

Commercial Invoice



Clinical Services

Shipping From:
 Almac Clinical Services
 9 Charlestown Road,
 Seagoe Industrial Estate,
 Craigavon, Co. Armagh
 BT63 5PW, United Kingdom
 Phone: +44 (0) 28 3836 2436 XI EORI XI792090419000

Date: 30-Dec-25
 Shipment Reference: 13023680
 Airway Bill Number: TBC
 Courier: Quicksat
 Permit Number: N/A
 Sponsor: ASTRAZENECA UK LTD
 Protocol: D9722C00001

Consignee:
 Trialog Clinical Trials Ltd.
 55 Hamayyan St.
 Industrial Zone
 Modin, 7178499, Israel

Contact: Noa Feit
Tel: +972 8 660 4600
Email:

Importer of Record:
 Trialog Clinical Trials Ltd.
 55 Hamayyan St.
 Industrial Zone,
 Modin
 7178499
 Israel

Contact: Jean Ossad
Tel: +972 8 6604600 Ext: 4626
Email: import@trialog.co.il / jean@trialog.co.il

Broker:
 Couriers Own

Declarations: Not for Sale or Re-sale

No Commercial Value For Clinical Trial Use Only

Incoterms: DDP

Provided to Patients Free of Charge

Non-Hazardous / Non- Toxic

Value for Customs Purposes Only

Item	Harmonization Code/ Storage Conditions	Detailed Description of Goods	Net Weight (Kgs)	Qty	Unit Value (USD)	Sub Total
1	HTS 3004.90	Labelled bottle containing Arimidex (Arimazole) 1 mg tablet x32 for protocol D9722C00001 [UOM=bottle]	per bottle	6	\$12.79 per bottle	\$76.74
	Storage Conditions: +15°C TO +25°C					
2	HTS3004.90	Labelled bottle of AZD5305 20 mg Tablets x 30 for Protocol D9722C00001 [UOM = Bottle]	per bottle	60	\$134.28 per bottle	\$8,056.80
	Storage Conditions: +15°C TO +25°C					
3	HTS3004.90	Labelled bottle of Camizestrant (AZD9833) 75 mg Tablet x32 for Protocol D9722C00001 [UOM = bottle]	per bottle	20	\$134.15 per bottle	\$2,683.00
	Storage Conditions: +15°C TO +25°C					
4	HTS3004.90	Labelled Commercial Carton containing Verzenios (Abemaciclib) 150 mg Tablet x28 for Protocol D9722C00001 [UOM = carton]	per carton	18	\$994.57 per carton	\$17,902.26
	Storage Conditions: +15°C TO +25°C					
5	HTS3004.90	Labelled Commercial Carton containing Verzenios (Abemaciclib) 100 mg Tablet x28 for Protocol D9722C00001 [UOM = carton]	per carton	8	\$1,018.26 per carton	\$8,146.08
	Storage Conditions: +15°C TO +25°C					
6	HTS3004.90	Labelled Commercial Carton containing Verzenios (Abemaciclib) 50 mg Tablet x28 for Protocol D9722C00001 [UOM = carton]	per carton	3	\$999.23 per carton	\$2,997.69
	Storage Conditions: +15°C TO +25°C					
7	HTS3004.90	Labelled commercial carton of IBRANCE (Palbociclib) 125 mg Tablet x21 for Protocol D9722C00001 [UOM = carton]	per carton	2	\$4,709.25 per carton	\$9,418.50
	Storage Conditions: +15°C TO +25°C					
8	HTS3004.90	Labelled commercial carton of Kisqali (Ribociclib) 200 mg Tablet x63 in Blister for Protocol D9722C00001 [UOM = carton]	per carton	8	\$2,545.42 per carton	\$20,363.36
	Storage Conditions: +15°C TO +25°C					
9	HTS3004.90	Exemestan [Pfizer] (Exemestane) 25 mg 30 film coated tablets, blister in carton for protocol D9722C00001 (Germany)	per carton	2	\$87.60 per carton	\$175.20
	Storage Conditions: +15°C TO +25°C					
10	HTS3004.90	Labelled commercial carton Letrozole Accord Healthcare (Letrozole 2.5 mg Tablet x30 in Blister for Protocol D9722C00001 [UOM = carton]	per carton	10	\$10.77 per carton	\$107.70
	Storage Conditions: +15°C TO +25°C					

Total (USD): \$69,927.33

Total Packages:

Total Net Weight (Kgs):

Total Gross Weight (Kgs):

I declare that the above information is true and correct and to the best of my knowledge, and the contents of this shipment are as stated for and on the behalf of Almac Clinical Services.

We do hereby authorise Quicksat to execute any additional documents necessary for the export of merchandise described herein on my / our behalf.

Signature	Print Name	Position	Date
	JONATHAN ELLIOTT	SENIOR DISTRIBUTION ASSOCIATE	30-Dec-25

Almac Clinical Services Limited is a member of the Almac Group. Reg. Office: Almac House, 20 Seagoe Industrial Estate, Craigavon, BT63 5QD
 United Kingdom Reg. No: NI. 41905 VAT Reg. No: GB 792 0904 19



Expiry date statement
Arimidex clinical tablets, 1 mg

To whom it may concern:

Expiry date statement for Arimidex clinical tablets, 1 mg, batch TA7602

The undersigned, on behalf of AstraZeneca (Gothenburg, SE), declares that batch TA7602 of Arimidex clinical tablets, 1 mg, has been manufactured by AstraZeneca Pharmaceuticals LP, 587 Old Baltimore Pike, Newark, US and packed and labelled in high density polyethylene (HDPE) bottles at Fisher Clinical Services UK Ltd, Langhurstwood Road, Horsham, UK.

The finished product has an expiry date of end December 2027 and is produced for clinical trial use, with a shelf life of up to 5 years from the date of manufacture, when tablets are stored in HDPE bottles below 30°C.

Electronic signatures are located on the last page of the PDF.

Signature Page for VV-RIM-06305049 v1.0

Approve: Document Level Task	Mark Drew
Verdict: Approved	Management Approval 13-Jun-2024 13:54:02 GMT+0000

Signature Page for VV-RIM-06305049 v1.0

**AstraZeneca Pharmaceuticals LP**587 Old Baltimore Pike
Newark DE 19702Telephone #: 302-286-3500
Website: www.astrazeneca-us.com**CERTIFICATE OF MANUFACTURE
ARIMIDEX 1mg CLINICAL BULK TABLETS DRUM**Packaging Batch Number: **TA7602**Date of Expiry: **JUNE 2025**Manufacturing Batch Number: **TA7602**Date of Manufacture: **24 JAN 2023**Importing Country: **United Kingdom**NDC Code: **110025985**Supplied to: **Fisher Clinical Services UK**Average Tablet Weight: **101.6 mg**Active Ingredient (Source/Vendor Batch): **4000765 AZ batch # 600573
Vendor batch # 2113780**Manufacturing Authorisation Number: **2517100**

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured including packaging/labelling and quality control at above mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Released By: Loretta Lange Loretta Lange QA Specialist
(Printed Name) (Signature) (Title)

Released On: 15 February 2023
(Date)



AstraZeneca Pharmaceuticals LP
587 Old Baltimore Pike

Newark, DE 19702
www.astrazeneca-us.com

Tel. (302) 286 - 3500

CERTIFICATE OF ANALYSIS

Arimidex 1 MG Clinical Active

Batch Number:	TA7602
Date of Manufacture:	Jan-2023
Date of Expiry:	Jun-2025
Importing Country:	United Kingdom

TEST/PROCEDURE	ACCEPTANCE CRITERIA	RESULT
Appearance & Color Of Arimidex 1 mg Tab	Round, white, biconvex film coated plain tablet.	Complies
ID by IR	IR ID; Conforms	Complies
USP Dissolution - ROW		
Average		101.6
USP Dissolution Summary - ROW	Q=80%/T=30 minutes	Complies
Water Content of Arimidex Tablets	<= 7.0 %	5.4 %
Assay ZD1033	95 - 105 % label claim	98 % label claim
Arimidex Tablets-Degradation Products		
Bisamide	<= 0.1 % w/w	0.0 % w/w
Monoacid Monoamide	<= 0.1 % w/w	0.0 % w/w
Monoamide Mononitrile	<= 0.1 % w/w	0.1 % w/w
Bisacid	<= 0.1 % w/w	0.0 % w/w
Monoacid Mononitrile	<= 0.1 % w/w	0.0 % w/w
No Individuals	<= 0.1 % w/w	0.0 % w/w
Total	<= 0.2 % w/w	0.1 % w/w
Content Uniformity		
Average		98.7731
Content Uniformity Summary	Meets USP Requirements	Complies



AstraZeneca Pharmaceuticals LP
587 Old Baltimore Pike

Newark, DE 19702
www.astrazeneca-us.com

Tel. (302) 286 - 3500

CERTIFICATE OF ANALYSIS

Arimidex 1 MG Clinical Active

Batch Number: TA7602
Date of Manufacture: Jan-2023
Date of Expiry: Jun-2025
Importing Country: United Kingdom

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control at the above mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the specifications in the Marketing Authorisation of the importing country. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP.

Released by : Lange, Loretta **QA Specialist**

Released On : 15-Feb-2023

(This electronic signature is the legally binding equivalent of a hand written signature)



CERTIFICATE OF ANALYSIS

Product: AZD5305 20 MG GREEN FILM-COATED ROUND TABLET

Reference number: 33442 Date of Manufacture: 15 Apr 2024
Batch / lot number: BAAH Specification Reference: SPEC-0150177 v5.0

Test procedure	Result
Description	Plain, green, round, biconvex film-coated tablet
Identification	The retention time of AZD5305 in the sample chromatogram corresponds to that of AZD5305 in the Reference Standard chromatogram
Assay	99 % label claim
Organic Impurities	
Individual organic impurities ^a	REL RT 0.78 = 0.12%
Total organic impurities ^b	0.72% (8)
Dissolution	
T=30 minutes	Mean % dissolved: 99 % label claim
Uniformity of dosage units	Complies Meets the requirements of the USP/Ph. Eur./JP (USP<905>/Ph. Eur. 2.9.40) Acceptance value = 4.5
Water content	1.99% w/w
Microbial quality	
Total aerobic microbial count < 10 ³ CFU/g	Total aerobic microbial count < 10 CFU/g
Total yeasts and moulds count < 10 ² CFU/g	Total yeasts and moulds count < 10 CFU/g
No objectionable micro-organisms in the total counts	No objectionable micro-organisms in the total counts
Absence of Escherichia coli	Complies

^a Only the largest impurity is reported.

^b Total organic impurities consist of impurities ≥ 0.05%. () Indicates total number of impurities.

Appendix 1 Mandatory non-specification tests

The following tests should be performed at the same time as the release testing but are not part of the specification tests.

Test procedure	Result
Disintegration	1.07 min
Water activity	0.12 aw

Document Approvals

Business Approval	Claire Elliot Claire.Elliott@astrazeneca.com 30-Jul-2024 15:13:11 GMT+0000
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Number: CERT-193469

Version: 1.0

Status: Effective Effective Date: 06 Feb 2025

ALCOBENDAS_D831275_TA448324EGE_DE

3 February 2025

Lilly, S.A
Avenida de la Industria, 30
28108 Alcobendas, (Madrid)
Phone: (+34) 91663 50 00



Certificate of Analysis

To whom it may concern,

I certify that the below information is a true copy and accurate representation of the data contained within Darwin.

Finished Product Name: VERZENIOS TAB 50MG X14X2BLCD GE

Finished Product Item Code: TA448324EGE

Finished Product Batch Number: D831275

Bulk Batch Number: D765892

Date of Manufacture: 04-Aug-2024

Expiry Date: 07 2027

Countries: Germany

Component	Method	Method Type	Result	Unit	Acceptance Criteria
Abemaciclib	G1929	HPLC	100.7	Percent of Label Claim	Abemaciclib>=95.0 AND Abemaciclib<=105.0
Abemaciclib	G1929	HPLC	50.4	mg/Tablet	Abemaciclib>=47.5 AND Abemaciclib<=52.5
Any Unspecified Degradation Product	G1929	HPLC	<= 0.05	Percent	Any Unspecified Degradation Product<=0.2
Description	G1925	Visual	Modified oval beige tablet with Lilly debossed on one side and 50 on the other.		Description="Modified oval beige tablet with Lilly debossed on one side and 50 on the other."
Dissolution AT 15 MINUTES	G1928	UV	101	Percent	Dissolution AT 15 MINUTES>=80
Dissolution AT 15 MINUTES	G1928	UV	Pass		Dissolution AT 15 MINUTES="Pass"
Identity	G1943	FTIR	The infrared spectrum compares favorably with that of the reference standard. Similar relative intensities of absorption are observed at the same wave numbers as that obtained from abemaciclib working reference material.		Identity="The infrared spectrum compares favorably with that of the reference standard. Similar relative intensities of absorption are observed at the same wave numbers as that obtained from abemaciclib working reference material."

This document has been electronically signed. Please see the attached signature page for document approver and effective date.

Batch Number: D831275

Material: TA448324EGE

Page 1 of 3

Number: CERT-193469 Version: 1.0 Status: Effective Effective Date: 06 Feb 2025
ALCOBENDAS_D831275_TA448324EGE_DE

obtained from
abemaciclib
working reference
material.

Total Degradation Products	G1929	HPLC	<= 0.05	Percent	Total Degradation Products<=0.5
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This document has been electronically signed. Please see the attached signature page for document approver and effective date.

Number: CERT-193469

Version: 1.0

Status: Effective

Effective Date: 06 Feb 2025

ALCOBENDAS_D831275_TA448324EGE_DE

3 February 2025

Lilly, S.A
Avenida de la Industria, 30
28108 Alcobendas, (Madrid)
Phone: (+34) 91663 50 00



Certificate of Compliance

To whom it may concern,

Finished Product Name: VERZENIOS TAB 50MG X14X2BLCD GE

Finished Product Item Code: TA448324EGE

Finished Product Batch Number: D831275

Date of Manufacture: 04-Aug-2024

Comments:

Was manufactured by Lilly del Caribe Inc. Puerto Rico Industrial Park -12.6Km 65th Infantry Road - Carolina PR 00985 Puerto Rico and packaged Lilly, S.A., Avenida de la Industria 30 Alcobendas 28108 Madrid Spain.

The manufacture was supervised by trained and qualified personnel in accordance with the EC Guidelines of Good Manufacturing Practices.

All raw and packaging materials were tested and found to comply with all regulatory commitments.

Samples taken from this batch were examined and tested in the analytical laboratories and comply with the registered specification (see attached Certificate of Analysis).

Reference samples from the batch and complete records of the manufacture and testing have been retained and copies would be available if required.

Any deviation from the approved manufacturing process that were made have been completed and the reports would be available in case of need.

The batch has been certified for release for sale by the undersigned who is an authorized Qualified Person according to European Community requirements.

For and on behalf of Lilly, S.A.

This document has been electronically signed. Please see the attached signature page for document approver and effective date.

Batch Number: D831275

Material: TA448324EGE

Page 3 of 3

Number: CERT-190334

Version: 1.0

Status: Effective

Effective Date: 02 Jan 2025

ALCOBENDAS_D818517_TA533724EGE_DE

27 December 2024

Lilly, S.A
Avenida de la Industria, 30
28108 Alcobendas, (Madrid)
Phone: (+34) 91663 50 00



Certificate of Analysis

To whom it may concern,

I certify that the below information is a true copy and accurate representation of the data contained within Darwin.

Finished Product Name: VERZENIOS TAB 150MG X14X2BLCD GE

Finished Product Item Code: TA533724EGE

Finished Product Batch Number: D818517

Bulk Batch Number: D746375

Date of Manufacture: 27-May-2024

Expiry Date: 04 2027

Countries: Germany

Component	Method	Method Type	Result	Unit	Acceptance Criteria
Abemaciclib	G1929	HPLC	101.1	Percent of Label Claim	Abemaciclib>=95.0 AND Abemaciclib<=105.0
Abemaciclib	G1929	HPLC	151.6	mg/Tablet	Abemaciclib>=142.5 AND Abemaciclib<=157.5
Any Unspecified Degradation Product	G1929	HPLC	<= 0.05	Percent	Any Unspecified Degradation Product<=0.2
Description	G1925	Visual	Modified oval yellow tablet with Lilly debossed on one side and 150 on the other.		Description="Modified oval yellow tablet with Lilly debossed on one side and 150 on the other."
Dissolution AT 15 MINUTES	G1928	UV	100	Percent	Dissolution AT 15 MINUTES>=80
Dissolution AT 15 MINUTES	G1928	UV	Pass		Dissolution AT 15 MINUTES="Pass"
Dissolution High AT 15 MINUTES	G1928	UV	101	Percent	Dissolution High AT 15 MINUTES>=80
Dissolution Low AT 15 MINUTES	G1928	UV	100	Percent	Dissolution Low AT 15 MINUTES>=65
Identity	G1943	FTIR	The infrared spectrum compares favorably with that of the reference standard. Similar		Identity="The infrared spectrum compares favorably with that of the reference standard. Similar relative intensities of absorption are observed at the same wave

This document has been electronically signed. Please see the attached signature page for document approver and effective date.

Batch Number: D818517

Material: TA533724EGE

Page 1 of 3

Number: CERT-190334 Version: 1.0 Status: Effective Effective Date: 02 Jan 2025
ALCOBENDAS_D818517_TA533724EGE_DE

Total Degradation Products	G1929	HPLC	<= 0.05	Percent	Total Degradation Products<=0.5
			relative intensities of absorption are observed at the same wave numbers as that obtained from abemaciclib working reference material.		numbers as that obtained from abemaciclib working reference material."

This document has been electronically signed. Please see the attached signature page for document approver and effective date.

Number: CERT-190334 Version: 1.0 Status: Effective Effective Date: 02 Jan 2025
ALCOBENDAS_D818517_TA533724EGE_DE

27 December 2024

Lilly, S.A.
Avenida de la Industria, 30
28108 Alcobendas, (Madrid)
Phone: (+34) 91663 50 00



Certificate of Compliance

To whom it may concern,

Finished Product Name: VERZENIOS TAB 150MG X14X2BLCD GE

Finished Product Item Code: TA533724EGE

Finished Product Batch Number: D818517

Date of Manufacture: 27-May-2024

Comments:

Was manufactured by Lilly del Caribe Inc. Puerto Rico Industrial Park -12.6Km 65th Infantry Road - Carolina PR 00985 Puerto Rico and packaged Lilly, S.A., Avenida de la Industria 30 Alcobendas 28108 Madrid Spain.

The manufacture was supervised by trained and qualified personnel in accordance with the EC Guidelines of Good Manufacturing Practices.

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Reference samples from the batch and complete records of the manufacture and testing have been retained and copies would be available if required.

Any deviation from the approved manufacturing process that were made have been completed and the reports would be available in case of need.

The batch has been certified for release for sale by the undersigned who is an authorized Qualified Person according to European Community requirements.

For and on behalf of Lilly, S.A.

This document has been electronically signed. Please see the attached signature page for document approver and effective date.

Batch Number: D818517

Material: TA533724EGE

Page 3 of 3



PFIZER MANUFACTURING
DEUTSCHLAND GMBH
MOOSWALDALEE 1
79108 FREIBURG IM BREISGAU, GERMANY

Certificate of Analysis

Material Number: F000046813
Description: IBRANCE 125mg FCT 3X7 BLS DE
Batch: LY4883
Specifications Reference: H000017283-05
Number:
Manufacture Date: 18-Nov-2024
Expiration Date: 31-Oct-2027
Source Lots: LG9219 - H000025129

Test	Specification	Test Method	Result
Appearance	Oval light purple film-coated tablet with "Pfizer" debossed on one tablet face and "PBC 125" debossed on the opposite tablet face	Visual inspection	Conforms
Identity		TM-8439A / LC and UV	
Identity / UV	UV spectrum of the major peak in the sample chromatogram is consistent with the UV spectrum of the major peak in the standard chromatogram		Conforms
Identity / LC	Retention time of the main peak in the test chromatogram is comparable to that of reference standard		Conforms
Assay and Purity		TM-8439A / LC	
Assay / LC	95.0 – 105.0% of label claim		99.6 % LC
PF-06694807	NMT 0.3%		<= 0.05 percent
PF-06830625	NMT 0.3%		<= 0.05 percent
PF-06470104	NMT 0.3%		<= 0.05 percent
Unspecified degradation products	NMT 0.2% (each)		<0.1 %
Total Degradation Products	NMT 1.0%		<0.1 %

Issued By:

Violeta-Chlorghita Siegweil

Date of Issue: 24-Jan-2025 07:41:35

This certificate was created by a validated system and is valid without manual signature.



PFIZER MANUFACTURING
DEUTSCHLAND GMBH
MOOSWALDALEE 1
79108 FREIBURG IM BREISGAU, GERMANY

Certificate of Analysis

Material Number: F000046813
Description: IBRANCE 125mg FCT 3X7 BLS DE
Batch: LY4883
Specifications Reference Number: H000017283-05
Manufacture Date: 18-Nov-2024
Expiration Date: 31-Oct-2027
Source Lots: LG9219 - H000025129

Test	Specification	Test Method	Result
Dissolution Palbociclib after 30 min	Ph. Eur. 2.9.3 ▲ USP-NF <711>, TM- 8440A / UV		
Result	Conforms to Ph. Eur. requirements where not less than 80% (Q) of the label claim is dissolved in 30 minutes		Pass
Average	-	97 %	
Minimum	-	95 %	
Maximum	-	98 %	
RSD	-	1.2 %	
Stage	-	1	
Uniformity of dosage units / Content uniformity	Ph. Eur. 2.9.40 ▲ USP-NF <905>, TM- 8441A / UV		
Result	Conforms to current Ph. Eur. 2.9.40 requirements		Pass
Average	-	99.9 %	
Minimum	-	99.1 %	
Maximum	-	101.3 %	
RSD	-	0.7 %	
Acceptance value	-	1.7 %	
Stage	-	1	

Issued By:

Violeta-Ghorghita Steguwt

Date of Issue: 24-Jan-2025 07:41:35

This certificate was created by a validated system and is valid without manual signature.



PFIZER MANUFACTURING
DEUTSCHLAND GMBH
MOOSWALDALLEE 1
79108 FREIBURG IM BREISGAU, GERMANY

Certificate of Analysis

Material Number: F000046813
Description: IBRANCE 125mg FCT 3X7 BLS DE
Batch: LY4883
Specifications Reference Number: H000017283-05
Manufacture Date: 18-Nov-2024
Expiration Date: 31-Oct-2027
Source Lots: LG9219 - H000025129

The Certificate of Analysis was created by a validated system upon Head of Quality Control approval and is valid without signature.

The spelling and ZIP code of the manufacturer Pfizer Manufacturing Deutschland GmbH was changed and formerly known as

Pfizer Manufacturing Deutschland GmbH
Betriebsstätte Freiburg
Mooswaldallee 1
79090 Freiburg

The correction of the ZIP code and spelling of the address of the manufacturer Pfizer Manufacturing Deutschland GmbH does not affect the localization of the manufacturing site or have any implications on the content of the manufacturing authorization and GMP certificate.

Issued By: Violeta-Chlorhita Stegwelt

Date of Issue: 24-Jan-2025 07:41:36

This certificate was created by a validated system and is valid without manual signature.



PFIZER MANUFACTURING
DEUTSCHLAND GMBH
MOOSWALDALLEE 1
79108 FREIBURG IM BREISGAU, GERMANY

Certificate of Compliance

Material Number:	F000046813
Description:	IBRANCE 125mg FCT 3X7 BLS DE
Destinations:	Germany
Batch:	LY4883
Manufacture Date:	18-Nov-2024
Expiration Date:	31-Oct-2027
Quantity Manufactured:	7602 Each
Date of Release:	23-Jan-2025
API Name:	Palbociclib
Package Type:	Blister
Dosage Type:	Film Coated Tablets

I hereby certify that all the manufacturing stages, including packaging / labeling and quality control, of this batch of finished product have been carried out in full compliance with the GMP requirements of the EU and with the requirements of the Marketing Authorisation(s) of the destination country/countries. The above information is authentic and accurate. The corresponding active ingredient was manufactured in compliance with GMP. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP. Any investigations, deviations and discrepancies have been approved.

This batch has been released by a Qualified Person.

The spelling and ZIP code of the manufacturer Pfizer Manufacturing Deutschland GmbH was changed and formerly known as

Pfizer Manufacturing Deutschland GmbH
Betriebsstätte Freiburg
Mooswaldallee 1
79090 Freiburg

The correction of the ZIP code and spelling of the address of the manufacturer Pfizer Manufacturing Deutschland GmbH does not affect the localization of the manufacturing site or have any implications on the content of the manufacturing authorization and GMP certificate.

Dispositioned By: MARION ARNOLD

Issued By: Violeta-Ghorghita Siegwart Date of Issue: 24-Jan-2025 07:41:36

This certificate was created by a validated system and is valid without manual signature.



PFIZER MANUFACTURING
DEUTSCHLAND GMBH
MOOSWALDALLEE 1
79108 FREIBURG IM BREISGAU, GERMANY

Certificate of Compliance

Disposition Date:

23-Jan-2025 15:42:47

This certificate was created by a validated system and is valid without manual signature.

Issued By:

Violeta-Gheorghita Steguwell

Date of Issue: 24-Jan-2025 07:41:35

This certificate was created by a validated system and is valid without manual signature.

10 March 2025

Lilly, S.A
 Avenida de la Industria, 30
 28108 Alcobendas, (Madrid)
 Phone: (+34) 91663 50 00



Certificate of Analysis

To whom it may concern,

I certify that the below information is a true copy and accurate representation of the data contained within Darwin.

Finished Product Name: VERZENIOS TAB 100MG X14X2BLCD GE**Finished Product Item Code:** TA481524EGE**Finished Product Batch Number:** D845357**Bulk Batch Number:** D773831**Date of Manufacture:** 30-Aug-2024**Expiry Date:** 07 2027**Countries:** Germany

Component	Method	Method Type	Result	Unit	Acceptance Criteria
Abemaciclib	G1929	HPLC	101.3	Percent of Label Claim	Abemaciclib>=95.0 AND Abemaciclib<=105.0
Abemaciclib	G1929	HPLC	101.3	mg/Tablet	Abemaciclib>=95.0 AND Abemaciclib<=105.0
Any Unspecified Degradation Product	G1929	HPLC	<= 0.05	Percent	Any Unspecified Degradation Product<=0.2
Description	G1925	Visual	Modified oval white to practically white tablet with Lilly debossed on one side and 100 on the other.		Description="Modified oval white to practically white tablet with Lilly debossed on one side and 100 on the other."
Dissolution AT 15 MINUTES	G1928	UV	100	Percent	Dissolution AT 15 MINUTES>=80
Dissolution AT 15 MINUTES	G1928	UV	Pass		Dissolution AT 15 MINUTES="Pass"
Identity	G1943	FTIR	The infrared spectrum compares favorably with that of the reference standard. Similar relative intensities of absorption are observed at the same wave numbers as that obtained from abemaciclib working reference material."		Identity="The infrared spectrum compares favorably with that of the reference standard. Similar relative intensities of absorption are observed at the same wave numbers as that obtained from abemaciclib working reference material."

This document has been electronically signed. Please see the attached signature page for document approver and effective date.

Number: CERT-196835

Version: 1.0

Status: Effective Effective Date: 12 Mar 2025

ALCOBENDAS_D845357_TA481524EGE_DB

numbers as that
obtained from
abemaciclib
working reference
material.

Total Degradation Products	G1929	HPLC	<= 0.05	Percent	Total Degradation Products<=0.5
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This document has been electronically signed. Please see the attached signature page for document approver and effective date.

Batch Number: D845357

Material: TA481524EGE

Page 2 of 3

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Number: CERT-196835

Version: 1.0

Status: Effective

Effective Date: 12 Mar 2025

ALCOBENDAS_D845357_TA481524EGE_DE

10 March 2025

Lilly, S.A.
Avenida de la Industria, 30
28108 Alcobendas, (Madrid)
Phone: (+34) 91663 50 00



Certificate of Compliance

To whom it may concern,

Finished Product Name: VERZENIOS TAB 100MG X14X2BLCD GE

Finished Product Item Code: TA481524EGE

Finished Product Batch Number: D845357

Date of Manufacture: 30-Aug-2024

Comments:

Was manufactured by Lilly del Caribe Inc. Puerto Rico Industrial Park -12.6Km 65th Infantry Road - Carolina PR 00985 Puerto Rico and packaged Lilly, S.A., Avenida de la Industria 30 Alcobendas 28108 Madrid Spain.

The manufacture was supervised by trained and qualified personnel in accordance with the EC Guidelines of Good Manufacturing Practices.

All raw and packaging materials were tested and found to comply with all regulatory commitments.

Samples taken from this batch were examined and tested in the analytical laboratories and comply with the registered specification (see attached Certificate of Analysis).

Reference samples from the batch and complete records of the manufacture and testing have been retained and copies would be available if required.

Any deviation from the approved manufacturing process that were made have been completed and the reports would be available in case of need.

The batch has been certified for release for sale by the undersigned who is an authorized Qualified Person according to European Community requirements.

For and on behalf of Lilly, S.A.

This document has been electronically signed. Please see the attached signature page for document approver and effective date.

Batch Number: D845357

Material: TA481524EGE

Page 3 of 3

Number: CERT-196835

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Batch Where-Used List
Top-Down Analysis

Material: TA4B15V1MECB
Print: 0102
Batch: D773831

Expand Transfer Postings

Top-Down Analysis

Line-Down Analysis		TA4815VIMECB ABEAACICLIB TABS 100MG VIM ECB		0102 D773831		0102 D773831 1 388,111 TS		No Restrictions		1 C	
		TA4815VIMECB ABEAACICLIB TABS 100MG VIM ECB		0102 D773831		0102 D773831 1 388,111 TS		No Restrictions		40	
Q1	D709568	QA578301	ABENACICLIB ST2 LONZA TE SYLOID 244FP SILICON DIOXIDE USP/NF MICROCRYSTALLINE CELLULOSE PH-101 SODIUM STARCH FUMARATE	0102 D709568	150 KG	Country Restrictions Exist	11880199 3 C	40	No Restrictions	11880199 3 C	40
Q1	D624474	QA570W	COLOR MIXTURE WHITE 85%14.422 LACTOSE SPRAY DRIED SPECIAL CARBOXYMETHYLCELLULOSE SODIUM CROSS	0102 D624474	6 KG	No Restrictions	11880199 3 C	40	No Restrictions	11880199 3 C	40
Q1	D673421	QA555F	QA223N	0102 D673421	42 KG	No Restrictions	11880199 3 C	40	No Restrictions	11880199 3 C	40
Q1	D63864	QA223N	QA292D	0102 D63864	14 G	No Restrictions	11880199 3 C	40	No Restrictions	11880199 3 C	40
Q1	D620920	QA292D	QD560697	0102 D620920	25 KG	No Restrictions	11880199 3 C	40	No Restrictions	11880199 3 C	40
Q1	D630697	QA289X	QA258N	0102 D630697	42,500 KG	No Restrictions	11880199 3 C	40	No Restrictions	11880199 3 C	40
Q1	D631923	QA258N	QA181M	0102 D631923	21,500 KG	No Restrictions	11880199 3 C	40	No Restrictions	11880199 3 C	40
Q1	D63194	QA181M	QA181M	0102 D63194	147 KG	No Restrictions	11880199 3 C	40	No Restrictions	11880199 3 C	40
Q1	D634526	* FD562	FIBREBOARD DRUM 380 X 840MM	0102 D634526	50,000 KG	No Restrictions	11880199 3 C	40	No Restrictions	11880199 3 C	40
Q1	D761065	FD562	FIBREBOARD DRUM 380 X 840MM	0102 D761065	29 EA	No Restrictions	11880199 3 C	40	No Restrictions	11880199 3 C	40
Q1	D768017	FD562	FIBREBOARD DRUM 380 X 840MM	0102 D768017	24 EA	No Restrictions	11880199 3 C	40	No Restrictions	11880199 3 C	40
Q1	D763434	FD562	FIBREBOARD DRUM 380 X 840MM	0102 D763434	16 EA	No Restrictions	11880199 3 C	40	No Restrictions	11880199 3 C	40
Q1	D775721	FD562	FIBREBOARD DRUM 380 X 840MM	0102 D775721	12 EA	No Restrictions	11880199 3 C	40	No Restrictions	11880199 3 C	40
Q1	D763111	FD562	FIBREBOARD DRUM 380 X 840MM	0102 D763111	1 EA	No Restrictions	11880199 3 C	40	No Restrictions	11880199 3 C	40
Q1	D756195	DL5215	CHARGE BAG 15L ARMOREFLEX 114	0102 D756195	40 EA	No Restrictions	11880199 3 C	40	No Restrictions	11880199 3 C	40
Q1	D654868	DL5215	CHARGE BAG 15L ARMOREFLEX 114	0102 D654868	1 280 EA	No Restrictions	4 C	4 C	No Restrictions	4 C	4 C
Q1	D561969	DL5213	CHARGE BAG 5L ARMOREFLEX 114	0102 D561969	20 EA	No Restrictions	11880199 3 C	40	No Restrictions	11880199 3 C	40
Q1	D617352	DL5213	CHARGE BAG 5L ARMOREFLEX 114	0102 D617352	4 EA	No Restrictions	11880199 3 C	40	No Restrictions	11880199 3 C	40
Q1	D650107	DL5130	PRIMARY DRUM LINER/LDPE DRUM LINER	0102 D650107	35 EA	No Restrictions	11880199 3 C	40	No Restrictions	11880199 3 C	40
Q1	D684411	DL5130	PRIMARY DRUM LINER/LDPE DRUM LINER	0102 D684411	28 EA	No Restrictions	11880199 3 C	40	No Restrictions	11880199 3 C	40
Q1	D650104	DL5130	PRIMARY DRUM LINER/LDPE DRUM LINER	0102 D650104	19 EA	No Restrictions	11880199 3 C	40	No Restrictions	11880199 3 C	40
Q1	D684412	DL5130	LINER DRUM 5 X 14 X 4mil	0102 D684412	12 EA	No Restrictions	11880199 3 C	40	No Restrictions	11880199 3 C	40
Q1	D520924	DL5126	FOIL DRUM LINER 34 3/4INX62 3/8INX4.5MIL	0102 D520924	3 EA	No Restrictions	11880199 3 C	40	No Restrictions	11880199 3 C	40
Q1	D743394	DL5060	FOIL DRUM LINER 34 3/4INX62 3/8INX4.5MIL	0102 D743394	27 EA	No Restrictions	11880199 3 C	40	No Restrictions	11880199 3 C	40
Q1	DL0562	DL5202	LINEAR POLYMER 26 V 30%:	0102 DL0562	3 EA	No Restrictions	11880199 3 C	40	No Restrictions	11880199 3 C	40
Q1	D723345	DL5202	LINEAR POLYMER 26 V 30%:	0102 D723345	13 EA	No Restrictions	11880199 3 C	40	No Restrictions	11880199 3 C	40

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Effective Date: 12 Mar 2025

Document Approval Signatures

Approved Date: 12 Mar 2025

Approval Verdict: Approve	Dayana Pallasco (L080250@lilly.com) Quality Approver 10-Mar-2025 00:34:02 GMT+0000
Approval Verdict: Approve	Candelas Barro (YS10691@lilly.com) Quality Approver 12-Mar-2025 09:26:41 GMT+0000
Reviewer / Approver Additional Details	N/A



CERTIFICATE OF ANALYSIS

Product: AZD9833 film-coated 75 mg tablets – CDC formulation (DP06895)

Reference number: Patheon CoA REP-0432949 v1.0 **Date of Manufacture:** 28 March 2024
Batch reference: L025966 (SmartSupplies) AV8491A (Patheon) **Specification:** SPEC-0149741 v 10.0

Test procedure	Result
Description	Complies
Identification	Complies
Assay	99.1% of label claim
Organic Impurities	
AZ14108616 (Aminopyridine)	Not Detected
AZ14107577 (cis-Isomer)	<0.05%
AZ14145164 (des-fluoro)	0.29%
Largest Single Unqualified Impurity	0.17%
Total Impurities	0.46% (2) ^a
Uniformity of Content	Complies, AV=2.7
Dissolution SGF @30 min	101% (99-103%)
Water content	2.6% w/w
Microbiological Limits	
Total Aerobic Microbial Count	<200 CFU/g
Total Combined Yeasts/Moulds Count	<20 CFU/g
No objectionable Micro-Organisms in the Total Counts	Complies
Absence of Escherichia coli	Complies

^a Figure in parenthesis represent the number of impurities ≥0.05% observed

1(1)

Electronic signatures are located on the last page of the pdf.

Check this is the latest version of the document before use.
Printed by Pavan Maddur Shashidhar on 23 May 2025 15:48 GMT+02:00

Document Approvals

Business Approval	Sophia Guldstrand Sophia.Guldstrand@astrazeneca.com 12-Aug-2024 08:34:51 GMT+0000
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Pfizer Italia S.r.l.

Uffici e Stabilimento Ascoli Piceno
Via del Commercio, 25/27
Località Marino del Tronto
63100 Ascoli Piceno (AP)
Tel. +39 0736 305.111
Fax +39 0736 305.263

**CERTIFICATE OF ANALYSIS**

F000147146

EXEMESTAN PFIZER 25MG TAB 2X15 BLST DE

Batch n. MA8819*Mfr date* AUG-2024*Exp date* JUL-2027**Description:**

Round, biconvex, off-white to slightly greyish sugar-coated tablets, about 6 mm diameter, printed with numbers 7663 on one side in black ink.

< -----TEST----- >	U.M	<---SPECIFICATION--->	<---RESULT--->
APPEARANCE		Same as description.	COMPLIES
IDENTITY (HPLC)		Same retention time as Exemestane working standard.	EXACT
IDENTIFICATION UV EXEMESTANE		Same U.V. spectrum as Exemestane working standard.	EXACT
TITANIUM DIOXIDE IDENTIFICATION (AAS)		POSITIVE	POSITIVE
UNIFORMITY OF CONTENT (PH.EUR)		COMPLIES	COMPLIES
TOTAL RELATED SUBSTANCES (HPLC)	%	N.M.T. 2.5	0.0
TRIKETONE (HPLC)	%	N.M.T. 1.0	0.0
EXEMESTANE 6,20 EPOXIDE (HPLC)	%	N.M.T. 0.5	0.0
ADD (HPLC)	%	N.M.T. 1.0	0.0
EACH INDIVIDUAL UNKNOWN	%	N.M.T. 0.1	0.0
TOTAL UNKNOWN (HPLC)	%	N.M.T. 0.5	0.0
DISSOLUTION TEST IN 45'	Q%	N.L.T. 80	COMPLIES
ASSAY (HPLC)	% l.a.	95.0 - 105.0	99.3
TOTAL VIABLE AEROBIC COUNT	CFU/g	L.T. 1000	0
FUNGI	CFU/g	L.T. 100	0
ESCHERICHIA COLI	/g	ABSENT	ABSENT

The batch meets the current analytical specification

The batch complies with GMP (Directive 91/356/EEC)

Q.O. RELEASED DATE:

21-JAN-2025

This certificate was created by a validated system and is valid without manual signature

Quality Operations
Lot Dispositioned By
FABIO SALVI

AstraZeneca
To Whom It May Concern

Statement of Authenticity

Brand name: Kisqali

Generic name (API): Ribociclib

Strength: 200 mg

Form: Film-coated tablets

Pack size: 63 tablets

MA holder: Novartis Europharm Limited

MA holder address: Vista Building, Elm Park, Merrion Road, Dublin 4, Ireland

Registered and marketed in: Germany

Country of purchase: Germany

MA number: EU/1/17/1221/005 (PZN12673170)

Batch number: PB5329

Expiry date: 06/2027

Quantity: 298 packs

PO number: 7101465645

I can confirm that the above products are registered and have been placed on the market in Germany by the marketing authorization holder or by the marketing authorization holder's appointed/authorized distributor.

The integrity of Inceptua's supplier has been verified.

The products can be traced back throughout the complete supply chain from the marketing authorization holder of the products for the specific region to Inceptua.

The products have been handled, controlled, and shipped according to the product's requirements from the time they left Inceptua's supplier to the delivery destination.

To the best of our knowledge the above products are non-falsified.

By approving this document, I certify that the requirements stated above for pedigree and associated documentation have been reviewed and found to be in compliance.

The authenticity of the unique identifiers has been verified and all unique identifiers have been decommissioned in accordance with Commission Delegated Regulation (EU) 2016/161.

Christina Neuschl

Christina Neuschl

Signer ID: AFAJTPKEXU...

19 May 2025, 09:55:28, BST

Signing Reason: I approved this document



PHARMADOX HEALTHCARE LTD.
KW20A Kordin Industrial Estate
Paola PLA3000, Malta

CERTIFICATE OF ANALYSIS

Product Name:	Letrozole, Accord, 2.5mg Film-coated tablets by 30 tablets		
Generic Name:	Letrozole Tablets 2.5mg		
Product QC Lab No:	FP24-11788	CoA No / Rev.:	Y24K0576/00
Client Batch No:	M2408748	Mfg. Date:	As per Manufacturer's CoC
Client Name:	Accord Healthcare	Exp. Date:	08/2027
Manufacturer's Name:	As per Manufacturer's CoC	Batch Qty.:	As per Manufacturer's CoC
Specification Ref No:	CF-616 : Sec 5 Ver 5	Analytical Method Ref No:	CF-616 : Sec 6 Ver 5

S. NO	TEST DESCRIPTION	SPECIFICATION		RESULT
1	Description	Yellow, round, biconvex, film coated tablets plain on both sides.		Complies
2	Avg. weight of tablet	103 ± 5 % (97.9 mg to 108.2 mg)		102.9 mg
3	Identification	A) The R_f value of the spot due to Letrozole in the chromatogram obtained with the test solution should be similar in R_f value of the spot obtained with reference solution. B) The retention time of the Letrozole peak in the chromatogram of the assay preparation should correspond with that of standard preparation as described under the assay.		Complies
4	Dissolution	Not less than 80 % (Q) in 30 mins		Min. 99 % Max. 102 % Avg. 101 %
5	Related substances			
	Any impurity	Not more than 0.1%		Not detected
	Total impurities	Not more than 0.4 %		0.00%
6	Assay	95.0 % to 105.0 % of label claim.		100.5%
7	Uniformity of dosage units by content uniformity	The acceptance value of the first 10 tablets should be less than or equal to 15.0. If the acceptance value is greater than 15.0, test next 20 tablets and calculate the acceptance value. The final acceptance value of the 30 tablets should be less than or equal to 15.0 and no individual content of the dosage unit should be less than $(1 - 25 \times 0.01) M$ or not more than $(1 + 25 \times 0.01) M$.		2.1
8	*Microbial limit test			
	A) Total viable aerobic count			
	i) Aerobic bacteria	Not more than 1000 cfu/g		N/A
	ii) Fungi	Not more than 100 cfu/g		N/A
	B) Pathogen			
	i) E. coli	Should be absent		N/A
	ii) Salmonella	Should be absent		N/A
	iii) S. aureus	Should be absent		N/A



PHARMADOX HEALTHCARE LTD.
KW20A Kordin Industrial Estate
Paola PLA3000, Malta

CERTIFICATE OF ANALYSIS

Product Name:	Letrozole, Accord, 2.5mg Film-coated tablets by 30 tablets		
Generic Name:	Letrozole Tablets 2.5mg		
Product QC Lab No:	FP24-11788	CoA No / Rev.:	Y24K0576/00
Client Batch No:	M2408748	Mfg. Date:	As per Manufacturer's CoC
Client Name:	Accord Healthcare	Exp. Date:	08/2027
Manufacturer's Name:	As per Manufacturer's CoC	Batch Qty.:	As per Manufacturer's CoC
Specification Ref No:	CF-616 : Sec 5 Ver 5	Analytical Method Ref No:	CF-616 : Sec 6 Ver 5

	<i>iV) Pseudomonas aeruginosa</i>	Should be absent	N/A
9	Identification of titanium dioxide	A yellow / orange colour should be produced.	Complies
10	Identification of Iron oxide yellow	A deep red colour should be produced.	Complies
11	Loss on drying	Not more than 5.0% w/w	2.6% w/w

Note: The reporting threshold for the impurity is 0.1%.

*Test to be performed for process validation/exhibit batches. For commercial batches it should be performed for first five batches followed by every fifth batch or one batch per year whichever is earlier.

Definitions: <LOQ – Below Limit of Quantification, <LOD – Below Limit of Detection, <DL – Below Disregard Limit, <RT- Below Reporting Threshold, N/A – Not Applicable.

Remarks: The result given on this certificate of analysis are determined at the time of analysis and relate to the sample supplied.

LIR reference (if applicable)	N/A
Procedure	NL/H/1383/01/DC RTD/090215/8
Comments	Samples sent directly from Intas. This is part of the Pre-Shipment Project.
Status	Batch COMPLIES with the specification

I hereby confirm that the QC testing referred to in the Technical Quality Agreement have been carried out in full compliance with the GMP requirements of the EU and the terms described in the Agreement for ensuring compliance with the requirements of the Marketing Authorisation(s) as provided by Accord Healthcare.

	Prepared By:	Approved By:
Name:	Afra Ummer	Lara Scerri
Title:	Quality Control Reviewer	Senior Quality Control Officer
Sign. & Date:	 06 DEC 2024	 06 DEC 2024