS CBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. TO DESERVATIONS, AND DO NOT REPRESENT ATHAL AGENCY DETERMINATION REGARDING YOUR COMPLANE, IF YOU HAVE AN OBJECTION OF ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. TO DESERVATION OF NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLANE, IF YOU HAVE AN OBJECTION OF ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF SUBMIT THIS INFORMATION TO FDA AT TO YOU HAVE ANY QUESTIONS, PLAN TO MALEMENT CORRECTIVE ACTION IN RESPONSE TO OBSERVATION TO FDA AT TO YOU HAVE ANY QUESTIONS, PLAN THE INSPECTION OF YOUR FIRM OF (NE) DESERVATION. ODDECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FIRM OF (NE) DESERVATION. ODJENCTION OR ACTION WITH THE FDA REPRESENT AT THE AGENCY DETERMINATION REGARDING YOUR COMPLANE, IF YOU HAVE ANY DUESTION AGENCY. OUL MUSETINGS, PLEASE CONTACT FOR AAT THE PHONE NUMBER AND ADDRESS ABOVE. DURING AN INSPECTION OF YOUR FIRM OF (NE) DESERVATION ON 100 MOY DUG FIRM OF (NE) SERVED:	10903 New Hampshire Avenue; White Oak Building 51, Room 2269, Silver Spring, MD 20993 Email: OPMABLAInspection483Responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry		05/30/2024 - 06/07/2024	
Industry Information: www.fda.gov/oc/industry 3002617771 VAME XAD TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: Ms. Lisbet Jensen Young, Site Lead TO: Ms. Lisbet Jensen Young, Site Lead STREET ADDRESS G33 Research Court G33 Research Court DITY, STATE AND 2IP CODE Image: Street ADDRESS Frederick, Maryland 21703 Image: Street ADDRESS Disperving Street Address G33 Research Court THIS DOCUMENT USTS COBSERVATIONS MADE BY THE FDA REPRESENTATINE(S) DURING THE INSPECTION OF YOUR FACILITY. TO SUBSERVATIONS, REPRESENT A FINAL AGENCY DETERMINATION RECOMPT COMPLANCE, IF YOU HAVE AN OUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE. DURING AN INSPECTION OF YOUR FIRM gr(ME) OBSERVED. DURING AN INSPECTION OF YOUR FIRM gr(ME) OBSERVED. Observation 1: Drug substance upstream manufacturing systems have unmitigated risk in assura performance, product quality. Specifically, You provided evidence of eleven (11) contamination events in upstream manufacture, Building [Danuary 2020 to 09 November 2023, with each manufacturing system used in the production of other products. You failed to identify and address system deficiencies in a timely manner. This is a repeat observation from the 03/02 - 19/2021 inspection. Missing failed for [Completion of a successful cleaning verification for equipment utilized for [Completion of 16 April 2022, pending the completion of a successful cleaning verification investigation for the validation failure. You fail to have a procedure for governance of c				
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c. On 30 May 2024, we observed a ceiling HEPA screen dislodged in ^{(b)(4)} area ^{(b)(4)} with	c. On 30 May 2024, we observed a ceiling HEPA screen	n dislodged in		(6) (4)
EMPLOYEE(S) SIGNATURE EMPLOYEE(S) NAME AND TITLE (Print or Type)				EISSUED
SEE REVERSE OF THIS PAGE Wayne Seifert, Senior Consumer Safety Officer Vidya Pai Kuossfleich, Senior Consumer Safety Officer Vidya Pai Kuossfleich, Senior Consumer Safety Officer Vidya Pai Kirsten Nickens, Lead Biologist & Christina Farris	REVERSE OF THIS PAGE Vidya Pari A Usgur I	Vidya Pai, Supervisory Ch Liqun Zhao, Pharmaceutic	emist al Scientist 06/0	07/2024

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FOOD AND DF	RUG ADMINISTRATION		
DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INS	DATE(S) OF INSPECTION	
Division of Pharmaceutical Manufacturing Assessment 10903 New Hampshire Avenue; White Oak Building 51, Room 2269, Silver Spring, MD 20993 Email: OPMABLAInspection483Responses@fda.hhs.gov		05/30/2024 - 06/07/2024	
		FEI NUMBER	
Industry Information: www.fda.gov/oc/industry	3002617771	3002617771	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED			
TO: Ms. Lisbet Jensen Young, Site Lead FIRM NAME	STREET ADDRESS		
AstraZeneca Pharmaceuticals LP Frederick Manufacturing Center			
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED		
Frederick, Maryland 21703	Drug Substance Manufacturer		
d. On 04 June 2024, we observed two cabinets within top external surface in an uncleaned state. You identif Program at Frederick Manufacturing Center (FMC) Si support of cleaning external cabinet horizontal surface e. On 06 June 2024, we observed within the Quality C (CTU) in varying alarm conditions. You fail to have a Observation 3: There is a failure to thoroughly docume Deviation investigation reports QE-090861 and QE-08 manufacturing process controls, inclusive of both critic parameters (NKPPs). The conclusion within the corress product impact as a result of the process deviation. Ho	ied SOP-0106918, "Facility Clean te, v37.0, effective date 22 May 20 s. ontrol Laboratory, numerous contr procedure for routine inspection of ent product quality impact of quali 24599 describe excursions of cal process parameters (CPPs) and ponding deviation reports indicate	024, as deficient in colled temperature units of CTU units. ty events. Specifically, ^{(b) (4)} drug substance non-key process ed that there was no	
thorough and clear evaluation of product quality impac of the data and information used to support the determ quality event.	and a state of the state of the second of the second state of the	- I was not set of the	
Observation 4: Analytical instruments in support of m data integrity. Specifically,	anufacture are not adequately con	trolled in assurance of	
You maintain manufacturing IPC test instrumentation. Integrity Tester, ^{(b)(4)} and You fail to conduct an instrument audit trial review at	(^{6) (4)} with each instrument	having an audit trail.	
		DATE IOOUED	
SEE War out	EMPLOYEE(S) NAME AND TITLE (Print or Type) Wayne Seifert, Senior Consumer Safety Off	icer DATE ISSUED	
PAGE Vityn Pai Login	Vidya Pai, Supervisory Chemist Liqun Zhao, Pharmaceutical Scientist Kristen Nickens, Lead Biologist & Christina	06/07/2024	
FORM FDA 483 (9/08) PREVIOUS EDITION OBSOLETE	NSPECTIONAL OBSERVATIONS()Intel Scient	disciplinary Page 2 of 2	

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