ЗАКЛЮЧЕНИЕ (ПОДТВЕРЖДЕНИЕ)

о соответствии серии или партии лекарственного препарата требованиям, установленным при его государственной регистрации
№ САМ-05-1225 от 17.12.2025

Торговое наименование	**Кабометикс®**
Международное непатентованное наименование (группировочное или химическое)	Кабозантиниб
Лекарственная форма	таблетки, покрытые пленочной оболочкой
Дозировка	**40 мг**
Форма выпуска (первичная упаковка, количество лекарственной формы в первичной упаковке, количество первичной упаковки в потребительской упаковке, комплектность)	таблетки, покрытые пленочной оболочкой, 40 мг, 30 шт. - флаконы - пачки картонные (30 шт.)
Номер серии (партии):	**CWNXD**
Объем серии (партии)	100
Дата производства	31.03.2025
Дата окончания срока годности	28.02.2029
Наименование и адрес производителя (с указанием стадий производства)	Патеон Инк., Канада (производство готовой ЛФ, первичная/вторичная/потребительская упаковка) Патеон Франция, Франция (выпускающий контроль качества)
Номер и дата регистрационного удостоверения	ЛП-№(008475)-(РГ-RU) от 17.01.2025
Номер нормативной документации	ЛП-№(008475)-(РГ-RU)-170125
Наименование и адрес держателя регистрационного удостоверения	Ипсен Фарма, Франция / Ipsen Pharma, France 65 Quai Georges Gorse 92100 Boulogne-Billancourt, France
Наименование и производитель активной (ых) субстанции (ий)	Кабозантиниб Пирамал Хелскеар (Канада) Лтд, Канада Серии **2200028**

Настоящим я подтверждаю, что лекарственный препарат **Кабометикс®** серия **CWNXD** производства Патеон Инк., Канада (производство готовой ЛФ, первичная/вторичная/потребительская упаковка), Патеон Франция, Франция (выпускающий контроль качества) **соответствует** требованиям, установленным при его государственной регистрации: ЛП-№(008475)-(РГ-RU)-170125.

Уполномоченное лицо на ввод в гражданский оборот
по доверенности ООО «ИПСЕН» от 03.03.2025
Власова М.Д.
Подпись

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Form			
[EXE] Batch certificate CABOMETYX 40MG batch CWNXD RU			
Document Number	Version	Status	Approved Date
FORM-000067757 - EXE000750491	1.0, CURRENT	Approved	Fri Aug 29 12:37:33 UTC 2025

BATCH CERTIFICATE

patheon
by Thermo Fisher Scientific

PATHEON France
40 boulevard de Champaret – CS 11006
38307 Bourgoin-Jallieu Cedex
Phone: +33 (0) 4 74 93 87 00
Fax: +33 (0) 4 74 93 87 81 Patheon.com

PRODUCT INFORMATION	
Name of Product (includes strength/potency, dosage form & package size-if applicable):	P563 CABOMETYX TABLETS 40 mg, 30CT
Imported from, if applicable:	Canada
Lot/Batch Number(s):	CWNXD
Code	304019433
Date of Fabrication/Manufacture: *(DD/MMM/YYYY)*	31/Mar/2025
Expiry Date: *(MMM/YYYY)*	Feb/2029
Deviation Report(s):	**YES** (DR #415807)
Certificate of Analysis Attached:	YES (provided by Patheon Toronto)
Quantity:	600 units
License n#:	2025_070_1_2
Serialized product	YES
Additional Information, if applicable:	Pack Description: 30 tablets together with silica gel (3 containers with silica gel 1 g each) and polyester fiber in a bottle of high density polyethylene. 1 bottle with patient information leaflet in a cardboard box. Shelf life (4 years) and storage conditions (Store at the temperature not above 25°C) Bulk : CWDDW - CWDFD Primary packaging : CWDFK Intended for RU market

QUALITY STATEMENT

I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging and quality control, at Patheon Toronto in full compliance with the GMP requirements of the local regulatory authority, with the requirements of the Marketing Authorisation of the importing country/countries. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP. The import and storage of the product are in accordance with requirements.
After importation, documentation review including review of any associated deviations, and a control at receipt have been done at Patheon Bourgoin and are compliant.

CONCLUSION

Batch release for shipment

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Electronic Signatures			
Author: Dezempte, Céline			
Document Number	Version	Status	Approved Date
FORM-000067757 - EXE000750491	1.0, CURRENT	Approved	Fri Aug 29 12:37:33 UTC 2025

Electronic Signatures

User	Date	Justification
Dumoulin, Fabien	29-Aug-2025 12:37:25 (GMT)	Qualified Person Approval

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EXELIXIS

CERTIFICATE OF RELEASE

Title: Cabometyx FG 40mg RU - COR - CWNXD		
Doc. Number: CERT-0510	**Vers.:** 1.0	**Approved Date:** 25 Jul 2025

Product Name and/or Batch Record Title: Cabometyx (Cabozantinib) Tablets 30 CT RU	**Strength/Concentration:** ☐N/A 40 MG	**Batch/Lot Quantity:** 600 Cartons
Product Batch/Lot No.: CWNXD	**Date of Manufacture:** 31MAR2025	
Product Storage Conditions: ☐N/A Store at the temperature not above 25°C	**Retest/Expiry Date:** ☐N/A 28FEB2029	
Contract Manufacturer/Location: Patheon Toronto	**Exelixis Specification No./Version:** ☐N/A SPEC-0056 v22.0	
Product Code(s)/Work Order No: 4000004862 / 1141652	**Contractor Master Batch Record(s) No./Rev:** Bill of Materials: 8; Label Information: 4 Packaging Instructions: 5; Finished Product Sampling: 3	
Product Type (check all that apply): ☐ Master Cell Bank ☐ Working Cell Bank ☐ GMP Intermediate ☐ API/Drug Substance ☐ Drug Product ☐ Primary Packaging ☒ Secondary Packaging		
Input Intermediate Batch/Lot No(s): ☒N/A	**Drug Product Batch/Lot No(s).:** ☐N/A CWDFD	
API Batch/Lot No(s): 2200028 ☐N/A	**Other Batch/Lot No(s):** ☐N/A Blend: CWDDW	
Primary Packaged Batch/ Lot No(s): CWDFK ☐N/A	**Market:** ☐N/A Russia	

Deviations
☒N/A
☒N/A
☒N/A
☒N/A
☒N/A
☒N/A

This is to certify that the above listed product was manufactured in a cGMP compliant facility, tested in accordance with applicable compendial requirements and meets the current Quality Agreement and Release Specifications set forth by Exelixis.

Exelixis has qualified the above listed manufacturer for the product type listed.

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EXELIXIS

CERTIFICATE OF RELEASE

Title: Cabometyx FG 40mg RU - COR - CWNXD		
Doc. Number: CERT-0510	**Vers.:** 1.0	**Approved Date:** 25 Jul 2025

Based on the review of the batch record and associated production and testing documents, the batch meets the specification for the intended market (as applicable) and is released for the intended use as indicated.

Disposition/Intended Use:

☒ Commercial ☐ Clinical ☐ Clinical Study No.:

☐Approved for Further Processing (AFP) ☐ Other: ☐Reject

Comments: ☐ N/A

Patheon Codes: Label 2000017309; Leaflet 2000018247; Carton 2000017279

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EXELIXIS

CERTIFICATE OF RELEASE

Title: Cabometyx FG 40mg RU - COR - CWNXD		
Doc. Number: CERT-0510	**Vers.:** 1.0	**Approved Date:** 25 Jul 2025

DOCUMENT CHANGE HISTORY

(LATEST VERSION ON TOP)

Ver.	Owner	Approved Date	Change Summary
1.0	J. Abejuela	Refer to Doc. Header	New Document

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Patheon
A HEALTHIER WORLD. DELIVERED.

TORONTO REGION OPERATIONS

Title: **CERTIFICATE OF MANUFACTURE**
Form: **F-053** Revision: 28
SOP Reference: **OPS 1027**
Effective Date: 28-FEB-2024

Certificate of Manufacture

Establishment License Number: 100074-A

Manufactured, Packaged and/or Labeled at:		Tested at:	
☒ Patheon Inc. Toronto Region Operations 2100 Syntex Court Mississauga, Ontario L5N 7K9 Canada Establishment License Number100074-A	☐ Patheon Inc. Patheon Whitby Operations 111 Consumers Drive Whitby, Ontario L1N 5Z5 Establishment License Number:100074-F	☒ *Patheon Inc.* *Toronto Region Operations* *2100 Syntex Court* *Mississauga,* *Ontario L5N 7K9* *Canada*	☐ *Patheon Inc.* *Patheon Whitby Operations* *111 Consumers Drive* *Whitby, Ontario L1N 5Z5* *Canada*

Product Name:	CABOMETYX (CABOZANTINIB) TABLETS 40 MG, 30 CT RU	Patheon Batch #:	CWNXD
		Client Batch #:	N/A
Serialized Product:	Yes ☒ No ☐	Marketing Auth. # (NDC, DIN, etc):	005558
Quantity:	600 Cartons / 12 Shippers / 1 Skid	Average Tablet or Capsule Weight:	N/A

Packaging Material #:	4000004862 4000003554	Packaging Batch #:	CWNXD CWDFK	Master #:	Bill of Materials: 8 Label Information: 4 Packaging Instructions: 5 Finished Product Sampling: 3 Bill of Materials: 4 Label Information: 4 Packaging Instructions: 3 Finished Product Sampling: 2

Manufacturing Material #:	3000003084 3000003074	Manufacturing Batch #:	CWDFD CWDDW	Master #:	Compression: 7 Coating: 8 Dispensing: 5 Granulation:9

Date of Manufacture:	31.Mar.2025	Fill Before Date:	05.Apr.2026	Expiry Date:	02 2029

Other Information:	N/A

Certification Statement:

CONFIDENTIAL

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TITLE: CERTIFICATE OF MANUFACTURE

Form #: F-053
Revision # 28

Material #: 4000004862 Batch #: CWNX1

I hereby certify that the above information is authentic and accurate. This batch has been fabricated / manufactured, including packaging and quality control at the above-mentioned sites in full compliance with the GMP requirements of the local Regulatory Authority. The batch processing, packaging and analysis records were reviewed and found to be in compliance with GMP. If applicable, explanations for accepted deviations are attached.

Investigation(s) Required: Yes ☒ No ☐ Deviation Report Nos. 415807

Conclusion: Batch released.
Complies with all specifications of the testing instruction.

FELIPE KINA QA ASSOCIATE

Print Name and Title of Authorized person

Signature of Authorized Person

14 JUL 2025

Date Certificate Issued

Patheon Final Disposition

PATHEON
QUALITY ASSURANCE
14 JUL 2025
F-K
RELEASED

«МГСЕМ»
1PSEN 0606

CONFIDENTIAL

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ThermoFisher SCIENTIFIC

Deviation Detail Report

QR ID:	415807	**QR State:**	Closed - Done
Division:	Thermo Fisher Scientific	**Site:**	TRO (Toronto)
Date Opened:	11-Oct-2022	**Date Due:**	25-Nov-2022
		Date Closed:	24-Nov-2022

General Information

Initial Information

Site:	TRO (Toronto)	**Date Opened:**	11-Oct-2022 10:55 AM
Initiator:	Victor Mascarenhas	**Original Date Due:**	25-Nov-2022
		Date Due:	25-Nov-2022
Assigned To:	Vanja Stevens		
Responsible Department:	Material Management		
Short Description:	Incoming packaging material missing vendor label.		
DR Type:	Incoming Material Defect	**Division Type Level 1:**	Pharmaceuticals
DR Type Sub Category:	N/A	**Division Type Level 2:**	Commercial
Other Sites Impacted:	Not Applicable	**Division Type Level 3:**	Commercial

Initial Deviation Information

Is Material Impacted?: No

Material Grid:

Material Site	Material Code #	Material Description	Local Material Lot #	Material Code # (manual)	Material Description (manual)	Local Material Lot # (manual)	Protocol Number	Receiving Number	Material Disposition	Material Scope	Comment
TRO	2000000000	ADHESIVE HOT MELT P 330	1108385			Vendor Lot: 220407			Full Lot Accepted		

Is Product Impacted?:	No		
Source of Discovery:	Other	**Specify Other:**	Packaging component.
~~**Date of Discovery:**~~	~~21-Jul-2022~~	~~**Date of Occurrence:**~~	~~21-Jul-2022~~
Discovered By:	Warehouse receiver		

Discovery Evaluation

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ThermoFisher SCIENTIFIC

Deviation Detail Report

QR ID:	415807	**QR State:**	Closed - Done
Division:	Thermo Fisher Scientific	**Site:**	TRO (Toronto)
Date Opened:	11-Oct-2022	**Date Due:**	25-Nov-2022
		Date Closed:	24-Nov-2022

***** No Fields in this Section have been Populated *****

Deviation

Deviation Details

Detailed Description: On July 21st Material 2000000000 ADHESIVE HOT MELT P 330 - P.O. 4500131550 arrived with 10 boxes. 6 boxes are missing supplier labels with description.

Immediate Action Taken: On 21st August Buyers were notified. On 22nd July Buyers and QA were notified.

Investigation Attachment: QR#415807 Attachment #1 - Photos of Incoming Shipment.pdf, QR#415807 Attachment #2 - Mercury Adhesives Packing list and cofa.pdf

Current Status of Material: Raw Material

Criticality Assessment

***** No Fields in this Section have been Populated *****

Investigation

Investigation and Evaluation

Investigation:

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ThermoFisher SCIENTIFIC

Deviation Detail Report

QR ID:	415807	**QR State:**	Closed - Done
Division:	Thermo Fisher Scientific	**Site:**	TRO (Toronto)
Date Opened:	11-Oct-2022	**Date Due:**	25-Nov-2022
		Date Closed:	24-Nov-2022

Material Impacted:

Material Name: ADHESIVE HOT MELT P 330
Material Code/Batch: 2000000000 Batch 1108385
Vendor: Mercury Adhesives
Vendor Lot: 220407
Quantity: 10 shippers (230.0kg)

Summary of Incident:

On 21-Jul-2022 Material 2000000000 ADHESIVE HOT MELT P 330 - P.O. 4500131550 arrived with 10 boxes. 6 boxes were found to have missing supplier labels with description.
The adhesive is used in the secondary packaging process (used to glue carton flaps).

Per SOP WHS6005 (SOP000071824 Rev35), for each incoming shipment, the vendor batch number, and material name must be present and must be verified against the vendor packing slip.

Further Inspection of Shipment -Refer to Attachment #1:

Upon further inspection, the following observations were made:
- 4 of the shippers were in original boxes with Vendor Name (Mercury Adhesives), item code (#330), material name: hot melt, vendor batch (#220407) and original vendor information printed directly on the corrugate.
- 6 of the shippers were in shipper boxes without Vendor Name or material name but did have present on them a vendor label with vendor's address and item code (#330) and the corrugate was stamped with the batch number (#220407).

All shippers therefore can be conclusively identified as being the same material from the same lot and the same vendor.

Packing List and Vendor CofA also accompanied the shipment and contained the following information (Refer to Attachment #2):
- PO#4500131550
- Vendor Name: Mercury Adhesives
- Item Number: #330
- Lot: 220407
- Quantity: 10 cartons

Summary:

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ThermoFisher SCIENTIFIC

Deviation Detail Report

QR ID:	415807	**QR State:**	Closed - Done
Division:	Thermo Fisher Scientific	**Site:**	TRO (Toronto)
Date Opened:	11-Oct-2022	**Date Due:**	25-Nov-2022
		Date Closed:	24-Nov-2022

It was concluded that all 10 shippers have information identifying the material number, vendor, and vendor lot which also matches the packing slip and vendor cofa therefore the material is acceptable for receipt and use in packaging.
For future shipments of adhesive, Patheon procurement team is in the process of changing to an alternate adhesive supplier (code 5000000047).

Error Classification Level I:	Shipping and Receiving of Goods	**Error Classification Level II:**	Incoming Product Shipment
Error Classification Level III:	Inspection upon Receipt Failure		

Health Hazard Assessment

Health Hazard Assessment Req?: No

Health Hazard Summary: n/a

Impact Assessment

***** No Fields in this Section have been Populated *****

Root Cause Information

Root Cause: The root cause was determined to be external - related to material vendor.

RCA Tools: Brainstorming

Root Cause Grid:

Root Cause Type	Root Cause Drill Down Category	Root Cause Drill Down Level 1	Root Cause Drill Down Level 2	Comment
Root Cause	Outside Of Site(s) Control	Customer Furnished / Controlled Material Needs Improvement	Material Manufacturer Needs Improvement	

Historical Review

Historical Review Details: Trackwise was queried for vendor "Mercury Adhesives". Query confirmed that there have been no previous deviations for this vendor.

Living Risk Assessment

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ThermoFisher SCIENTIFIC

Deviation Detail Report

QR ID:	415807	**QR State:**	Closed - Done
Division:	Thermo Fisher Scientific	**Site:**	TRO (Toronto)
Date Opened:	11-Oct-2022	**Date Due:**	25-Nov-2022
		Date Closed:	24-Nov-2022

Risk Assessment Available?: No

Control Strategy In-Place?: No

Event Risk Assessment

Risk Assessment: n/a

Remediation

***** No Fields in this Section have been Populated *****

Conclusion

Criticality: Minor

Conclusion(s):

A total of 10 cartons of material code 2000000000 from Mercury Adhesives were received without inconsistent labeling. Further evaluation of the shippers concluded that all shippers can be conclusively identified as being the same material from the same lot and the same vendor.

All shippers have information identifying the material number, vendor, and vendor lot which also matches the packing slip and vendor cofa therefore the material is acceptable for receipt and use in packaging.

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ThermoFisher SCIENTIFIC

Deviation Detail Report

QR ID:	415807	**QR State:**	Closed - Done
Division:	Thermo Fisher Scientific	**Site:**	TRO (Toronto)
Date Opened:	11-Oct-2022	**Date Due:**	25-Nov-2022
		Date Closed:	24-Nov-2022

e-Signatures

e-Signatures

Submitted By:	Vanja Stevens	**Submitted On:**	21-Nov-2022 08:36 AM
Quality Reviewed By:	Ritesh Gajjar	**Quality Reviewed On:**	21-Nov-2022 08:44 AM
Investigation Completed By:	Vanja Stevens	**Investigation Completed On:**	21-Nov-2022 10:46 AM
Functional Area Approval By:	Olive Kim	**Functional Area Approval On:**	21-Nov-2022 11:25 AM
QA Approval By:	Yogender Arya	**QA Approval On:**	24-Nov-2022 10:03 AM

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PATHEON INC.
FABRICATION, PACKAGING, LABELING and
FINAL PRODUCT SPECIFICATION TESTING
Toronto Region Operations (100074-A)
2100 Syntex Court. Mississauga, Ontario
L5N 7K9 Canada
(905) 821-4001

CERTIFICATE OF ANALYSIS
FINISHED PRODUCT

PRODUCT: CABOZANTINIB 40 MG COATED TABLETS 30 CT
CLIENT: EXELIXIS
MARKET: RU

FINISHED PRODUCT MATERIAL NO: 4000004862
FINISHED PRODUCT BATCH NO: CWNXD
DATE OF MANUFACTURE: 31/MAR/2025
EXPIRY DATE: 02 2029

CofA Rev. 1
ARF Rev. 2

Effective Date: 18-Dec-2024

TEST	SPECIFICATION	RESULTS
APPEARANCE Visual	Yellow film-coated triangle shaped tablets, debossed with "XL" on one side and "40" on the other side of the tablet	Yellow film-coated triangle shaped tablets, debossed with "XL" on one side and "40" on the other side of the tablet
VERIFICATION OF COMPONENTS Visual	Presence of Label, Leaflet and Carton	Presence of Label, Leaflet and Carton
	Comments:	NA

REVIEWED AND APPROVED BY: _____
Laboratory Operations Manager/Designate

14 JUL 2025
Date

PATHEON
QUALITY ASSURANCE
14 JUL 2025
F.K
ACCEPTED

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FINAL PRODUCT SPECIFICATION TESTING
Toronto Region Operations (100074-A)
2100 Syntex Court, Mississauga, Ontario
L5N 7K9 Canada
(905) 821-4001

CERTIFICATE OF ANALYSIS
FINISHED PRODUCT

PRODUCT: CABOZANTINIB 40 MG COATED TABLETS 30 CT (EU/ROW)
BRITESTOCK
CLIENT: EXELIXIS

FINISHED PRODUCT MATERIAL NO: 4000003554
FINISHED PRODUCT BATCH NO: CWDFK
DATE OF MANUFACTURE: 31/MAR/2025

ARF FP Rev 3
CofA Rev 3

EFFECTIVE DATE: 17-Dec-2024

TEST	SPECIFICATION	RESULTS
APPEARANCE Visual	Yellow film-coated triangle shaped tablets, debossed with "XL" on one side and "40" on the other side of the tablet	Yellow film-coated triangle shaped tablets, debossed with "XL" on one side and "40" on the other side of the tablet
	Comments:	NA

REVIEWED AND APPROVED BY: _____
Laboratory Operations Manager/Designate

DATE: 14 MAY 2025

PATHEON
QUALITY ASSURANCE
14 MAY 2025
ACCEPTED

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PATHEON INC.
FABRICATION, PACKAGING, LABELING and
FINAL PRODUCT SPECIFICATION TESTING
Toronto Region Operations (100074-A)
2100 Syntex Court. Mississauga, Ontario
L5N 7K9 Canada
(905) 821-4001

CERTIFICATE OF ANALYSIS
BULK PRODUCT

PRODUCT: CABOZANTINIB 40 MG COATED TABLETS (EU/ROW)

CLIENT: EXELIXIS
MATERIAL NUMBERS:
3000003084, 3000003114

BULK PRODUCT MATERIAL NO: 3000003084
BULK PRODUCT BATCH NO: CWDFD
DATE OF MANUFACTURE: 31/MAR/2025

ARF BP Rev 2
CofA Rev 2

EFFECTIVE DATE: 22/MAR/2018

TEST	SPECIFICATION	RESULTS
APPEARANCE Visual	Yellow film-coated triangle shaped tablets, debossed with "XL" on one side and "40" on the other side of the tablet	Yellow film-coated triangle shaped tablets, debossed with "XL" on one side and "40" on the other side of the tablet.
IDENTIFICATION (HPLC-UV AND UV Spectrum) CTMLP-2646	Conforms to reference standard	Conforms
POTENCY (wt%) CTMLP-2646	95.0% - 105.0% of Label Claim	
	1):	98.5%
	2):	98.2%
	Avg:	98.3%
IMPURITIES (HPLC) CTMLP-2646	a) Individual Unspecified Degradant: NMT 0.2%	ND
	b) Total: NMT 1.0%	ND

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FINAL PRODUCT SPECIFICATION TESTING
Toronto Region Operations (100074-A)
2100 Syntex Court, Mississauga, Ontario
L5N 7K9 Canada
(905) 821-4001

CERTIFICATE OF ANALYSIS
BULK PRODUCT

PRODUCT: CABOZANTINIB 40 MG COATED TABLETS (EU/ROW)

CLIENT: EXELIXIS
MATERIAL NUMBERS:
3000003084, 3000003114

BULK PRODUCT MATERIAL NO: 3000003084
BULK PRODUCT BATCH NO: CWDFD
DATE OF MANUFACTURE: 31/MAR/2025

ARF BP Rev 2
CofA Rev 2

EFFECTIVE DATE: 22/MAR/2018

TEST	SPECIFICATION	RESULTS
CONTENT UNIFORMITY (HPLC-UV)		
CTMLP-2648	Conforms to current USP <905>	
	1)	99.9%
	2)	99.8%
	3)	100.5%
	4)	100.3%
	5)	100.0%
	6)	101.2%
	7)	99.6%
	8)	101.3%
	9)	101.0%
	10)	101.8%
	Avg10 =	100.5%
	Acceptance Value:	1.8
	Stage 2	
	1)	NA
	2)	NA
	3)	NA
	4)	NA
	5)	NA
	6)	NA
	7)	NA
	8)	NA
	9)	NA
	10)	NA
	11)	NA
	12)	NA
	13)	NA
	14)	NA
	15)	NA
	16)	NA
	17)	NA
	18)	NA
	19)	NA
	20)	NA
	Avg30=	NA
	Acceptance Value:	NA

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PATHEON INC.
FABRICATION, PACKAGING, LABELING and
FINAL PRODUCT SPECIFICATION TESTING
Toronto Region Operations (100074-A)
2100 Syntex Court, Mississauga, Ontario
L5N 7K9 Canada
(905) 821-4001

CERTIFICATE OF ANALYSIS
BULK PRODUCT

PRODUCT: CABOZANTINIB 40 MG COATED TABLETS (EU/ROW)

CLIENT: EXELIXIS
MATERIAL NUMBERS:
3000003084, 3000003114

BULK PRODUCT MATERIAL NO: 3000003084
BULK PRODUCT BATCH NO: CWDFD
DATE OF MANUFACTURE: 31/MAR/2025

ARF BP Rev 2
CofA Rev 2

EFFECTIVE DATE: 22/MAR/2018

TEST	SPECIFICATION	RESULTS				
DISSOLUTION (HPLC-UV) CTMLP-2647	Meets USP <711> Apparatus 2 Q = 80% in 15 minutes	15	30	45	60	90
	Stage 1					
	1)	100%	100%	101%	100%	101%
	2)	100%	101%	101%	101%	101%
	3)	102%	103%	103%	103%	103%
	4)	101%	102%	102%	102%	102%
	5)	97%	98%	99%	99%	99%
	6)	101%	102%	102%	102%	102%
	Min:	97%	98%	99%	99%	99%
	Max:	102%	103%	103%	103%	103%
	Mean:	100%	101%	101%	101%	101%
	%RSD:	1.8	1.6	1.4	1.4	1.3
	Stage 2					
	7)	NA	NA	NA	NA	NA
	8)	NA	NA	NA	NA	NA
	9)	NA	NA	NA	NA	NA
	10)	NA	NA	NA	NA	NA
	11)	NA	NA	NA	NA	NA
	12)	NA	NA	NA	NA	NA
	Min:	NA	NA	NA	NA	NA
	Max:	NA	NA	NA	NA	NA
	Mean:	NA	NA	NA	NA	NA
	%RSD:	NA	NA	NA	NA	NA

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CERTIFICATE OF ANALYSIS
BULK PRODUCT

PRODUCT: CABOZANTINIB 40 MG COATED TABLETS (EU/ROW)

CLIENT: EXELIXIS
MATERIAL NUMBERS:
3000003084, 3000003114

BULK PRODUCT MATERIAL NO: 3000003084
BULK PRODUCT BATCH NO: CWDFD
DATE OF MANUFACTURE: 31/MAR/2025

ARF BP Rev 2
CofA Rev 2

EFFECTIVE DATE: 22/MAR/2018

TEST	SPECIFICATION	RESULTS				
(Continued)						
CTMLP-2647	Meets USP <711> Apparatus 2 Q = 80% in 15 minutes	15	30	45	60	90
	Stage 3					
	13)	NA	NA	NA	NA	NA
	14)	NA	NA	NA	NA	NA
	15)	NA	NA	NA	NA	NA
	16)	NA	NA	NA	NA	NA
	17)	NA	NA	NA	NA	NA
	18)	NA	NA	NA	NA	NA
	19)	NA	NA	NA	NA	NA
	20)	NA	NA	NA	NA	NA
	21)	NA	NA	NA	NA	NA
	22)	NA	NA	NA	NA	NA
	23)	NA	NA	NA	NA	NA
	24)	NA	NA	NA	NA	NA
	Min:	NA	NA	NA	NA	NA
	Max:	NA	NA	NA	NA	NA
	Mean:	NA	NA	NA	NA	NA
	%RSD:	NA	NA	NA	NA	NA

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Toronto Region Operations (100074-A)
2100 Syntex Court, Mississauga, Ontario
L5N 7K9 Canada
(905) 821-4001

CERTIFICATE OF ANALYSIS
BULK PRODUCT

PRODUCT: CABOZANTINIB 40 MG COATED TABLETS (EU/ROW)

CLIENT: EXELIXIS | **BULK PRODUCT MATERIAL NO: 3000003084**

MATERIAL NUMBERS: | **BULK PRODUCT BATCH NO: CWDFD**

3000003084, 3000003114 | **DATE OF MANUFACTURE: 31/MAR/2025**

ARF BP Rev 2
CofA Rev 2

EFFECTIVE DATE: 22/MAR/2018

TEST	SPECIFICATION		RESULTS
MOISTURE BY KF			
CTMLP-2649	NMT 3.5%		
		1):	1.8%
		2):	1.9%
		Avg:	1.8%
GTIs			
CTMLP-2712	XL 184-1-1: NMT 24 ppm		
		1):	3 ppm
		2):	3 ppm
		Avg:	3 ppm
	XL 184-1-4: NMT 15 ppm		
		1):	<3 ppm
		2):	<3 ppm
		Avg:	<3 ppm
MICROBIAL LIMITS			
Harmonized USP <61> and <62> and EP 2.6.12 and 2.6.13			
(MM-1381)			
Total aerobic count	NMT 1000 CFU/g		<100 cfu/g
Total combined yeasts and molds	NMT 100 CFU/g		<50 cfu/g
Absence of *P. aeruginosa*	Absence		Absence
Absence of *E. coli*	Absence		Absence
Absence of *S. aureus*	Absence		Absence
Absence of *Salmonella spp.*	Absence		Absence

Comments: Refer to QR# 1042038

REVIEWED AND APPROVED BY: _____
QC Manager/Designate

DATE: 14 MAY 2025

PATHEON
QUALITY ASSURANCE

14 MAY 2025
F-K

ACCEPTED

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Thermo Fisher SCIENTIFIC

OOS/OOT/E(U)M Detail Report

QR ID:	1042038	**QR State:**	Closed - Done
Division:	Thermo Fisher Scientific	**Site:**	TRO (Toronto)
Date Opened:	25-Apr-2025	**Date Due:**	25-May-2025
		Date Closed:	14-May-2025

General Information

General Information

Site:	TRO (Toronto)	**Testing Laboratory:**	LAB Operations
Incident Type:	OOS / OOT	**Date Opened:**	25-Apr-2025 05:39 PM
Initiator:	Chris Connolly	**Date of Event:**	25-Apr-2025
Assigned To:	Beena Moothan	**Date Identified:**	25-Apr-2025
Discovered By:	Neeta Srivastava	**Original Date Due:**	25-May-2025
Short Description:	Out of specification assay result for XL184 20 mg Tablets batch CWDDH.	**Date Due:**	25-May-2025
Other Sites Impacted:	Not Applicable	**Division Type Level 1:**	Pharmaceuticals
Client:	Exelixis	**Division Type Level 2:**	Commercial
		Division Type Level 3:	Commercial (Non-Sterile)

OOS/OOT

Testing Result / Sampling Information

Detailed Description:

On 25/APR/2025, the results of assay and related substances testing of XL184 Tablet batches were obtained for release. 20 mg batch CWDDH was found to have one replicate assay result that was out of specification, at 94.1%, as compared to 97.2% for the other sample preparation (limit 95.0-105.0%). Individual assay results for 8 other batches tested at the same time ranged from 96.2% to 99.4%. The one low assay determination for batch CWDDH was noted to be lower than the results from content uniformity testing which were obtained in a separate analysis (average content uniformity result: 98.2%). The assay for the other 8 batches were in agreement with their corresponding content uniformity results.

The OOS assay result for batch CWDDH will be investigated.

Investigation Type: Out of Specification (Laboratory)

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ThermoFisher SCIENTIFIC

OOS/OOT/E(U)M Detail Report

QR ID:	1042038	**QR State:**	Closed - Done
Division:	Thermo Fisher Scientific	**Site:**	TRO (Toronto)
Date Opened:	25-Apr-2025	**Date Due:**	25-May-2025
		Date Closed:	14-May-2025

Reason for Investigation: Low

Method ID # and Version #: CTMLP-2646, Rev. 3

Test Category(s): Assay

Is Sample Impacted: No

Test Results: preparation 1: 97.2%
preparation 2: 94.1%

Test Specification / Limits: 95.0-105.0% of label claim

Is Material Impacted?: No

Is Product Impacted?: No

Product Grid:

Product Site	Product Code #	Product Description	Local Product Lot #	Product Code # (manual)	Product Description (manual)	Local Product Lot # (manual)	Qty Under Investigation	Recommended Batch Rejected	Recommended Batch Accepted	Comment	Disposition
TRO	3000004228	CABOZANTINIB EU/ROW 20MG CTD TBS (30 KG)	CWDDH								

Attachment(s): Attachment-1 to QR 1042038, summary of original sample prep. and assay results.pdf, Attachment-2 to QR 1042038, Original and retest assay results.pdf

Phase I Investigation

Start Phase I Investigation

Start Phase I Investigation By: Chris Connolly

Start Phase I Investigation On: 25-Apr-2025 06:17 PM

Samples

Collected/Received Properly?: Yes

Labeled Correctly?: Yes

Stored Correctly?: Yes

Container Integrity?: Yes

Sampling Observations: Bulk product samples of Cabozantinib tablets were packed in HDPE bottles. All lots were correctly labeled as per the material code and strength. No errors were noted.

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Thermo Fisher SCIENTIFIC

OOS/OOT/E(U)M Detail Report

QR ID:	1042038	**QR State:**	Closed - Done
Division:	Thermo Fisher Scientific	**Site:**	TRO (Toronto)
Date Opened:	25-Apr-2025	**Date Due:**	25-May-2025
		Date Closed:	14-May-2025

Test Method

Correct for Analysis?:	Yes	**Correct Version?:**	Yes
Correct for Intended Use?:	Yes	**All Steps Followed?:**	Yes
Correct Specification Used?:	Yes		

Test / Spec. Observations:

Below listed material specifications are applicable to the bulk product lots under investigation:
3000004228 for 20 mg
3000003084 for 40 mg
3000003088 for 60 mg

The acceptance criteria for assay in the above specifications is 95.0 - 105.0% of label claim.

Documentation Review

Any DR/CC Against?:	No	**Is the Sample Correct?:**	Yes
Proper Documentation?:	Yes	**Prepared & Used Within Expiry?:**	Yes

Documentation Observations:

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ThermoFisher SCIENTIFIC

OOS/OOT/E(U)M Detail Report

QR ID:	1042038	**QR State:**	Closed - Done
Division:	Thermo Fisher Scientific	**Site:**	TRO (Toronto)
Date Opened:	25-Apr-2025	**Date Due:**	25-May-2025
		Date Closed:	14-May-2025

Current and effective specifications were used for samples analyzed. No error was noted for lot number, material code and strength. Standard and sample preparations and HPLC analysis was documented in the lab notebook PLSL-6941, p41 for the original test and PLSL-6904, p41 for repeat test. Mobile phase preparation in the original test has reference to PLSN-5027, p001 and was stable up to 29/Apr/2025. Diluent prepared on 16/Apr/2025 (PLSN-2630, p146) was stable up to 23/Apr/2025 and that prepared on 23/Apr/2025 (PLSN-2629, p152) was stable up to 30/Apr/2025. Documentation in the notebooks followed good documentation practices.

Analysis was performed using the correct method and version, CTMLP-2646, Rev. 3. Bulk solutions were prepared correctly. Reagents used for bulk solution preparations were within expiry. Standard solutions in the original analysis were referenced from notebook PLSN-2629, p147 and were stable up to 28/Apr/2025. Average weight of tablets and tablet powder for lots CWDDH, CWDDN, CWDFB, CWDFC, CWDFD and CWDFF was determined on 22/Apr/2025. Sample dilutions of these lots were prepared on 22/Apr/2025. Diluent used for these preparations was from PLSN-2630, expiring on 23/Apr/2025. Sample solutions prepared on 22/Apr/2025 were stable up to 28/Apr/2025. On 23/Apr/2025 analysis was continued for additional lots of CWDHN, CWDHP and CWFZX, for average weight determination, sample powder preparation and sample solution preparations. Balance# 47 (calibration due 04/Mar/2026) was used for average weight and sample powder weights. Timer# LAB-5955 (calibration due 10/Dec/2025) and shaker# 12 (calibration due 16/Apr/2026) were used for sample preparations on 22/Apr/2025 and 23/Apr/2025. Average weights of the 20 mg, 40 mg and 60 mg lots were as expected. The tablet powder quantity weighed for all samples were in agreement for duplicate preparations.

The UHPLC# 214 (calibration due 14/Jul/2025) and HPLC column # 903/14 were used for HPLC analysis. The column details were confirmed to be correct. The Empower project is TRO\TRO_GXP\2025Q2\AO\UVWXYZ. Trial analysis was performed in SSID 36924, and the actual run was performed in SSID 37297. Sensitivity solution was freshly prepared on the same day as that of HPLC analysis. Results were generated in RSID 40323 on 25/Apr/2025 and are summarized in attachment-1. This summary also contains details of average weight and sample weights for all samples. Of the 18 sample preparations, an out of specification result was obtained for the sample preparation-2 of lot CWDDH with 94.1% result which is less than the acceptance criteria of 95.0 - 105.0%. Assay results for all other preparations and impurity results for all preparations were within the acceptance criteria.

Data Review

System Suitability Met?:	Yes	**Reproducibility Met?:**	Yes
Chromatography Acceptable?:	Yes	**Correct Column Selected?:**	Yes
Correct Wavelength & Injection:	Yes	**Appropriate Reagents Used?:**	Yes
Appropriate Wavelength:	Yes	**Calculations Correct?:**	Yes
All Wt, Vol, & Conc Correct?:	Yes		

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ThermoFisher SCIENTIFIC

OOS/OOT/E(U)M Detail Report

QR ID:	1042038	**QR State:**	Closed - Done
Division:	Thermo Fisher Scientific	**Site:**	TRO (Toronto)
Date Opened:	25-Apr-2025	**Date Due:**	25-May-2025
		Date Closed:	14-May-2025

Data Review Observations:

The data was reviewed by document reviewer, no errors were found, based on the documented raw data and Empower analysis. System suitability criteria were met as per method requirement. The chromatograms were checked. Baseline for chromatograms of all preparations was as expected in the method. Standard peak area response was confirmed to be consistent with historical analyses.

Historical Information

Sample Tested Before?: No

Results Consistent?: Not Applicable

Historical Observations: Samples analyzed are bulk product release and were tested for the first time. There are no historical results from any of the 9 batches tested.

Agreement with Other Tests

Any Other Relevant Tests?: Yes

Agreement with Other Tests:

The bulk products were also analyzed for appearance, water content, impurities, content uniformity, dissolution, genotoxic impurities (GTI) and microbial examination. Results from these tests were within acceptance criteria of the respective specifications.

For the lot CWDDH with OOS assay result, the active content obtained in content uniformity test was 96.1 - 100.5%, average of 98.2%; dissolution results at the Q value of 15 minutes are between 94% - 99%, average of 96%. Moisture content was 1.7% - 1.9%, average of 1.8%, the GTI results were 3 ppm for both preparations and average for XL184-1-1 and <3 ppm for both preparations and average for XL184-1-4 impurity. Microbial enumeration tests were within acceptance criteria and appearance was obtained as per the description in the specification.

Equipment

Calibration Current?: Yes

Settings Correct?: Yes

Break, Leakage, Blockage?: No

PM Current?: Yes

Vials Punctured and Injected?: Yes

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ThermoFisher SCIENTIFIC

OOS/OOT/E(U)M Detail Report

QR ID:	1042038	**QR State:**	Closed - Done
Division:	Thermo Fisher Scientific	**Site:**	TRO (Toronto)
Date Opened:	25-Apr-2025	**Date Due:**	25-May-2025
		Date Closed:	14-May-2025

Equipment and Instrument: Equipment used for analysis are as below:

1. Balance# 47: Calibration due 04/Mar/2026
2. Shaker# 12: Calibration due 16/Apr/2026
3. Timer# LAB-5955: Calibration due 10/Dec/2025
4. UHPLC# 214: Calibration due 14/Jul/2025
5. Column# 903/14

Analyst Training Review

Training Current?: Yes

Analyst Training Observations:

The analyst NS is a level Scientist-III and has extensive experience of testing assay and impurity tests using tablet powder formulations. She has performed multiple analyses of XL184 tablets assay and impurity tests using CTMLP-2646 and is very familiar with the test.

The training records for NS in the Success Factors Learning Management System were confirmed to be completed up to date.

Material Review

Reference Standards Correct?:	Yes	**Vol. Flasks Match Doc.?:**	Yes
Stored Appropriately?:	Yes	**Undispersed Material Noted?:**	No
Flasks Contain Defects?:	No	**Glassware Contaminated?:**	No

Material Observations:

The original volumetric flasks and tablet powder preparations were physically examined by the Lab manager. No unusual observations were noted for the standard and sample solutions. There are no dilutions to the sample preparations. Tablets were examined for the impacted lot, no defects were observed.

Phase I Investigation

Investigation & Evaluation:

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Thermo Fisher SCIENTIFIC

OOS/OOT/E(U)M Detail Report

QR ID:	1042038	**QR State:**	Closed - Done
Division:	Thermo Fisher Scientific	**Site:**	TRO (Toronto)
Date Opened:	25-Apr-2025	**Date Due:**	25-May-2025
		Date Closed:	14-May-2025

A preliminary investigation was performed on 25/Apr/2025 by re-injecting the sample solutions of lot CWDDH from original vials and original solutions re-vialed of the duplicate preparations of lot CWDDH on the same UHPLC using the original mobile phase, standard solutions and chromatographic set up in SSID 43428. Sensitivity solution was freshly prepared. Original tablet powder was not sufficient to prepare fresh solution using original powder. Results were obtained in RSID 47763. The original results were confirmed for both preparations.

Sample prep.-1
Original result: 97.2%
Original vial re-injected: 97.2%
Re-vialed solution: 97.1%

Sample prep.-2:
Original result: 94.1%
Original vial re-injected: 94.2%
Re-vialed solution: 94.1%

Attachment-1 contains a summary of the average weight, tablet powder weights for sample preparation-1 and 2 for all samples analyzed in the original analysis SSID 32397. The average weight of the 20 mg lot CWDDH was as expected (~81 mg) for the 20 mg strength. Sample powder weights for duplicate preparations are correct as per method requirement (~ 420 mg) and are in agreement with each other. Chromatography of all injections in the HPLC run was as expected. No increase in impurity was observed in the sample preparation-2 of lot CWDDH. The HPLC parameters and column were correct as per the method. No error was identified for the HPLC set up.

The composite powder for the OOS batch did not appear to be different from the powders for other samples tested at the same time. The analyst that performed the test is experienced with the test. During interview it was confirmed that porcelain mortar and pestle were used to prepare the tablet powder for all lots. The analyst was under the incorrect impression that the material type for the mortar and pestle was not critical. The method specifies to use glass mortar and pestle. All lots tested during this analysis had tablet powder prepared using porcelain mortar and pestle. The procedure was deviated for all lots. It was confirmed that in the past the analyst had used glass mortar and pestle for tablet powder preparation for analyses using CTMLP-2646, Rev. 3. The scope of the QR was extended to all lots analyzed in the original analysis with respect to deviation to the method.

The use of glass mortar and pestle for tablet powder preparation was added to the method CTMLP-2646, Rev. 2 as a Notes to analyst (EXL-NTA-236-0818) with reference to CAPA #440935 to an unexpected results investigation in QR# 405281 in Nov/2022. A study was performed in 2017 for use of porcelain versus glass mortar and pestle, as part of DR #132335 (Phase 2 for OOS investigation 131696, generated on 27/JUL/2017 for OOS assay results of 10 mg bulk product batch# YHSS and finished product batch# YKSV). The results from that study were comparable for the preparations with

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ThermoFisher SCIENTIFIC

OOS/OOT/E(U)M Detail Report

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Division:	Thermo Fisher Scientific	**Site:**	TRO (Toronto)
Date Opened:	25-Apr-2025	**Date Due:**	25-May-2025
		Date Closed:	14-May-2025

the two types of mortars/pestles. The glass mortar could provide better visualization and better indication of powder sticking on the mortar walls (which could lead to API loss and lower assay results). API loss during grinding has been established previously with the observation that the grinding process most likely removes the API from the homogeneous powder (the API gets stuck on the mortar and pestle wall) and extra care is required when transferring the powder to a scintillation vial for storage, to scrape the mortar and pestle in order to get the API back into the mass. In the revision 3 of CTMLP-2646, the use of glass mortar and pestle for tablet grinding was added to the procedure for sample preparation.

To eliminate the risk of API loss, an assay method has been validated with use of intact tablets however, it is not yet implemented as it is pending regulatory approval.

The OOS result was limited to one lot, CWDDH, however the incorrect mortar and pestle was used for tablet grinding of other 8 lots tested at the same time. Hence all 9 samples were impacted by the procedure deviation and were scheduled for a retest. The original data was invalidated for all the lots prepared between 22/Apr/2025 and 23/Apr/2025, analyzed in SSID 37297. A retest was performed on 02/May/2025 for assay and related substances. Fresh tablet powder was prepared using glass mortar and pestle for all lots. Assay and impurity results for lot CWDDH and all other lots was performed in SSID 52320 on the same UHPLC and column and fresh mobile phase and diluent preparation (reference PLSN-5027, p003). Results were processed in RSID 57391. Assay, ID and related substances met the acceptance criteria of the specification. Assay for duplicate preparations of lot CWDDH was 96.6% and 96.5%, with an average of 96.5%. For all other lots the assay results were in agreement with the original results. Related substances result in the original and retest analysis were observed below the quantitation threshold.

Impact assessment:

The retest analysis result of lot CWDDH were within the 95.0 - 105.0% acceptance criteria, thus confirming that it is not a true OOS, and was not product related. Based on the above evaluation, the use of incorrect mortar and pestle impacted the assay result of one of the totals of 9 lots tested in the original analysis. The OOS reference is thus limited to the lot CWDDH. Since the incorrect procedure was applied to all 9 lots, the assay and impurity results for bulk product release will be reported from retest analysis with reference to this QR.

Is this a Repeated Incident?:	Yes	**Repeated Incidents:**	QR: 399800 | OOS/OOT/E(U)M | Opened: 16-Sep-2022 | Closed - Done, QR: 405281 | OOS/OOT/E(U)M | Opened: 26-Sep-2022 | Closed - Done, QR: 439706 | OOS/OOT/E(U)M | Opened: 15-Nov-2022 | Closed - Done

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ThermoFisher SCIENTIFIC

OOS/OOT/E(U)M Detail Report

QR ID:	1042038	**QR State:**	Closed - Done
Division:	Thermo Fisher Scientific	**Site:**	TRO (Toronto)
Date Opened:	25-Apr-2025	**Date Due:**	25-May-2025
		Date Closed:	14-May-2025

Repeated Incident Details:

A query in Track Wise using the key words "XL184, Cabozantinib, Cabometyx, assay, potency" was performed for the period 01/Apr/2022 - 10/May/2025, which revealed two incidences of low assay results, hence the current incidence is a repeat occurrence. The QR 399800 and QR 405281 were for low assay results for the active. In both incidences the root cause was identified to be API loss during the tablet powdering and powder transfer steps of the assay sample preparation. API loss during grinding has been established previously with the observation that the grinding process most likely removes the API from the homogeneous powder.

Data from the investigation for QR 405281 showed that comparable results to the intact tablets procedure can be achieved using the grinding procedure when care is taken to scrape any remaining powder from the mortar and pestle surfaces and re-homogenize the powder back into the ground mass. Therefore, until implementation of the intact tablet method, the NTA document (EXL-NTA-236-0818-R2) linked to method CTMLP-2646 was revised to EXL-NTA-236-0818-R3:

- instruct the analysts to use glass mortars/pestles since these provide better visibility for powder potentially remaining on the mortar and pestle surfaces after grinding and transferring of the composite powder to a scintillation vial for storage.
- instruct the analysts to scrape the mortar and pestle surfaces in order to eliminate any remaining powder adhered to the surfaces and re-homogenize it with the composite sample before transfer to the scintillation vial.

The use of glass mortar and pestles was included in the revision 3 of CTMLP-2646 in Sep/2023. All requirements from the notes to analyst were included in the method revision.

The search in Track Wise for the analyst NS revealed one incident for deviating test procedures. The QR 883863 was initiated for a different Exelixis project, in which the incorrect sample amount was weighed in original analysis for stability samples. The retest of the samples was performed as a late test. An awareness training memo was signed between the analysts involved that included the analyst NS, and the supervisor BM.

For the current analysis, a discussion was held with the analyst NS for paying additional attention to read the method requirements in detail prior to starting analysis. A CAPA, QR# 1052882 was initiated to monitor the performance of the analyst NS (employee ID 00213384) on a daily basis for a period of 4-weeks. During the monitoring details of the method followed, documentation practice and bench work will be examined. Any investigations initiated due to analyst error will be noted.

A second CAPA QR# 1053916 was initiated to add a Notes to Analyst to CTMLP-2646, to highlight the use of glass mortar and pestle for tablet powder preparation of XL184 tablets for assay and related substances test.

The documentation for use of glass mortar and pestle for tablet grinding will be added to the currently ongoing revision of the GMP form# PLS-F-1049 (notebook for documentation of XL184 assay and related substances test).

Передан через Диадок 27.02.2026 15:54 GMT+03:00;
09cbbb13-c88a-46a0-aad4-5cd9067dd589
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ThermoFisher SCIENTIFIC

OOS/OOT/E(U)M Detail Report

QR ID:	1042038	**QR State:**	Closed - Done
Division:	Thermo Fisher Scientific	**Site:**	TRO (Toronto)
Date Opened:	25-Apr-2025	**Date Due:**	25-May-2025
		Date Closed:	14-May-2025

Action Taken:

- A retest was performed on all 9 lots for assay and related substances from fresh tablet powder preparation using the correct equipment.
- CAPA, QR# 1052882 was initiated to monitor the performance of the analyst NS (employee ID 00213384) on a daily basis for a period of 4-weeks. During the monitoring details of the method followed, documentation practice and bench work will be examined. Any investigations initiated due to analyst error will be noted.
- CAPA QR# 1053916 was initiated to add a Notes to Analyst to CTMLP-2646, to highlight the use of glass mortar and pestle for tablet powder preparation of XL184 tablets for assay and related substances test.
- The documentation for use of glass mortar and pestle for tablet grinding will be added to the currently ongoing revision of the GMP form# PLS-F-1049 (notebook for documentation of XL184 assay and related substances test).

Phase I Conclusion

Assessment:	Assignable Cause - Lab Error (Phase I only)	**Laboratory Error Category:**	Sample / Solution Preparation

RCA / Conclusions

Root Cause Analysis

Lab Causal Factor Level 1:	Method Not Followed	**Lab Causal Factor Level 2:**	Incorrect equipment used

Root Cause Grid:

Передан через Диадок 27.02.2026 15:54 GMT+03:00;
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Страница 31 из 51

ThermoFisher SCIENTIFIC

OOS/OOT/E(U)M Detail Report

QR ID:	1042038	**QR State:**	Closed - Done
Division:	Thermo Fisher Scientific	**Site:**	TRO (Toronto)
Date Opened:	25-Apr-2025	**Date Due:**	25-May-2025
		Date Closed:	14-May-2025

Root Cause Type	Root Cause Drill Down Category	Root Cause Drill Down Level 1	Root Cause Drill Down Level 2	Comment
Root Cause	Procedure	Followed Incorrectly	Checked Misused	The analyst did not pay attention to the sample preparation procedure that emphasized the use of glass mortar and pestle for tablet grinding.
Root Cause	Human Performance Difficulty (Causal Factor)	Human Error	Violation (incorrect, missed or wrong entry)	The analyst used incorrect equipment although experienced on the method, did not consider the material type for mortar and pestle to be critical for sample preparation.

Root Cause:

The use of porcelain mortar and pestle instead of glass mortar and pestle for tablet powder grinding procedure was concluded as the root cause of the OOS result for lot CWDDH sample prep.-2. The causal factor for this error was a deviation to the procedure, which the analyst NS did not consider critical for sample preparation

RCA Tools: Other **Explain - Other:** Analyst interview

Phase I Conclusion

Conclusion:

Передан через Диадок 27.02.2026 15:54 GMT+03:00;
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ThermoFisher SCIENTIFIC

OOS/OOT/E(U)M Detail Report

QR ID:	1042038	**QR State:**	Closed - Done
Division:	Thermo Fisher Scientific	**Site:**	TRO (Toronto)
Date Opened:	25-Apr-2025	**Date Due:**	25-May-2025
		Date Closed:	14-May-2025

The original analysis was confirmed to be performed using an incorrect equipment, porcelain mortar and pestle were used instead of the specified, glass mortar and pestle. The analyst deviated from the procedure mentioned in CTMLP-2646, Rev. 3. Retest results determined that the low assay in sample preparation-2 of lot CWDDH in the original analysis was not product related. The retest analysis result of lot CWDDH were within the 95.0 - 105.0% acceptance criteria, thus confirming that it is not a true OOS, and was not product related. Based on the above evaluation, the use of incorrect mortar and pestle impacted the assay result of one of the total of 9 lots tested in the original analysis. The OOS reference is thus limited to the lot CWDDH. Since the incorrect procedure was applied to all 9 lots, the assay and impurity results for bulk product release will be reported from retest analysis with reference to this QR.

For the current analysis, a discussion was held with the analyst NS for paying additional attention to read the method requirements in detail prior to starting analysis. A CAPA, QR# 1052882 was initiated to monitor the performance of the analyst NS (employee ID 00213384) on a daily basis for a period of 4-weeks. During the monitoring details of the method followed, documentation practice and bench work will be examined. Any investigations initiated due to analyst error will be noted.

A second CAPA QR# 1053916 was initiated to add a Notes to Analyst to CTMLP-2646, to highlight the use of glass mortar and pestle for tablet powder preparation of XL184 tablets for assay and related substances test.

The documentation for use of glass mortar and pestle for tablet grinding will be added to the currently ongoing revision of the GMP form# PLS-F-1049 (notebook for documentation of XL184 assay and related substances test).

Through historical investigations for low assay it has been observed that API loss during grinding has been established previously with the observation that the grinding process most likely removes the API from the homogeneous powder (the API gets stuck on the mortar and pestle wall) and extra care is required when transferring the powder to a scintillation vial for storage, to scrape the mortar and pestle in order to get the API back into the mass. In the revision 3 of CTMLP-2646, the use of glass mortar and pestle for tablet grinding was added to the procedure for sample preparation. To eliminate the risk of API loss, an assay method has been validated with use of intact tablets however, it is not yet implemented as it is pending regulatory approval. It is expected that with the use of intact tablets procedure for sample preparation similar occurrences for unexpected / OOS results is assay of XL184 tablets can be overcome.

Product Impact Statement

Product Impact Statement: The retest analysis result of lot CWDDH were within the 95.0 - 105.0% acceptance criteria, thus confirming that it is not a true OOS, and was not product related. A product related error was ruled out.

QA Comments

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ThermoFisher SCIENTIFIC

OOS/OOT/E(U)M Detail Report

QR ID:	1042038	**QR State:**	Closed - Done
Division:	Thermo Fisher Scientific	**Site:**	TRO (Toronto)
Date Opened:	25-Apr-2025	**Date Due:**	25-May-2025
		Date Closed:	14-May-2025

QA Comments: Investigation has been reviewed and is acceptable.

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Страница 34 из 51

ThermoFisher SCIENTIFIC

OOS/OOT/E(U)M Detail Report

QR ID:	1042038	**QR State:**	Closed - Done
Division:	Thermo Fisher Scientific	**Site:**	TRO (Toronto)
Date Opened:	25-Apr-2025	**Date Due:**	25-May-2025
		Date Closed:	14-May-2025

e-Signatures

e-Signatures

Phase I Investgtn Complete By:	Beena Moothan	**Phase I Investgtn Complete On:**	13-May-2025 07:11 PM
Lab Approved By:	Ayube Rahim	**Lab Approved On:**	13-May-2025 07:53 PM
QA Approval By:	Roland Rajroop	**QA Approval On:**	13-May-2025 08:15 PM

Передан через Диадок 27.02.2026 15:54 GMT+03:00;
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Форма			
Сертификат на серию Кабометикс 40 мг CWNXD (RU)			
Номер документа	Версия	Статус	Дата утверждения
FORM-000067757 – EXE000750491	1,0, текущая	Утверждено	29 августа 2025

patheon
by Thermo Fisher Scientific

Сертификат на серию

ПАТЕОН Франция
40, бульвар Шампаре – CS 11006
38307 Бургуин-Жалльё Цедекс
Тел: +33 (0) 4 74 93 87 00
Факс: +33 (0) 4 74 93 87 81 Patheon.com

ИНФОРМАЦИЯ О ПРОДУКТЕ

Наименование продукта (включая эффективность/активность, дозировку и размер упаковки, если применимо):	КАБОМЕТИКС 40 мг 30 шт.
Импортируемая из, если применимо:	Канада
Серия/Номер серии:	CWNXD
Код:	304019433
Дата производства:	31 марта 2025
Срок годности:	Февраль 2029
Отчет(ы) об отклонениях:	Да ☒ Нет☐ **(DR №415807)**
Приложенный сертификат анализа:	Да ☒ Нет ☐ (Предоставлен Патеон Торонто)
Количество:	600 единиц
№ лицензии:	2025_070_1_2
Сериализованный продукт:	Да ☒ Нет☐
Дополнительная информация, если применимо:	Упаковка: по 30 таблеток вместе с силикагелем (3 контейнера с силикагелем по 1 г каждый) и полиэфирным волокном во флакон из полиэтилена высокой плотности. 1 флакон с инструкцией по применению в пачку картонную. Срок годности – 4 года, хранить при температуре не выше 25^{0}C Балк: CWDDW - CWDFD Первичная упаковка: CWDFK Предназначен для российского рынка (RU)

ПОДТВЕРЖДЕНИЕ/ЗАЯВЛЕНИЕ О СЕРТИФИКАЦИИ

Настоящим подтверждается, что приведенная выше информация является достоверной и точной. Данная серия продукта была произведена, включая упаковку и контроль качества, Патеон Торонто в полном соответствии с требованиями GMP местного регуляторного органа, со спецификацией, предоставленной Клиентом и с согласованием процесса и соглашением о качестве. Записи о производстве серии, упаковке и анализах были просмотрены и находятся в соответствии с GMP. Импорт и хранение продукта в соответствии с требованиями.
Импорт, проверка документации и контроль при получении были выполнены на Патеон Бургуин и соответствуют требованиям.

ЗАКЛЮЧЕНИЕ

Серия выпущена

Передан через Диадок 27.02.2026 15:54 GMT+03:00;
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Электронные подписи			
Номер документа	Версия	Статус	Дата утверждения
FORM-000067757 – EXE000750491	1,0, текущая	Утверждено	29 августа 2025

Электронные подписи

Пользователь	Дата	Значение подписи
Думолин, Фабьен (подпись)	29 августа 2025 12:37:25 (GMT)	Утверждено Уполномоченным лицом

Передан через Диадок 27.02.2026 15:54 GMT+03:00;
09cbbb13-c88a-46a0-aad4-5cd9067dd589
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EXELIXIS	**Сертификат на выпуск**

Кабометикс ГП 40 мг RU-COR-CWNXD

Номер документа: CERT-0510	Версия: 1.0	Дата вступления в силу: 25 июля 2025

Наименование продукта (как указано в досье на серию): **Кабометикс (Кабозантиниб), таблетки, 30 шт (RU)**	Количество/Концентрация: **40 мг / НП**	Серия/Количество серий: **600 пачек картонных**
Серия продукта/Лот №: **CWNXD**	Дата производства: **31 марта 2025**	
Условия хранения продукта: ☐ N/A **При температуре не выше 25 °C**	Ретест/Дата окончания срока годности: ☐ N/A **28 февраля 2029**	
Контрактный производитель: **Патеон Торонто**	Спецификация Экселиксис №/Версия: ☐ N/A **Спецификация-0056 в.22.0**	
Код(ы) контрактного продукта/Заказ-наряд №: **4000004862 / 1141652**	№ основной записи контрактора/Версия: ВОМ: 8 Информация на этикетке: 4, Инструкции упаковки: 5, Отбор проб готового продукта: 3.	
Тип продукта (отметить применимое): ☐ АФИ/Субстанция ☐ Лекарственный продукт ☐ Первичная упаковка ☒ Вторичная упаковка		
Номер серии полупродукта: ☒ N/A	№ серии продукта: ☐ N/A **CWDFD**	
№ серии АФС: **2200028** ☐ N/A	Другой № серии/лота: ☐ N/A Общая смесь: **CWDDW**	
№ серии первичной упаковки: ☐ N/A **CWDFK**	Рынок: ☐ N/A РФ	

Отклонения
☒ N/A
☒ N/A
☒ N/A
☒ N/A
☒ N/A

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EXELIXIS	**Сертификат на выпуск**	
Кабометикс ГП 40 мг RU-COR- CWNXD		
Номер документа: CERT-0510	Версия: 1.0	Дата вступления в силу: 25 июля 2025

Настоящим подтверждается, что вышеуказанный продукт был изготовлен на соответствующей cGMP производственной площадке и проверен в соответствии с применимыми фармакопейными требованиями, и соответствует Спецификации на выпуск, изложенной Экселиксис. Компания Экселиксис квалифицировала вышеуказанного производителя для указанного типа продукта. На основании обзора досье на серию и соответствующей документации по производству и испытаниям, серия соответствует спецификации и выпущена.

Использование по назначению: ☒ Коммерческое ☐ № клинического исследования ☐ Брак ☐ Другое
Комментарии: НП 1. Коды упаковки: этикетка 2000017309, инструкция 2000018247, картонная пачка 2000017279.

Этот документ был согласован в электронной системе.

Передан через Диадок 27.02.2026 15:54 GMT+03:00;
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EXELIXIS	**Сертификат на выпуск**

Кабометикс ГП 40 мг RU-COR- CWNXD

Номер документа: CERT-0510	Версия: 1.0	Дата вступления в силу: 25 июля 2025

История изменений:

Версия	Сотрудник	Дата утверждения	Изменения
1.0	Дж.Абежуела	Ссылка на владельца документа	Новый документ

Передан через Диадок 27.02.2026 15:54 GMT+03:00;
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Региональное подразделение Торонто
Заголовок: **Сертификат на производство**
Форма: **F-053** Версия: 28
СОП: **OPS 1027**
Дата вступления в силу: 28 февраля 2024

Сертификат производства

Установленный номер лицензии: 100074-A

Произведено, Упаковано и/или промаркировано на:		Анализировано на:		
☒ Патеон Инк. Региональное подразделение Торонто 2100 Синтекс Корт Миссисога, Онтарио L5T 7K9 Канада Установленный номер лицензии: 100074-A	☐ Патеон Инк. Подразделение Патеон Уилби 111 Консьюмерс Драйв Уилби, Онтарио L1N 5Z5 Установленный номер лицензии: 100074-F	☒ Патеон Инк. Региональное подразделение Торонто 2100 Синтекс Корт Миссисога, Онтарио L5T 7K9 Канада	☐ Патеон Инк. Подразделение Патеон Уилби 111 Консьюмерс Драйв Уилби, Онтарио L1N 5Z5 Канада	☐ Патеон Инк. Лаборатория Патеон 977 Сенчьюри Драйв Берлингтон, Онтарио L7L 5J8 Канада

Наименование продукта:	Кабометикс (Кабозантиниб), таблетки, 40 мг – 30 шт (RU)	**№ серии Патеон:**	CWNXD
		№ серии Клиента:	Не применимо
Сериализованный продукт:	Да ☒ Нет ☐	**№ регистрационного удостоверения (NDC, DIN и т.д.):**	005558
Количество:	600 упаковок / 12 транспортных коробов / 1 поддон	**Средний вес таблетки или капсулы:**	Не применимо

№ упаковочного материала:	4000004862 4000003554	**№ серии упаковки:**	CWNXD CWDFK	**№ мастера:**	Спецификация материалов: 8 Информация на этикетке: 4 Упаковочная инструкция: 5 Отбор пробы готового продукта: 3 Спецификация материалов: 4 Информация на этикетке: 4 Упаковочная инструкция: 3 Отбор пробы готового продукта: 2

№ произведенного материала:	3000003084 3000003074	**№ производственной серии:**	CWDFD CWDDW	**№ мастера**	Прессование: 7 Покрытие пленочной оболочкой: 8 Диспенгирование: 5 Грануляция:9

Дата производства:	31 марта 2025	**Заполнение до даты:**	05 апреля 2026	**Срок годности:**	02 2029

Другая информация:	Не применимо

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СЕРТИФИКАТ ПРОИЗВОДСТВА

Форма: F-053 Версия: 28

№ Материала: 4000004862 № серии: CWNXD

Я настоящим гарантирую, что представленная выше информация аутентична и точна. Данная серия произведена, включая упаковку и контроля качества на указанных выше производственных площадках в соответствии с локальными требованиями GMP.
Записи о производстве, упаковке и анализе серий были просмотрены и найдены соответствующими требованиям GMP. Если применимо, разъяснение для принятых отклонениях прикреплено.

Требуется расследование: Да ☒ Нет☐ № 415807

Заключение: Серия выпущена
Соответствует всем спецификациям по инструкциям для тестирования.

Фелипе Кина, Специалист службы качества

Подпись уполномоченного лица

Имя и должность уполномоченного лица

(подпись)

14 июля 2025 Дата выпуска сертификата

СЛУЖБА ОБЕСПЕЧЕНИЯ КАЧЕСТВА ПАТЕОН

14 июля 2025

(Подпись)

ВЫПУЩЕНО

Передан через Диадок 27.02.2026 15:54 GMT+03:00;
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ПАТЕОН ИНК.
Производство, Упаковка, Маркировка и Выпускающий контроль
Региональное подразделение Торонто (100074-A)
2100 Синтекс Корт, Миссиссога, Онтарио,
L5N 7K9, Канада
(905) 821-4001

СЕРТИФИКАТ АНАЛИЗА
ГОТОВЫЙ ПРОДУКТ

ПРОДУКТ: КАБОЗАНТИНИБ 40 МГ, ТАБЛЕТКИ, ПОКРЫТЫЕ ПЛЕНОЧНОЙ ОБОЛОЧКОЙ 30 ТАБЛЕТОК (EU/ROW)

КЛИЕНТ: ЭКСЕЛИКСИС

№ МАТЕРИАЛА ГОТОВОГО ПРОДУКТА: 4000004862
№ СЕРИИ ГОТОВОГО ПРОДУКТА: CWNXD
ДАТА ПРОИЗВОДСТВА: 31 МАРТА 2025
СРОК ГОДНОСТИ: 02 2029

ARF FP Вер. 1
Сертификат анализа Вер. 2 Дата вступления в силу: 18 декабря 2024

Испытание	Спецификация	Результат
ОПИСАНИЕ		
Визуально	Желтые таблетки треугольной формы, покрытые пленочной оболочкой, с гравировкой «XL» на одной стороне, и «40» на другой стороне таблетки.	Желтые таблетки треугольной формы, покрытые пленочной оболочкой, с гравировкой «XL» на одной стороне, и «40» на другой стороне таблетки.
ОРИГИНАЛЬНЫЙ СЕРТИФИКАТ АНАЛИЗА ВЫПУСКА НА БАЛК ПРОДУКТА		
Пересмотреть и приложить	Соответствующий номер серии выпущенного сертификата анализа на балк должен быть приложен	Соответствующий номер серии выпущенного сертификата анализа на балк приложен

Комментарии: Не применимо

Просмотрено и утверждено: подпись
(Менеджер контроля качества)

Дата: 14 июля 2025

СЛУЖБА
ОБЕСПЕЧЕНИЯ
КАЧЕСТВА ПАТЕОН
14 июля 2025
(Подпись)
ВЫПУЩЕНО

Передан через Диадок 27.02.2026 15:54 GMT+03:00;
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ПАТЕОН ИНК.
Производство, Упаковка, Маркировка и Выпускающий контроль
Региональное подразделение Торонто (100074-А)
2100 Синтекс Корт, Миссиссога, Онтарио,
L5N 7K9, Канада
(905) 821-4001

СЕРТИФИКАТ АНАЛИЗА ГОТОВЫЙ ПРОДУКТ		
ПРОДУКТ: КАБОЗАНТИНИБ 40 МГ, ТАБЛЕТКИ, ПОКРЫТЫЕ ПЛЕНОЧНОЙ ОБОЛОЧКОЙ 30 ТАБЛЕТОК (EU/ROW)		
КЛИЕНТ: ЭКСЕЛИКСИС	**№ МАТЕРИАЛА ГОТОВОГО ПРОДУКТА: 4000003554** **№ СЕРИИ ГОТОВОГО ПРОДУКТА: CWDFK** **ДАТА ПРОИЗВОДСТВА: 31 МАРТА 2025**	
ARF FP Вер. 3 Сертификат анализа Вер. 3	Дата вступления в силу: 17 декабря 2024	
Испытание	Спецификация	Результат
ОПИСАНИЕ		
Визуально	Желтые таблетки треугольной формы, покрытые пленочной оболочкой, с гравировкой «XL» на одной стороне, и «40» на другой стороне таблетки.	Желтые таблетки треугольной формы, покрытые пленочной оболочкой, с гравировкой «XL» на одной стороне, и «40» на другой стороне таблетки.

Просмотрено и утверждено: подпись
(Менеджер контроля качества)

Дата: 14 мая 2025

СЛУЖБА
ОБЕСПЕЧЕНИЯ
КАЧЕСТВА ПАТЕОН
14 мая 2025
(Подпись)
ВЫПУЩЕНО

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ПАТЕОН ИНК.
Производство, Упаковка, Маркировка и Выпускающий контроль
Региональное подразделение Торонто (100074-А)
2100 Синтекс Корт, Миссиссога, Онтарио,
L5N 7K9, Канада
(905) 821-4001

СЕРТИФИКАТ АНАЛИЗА
НЕРАСФАСОВАННЫЙ (БАЛК) ПРОДУКТ

ПРОДУКТ: КАБОЗАНТИНИБ 40 МГ, ТАБЛЕТКИ, ПОКРЫТЫЕ ПЛЕНОЧНОЙ ОБОЛОЧКОЙ (EU/ROW)

КЛИЕНТ: ЭКСЕЛИКС
НОМЕРА МАТЕРИАЛОВ:
3000003084, 3000003114

№ МАТЕРИАЛА БАЛКА ПРОДУКТА: 3000003084
№ СЕРИИ БАЛКА ПРОДУКТА: CWDFD
ДАТА ПРОИЗВОДСТВА: 31 марта 2025

ARF FP Вер. 2
Сертификат анализа Вер. 2 — Дата вступления в силу: 22 марта 2018

Испытание	Спецификация	Результат
ОПИСАНИЕ		
Визуально	Желтые таблетки треугольной формы, покрытые пленочной оболочкой, с гравировкой «XL» на одной стороне, и «40» на другой стороне таблетки.	Желтые таблетки треугольной формы, покрытые пленочной оболочкой, с гравировкой «XL» на одной стороне, и «40» на другой стороне таблетки.
ПОДЛИННОСТЬ		
(ВЭЖХ-УФ и УФ-спектр) CTMLP-2646	Соответствует эталонному стандарту.	Соответствует
АКТИВНОСТЬ (% МАСС.)		
CTMLP-2646	95,0 % - 105,0 % от величины на маркировке	
	1)	98,5%
	2)	98,2%
	Средн.:	98,3%
ПРИМЕСИ (ВЭЖХ)		
CTMLP-2646	А) Индивидуальные неопределенные продукты распада: Не более 0,2 %	Не обнаружено
	Б) Всего: Не более 1,0 %	Не обнаружено

«ИПСЕН» IPSEN ООО ДЛЯ ДОКУМЕНТОВ МОСКВА

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ПАТЕОН ИНК.
Производство, Упаковка, Маркировка и Выпускающий контроль
Региональное подразделение Торонто (100074-A)
2100 Синтекс Корт, Миссиссога, Онтарио,
L5N 7K9, Канада
(905) 821-4001

СЕРТИФИКАТ АНАЛИЗА НЕРАСФАСОВАННЫЙ (БАЛК) ПРОДУКТ

ПРОДУКТ: КАБОЗАНТИНИБ 40 МГ, ТАБЛЕТКИ, ПОКРЫТЫЕ ПЛЕНОЧНОЙ ОБОЛОЧКОЙ (EU/ROW)

КЛИЕНТ: ЭКСЕЛИКС **№ МАТЕРИАЛА БАЛКА ПРОДУКТА: 3000003084**
НОМЕРА МАТЕРИАЛОВ: **№ СЕРИИ БАЛКА ПРОДУКТА: CWDFD**
3000003084, 3000003114 **ДАТА ПРОИЗВОДСТВА: 31 марта 2025**

ARF FP Вер. 2
Сертификат анализа Вер. 2 Дата вступления в силу: 22 марта 2018

Испытание	Спецификация	Результат
Однородность дозирования (ВЭЖХ-УФ)		
CTMLP-2648	Соответствует текущему изданию Фарм. США <905>	
	1)	99,9%
	2)	99,8%
	3)	100,5%
	4)	100,3%
	5)	100,0%
	6)	101,2%
	7)	99,6%
	8)	101,3%
	9)	101,0%
	10)	101,8%
	Средн.10:	100,5%
	Критерий приемлемости:	1,8
	Стадия 2	
	1)	Не применимо
	2)	Не применимо
	3)	Не применимо
	4)	Не применимо
	5)	Не применимо
	6)	Не применимо
	7)	Не применимо
	8)	Не применимо
	9)	Не применимо
	10)	Не применимо
	11)	Не применимо
	12)	Не применимо
	13)	Не применимо
	14)	Не применимо
	15)	Не применимо
	16)	Не применимо
	17)	Не применимо
	18)	Не применимо
	19)	Не применимо
	20)	Не применимо
	Средн.30:	Не применимо
	Критерий приемлемости:	Не применимо

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ПАТЕОН ИНК.
Производство, Упаковка, Маркировка и Выпускающий контроль
Региональное подразделение Торонто (100074-A)
2100 Синтекс Корт, Миссиссога, Онтарио,
L5N 7K9, Канада
(905) 821-4001

СЕРТИФИКАТ АНАЛИЗА
НЕРАСФАСОВАННЫЙ (БАЛК) ПРОДУКТ

ПРОДУКТ: КАБОЗАНТИНИБ 40 МГ, ТАБЛЕТКИ, ПОКРЫТЫЕ ПЛЕНОЧНОЙ ОБОЛОЧКОЙ (EU/ROW)

КЛИЕНТ: ЭКСЕЛИКС **№ МАТЕРИАЛА БАЛКА ПРОДУКТА: 3000003084**
НОМЕРА МАТЕРИАЛОВ: **№ СЕРИИ БАЛКА ПРОДУКТА: CWDFD**
3000003084, 3000003114 **ДАТА ПРОИЗВОДСТВА: 31 марта 2025**

ARF FP Вер. 2
Сертификат анализа Вер. 2 Дата вступления в силу: 22 марта 2018

Испытание	Спецификация	Результат				
Растворимость (ВЭЖХ-УФ)						
CTMLP-2647	Соответствует Фарм.США <711> Аппарат 2 Q = 80 % через 15 минут	15	30	45	60	90
	Стадия 1					
	1)	100%	100%	101%	100%	101%
	2)	100%	101%	101%	101%	101%
	3)	102%	103%	103%	103%	103%
	4)	101%	102%	102%	102%	102%
	5)	97%	98%	99%	99%	99%
	6)	101%	102%	102%	102%	102%
	Мин.:	97%	98%	99%	99%	99%
	Макс.:	102%	103%	103%	103%	103%
	Средн.:	100%	101%	101%	101%	101%
	% RSD:	1,8	1,6	1,4	1,4	1,3
	Стадия 2					
	7)	НП	НП	НП	НП	НП
	8)	НП	НП	НП	НП	НП
	9)	НП	НП	НП	НП	НП
	10)	НП	НП	НП	НП	НП
	11)	НП	НП	НП	НП	НП
	12)	НП	НП	НП	НП	НП
	Мин.:	НП	НП	НП	НП	НП
	Макс.:	НП	НП	НП	НП	НП
	Средн.:	НП	НП	НП	НП	НП
	% RSD:	НП	НП	НП	НП	НП

«ИПСЕН» IPSEN ООО

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ПАТЕОН ИНК.
Производство, Упаковка, Маркировка и Выпускающий контроль
Региональное подразделение Торонто (100074-A)
2100 Синтекс Корт, Миссиссога, Онтарио,
L5N 7K9, Канада
(905) 821-4001

СЕРТИФИКАТ АНАЛИЗА НЕРАСФАСОВАННЫЙ (БАЛК) ПРОДУКТ

ПРОДУКТ: КАБОЗАНТИНИБ 40 МГ, ТАБЛЕТКИ, ПОКРЫТЫЕ ПЛЕНОЧНОЙ ОБОЛОЧКОЙ (EU/ROW)

КЛИЕНТ: ЭКСЕЛИКС
НОМЕРА МАТЕРИАЛОВ:
3000003084, 3000003114

№ МАТЕРИАЛА БАЛКА ПРОДУКТА: 3000003084
№ СЕРИИ БАЛКА ПРОДУКТА: CWDFD
ДАТА ПРОИЗВОДСТВА: 31 марта 2025

ARF FP Вер. 2
Сертификат анализа Вер. 2
Дата вступления в силу: 22 марта 2018

Испытание	Спецификация	Результат				
(Продолжение)						
CTMLP-2647	Соответствует Фарм.США <711> Аппарат 2 Q = 80 % через 15 минут	15	30	45	60	90
	Стадия 3					
	13)	НП	НП	НП	НП	НП
	14)	НП	НП	НП	НП	НП
	15)	НП	НП	НП	НП	НП
	16)	НП	НП	НП	НП	НП
	17)	НП	НП	НП	НП	НП
	18)	НП	НП	НП	НП	НП
	19)	НП	НП	НП	НП	НП
	20)	НП	НП	НП	НП	НП
	21)	НП	НП	НП	НП	НП
	22)	НП	НП	НП	НП	НП
	23)	НП	НП	НП	НП	НП
	24)	НП	НП	НП	НП	НП
	Мин.:	НП	НП	НП	НП	НП
	Макс.:	НП	НП	НП	НП	НП
	Средн.:	НП	НП	НП	НП	НП
	% RSD:	НП	НП	НП	НП	НП
ВЛАЖНОСТЬ (ПО К. ФИШЕРУ)						
CTMLP-2649	Не более 3,5 %					
	1)	1,8 %				
	2)	1,9 %				
	Средн.:	1,8 %				
ГЕНОТОКСИЧЕСКИЕ ПРИМЕСИ						
CTMLP-2712	XL 184-1-1: Не более 24 ppm					
	1)	3 ppm				
	2)	3 ppm				
	Средн.:	3 ppm				
	XL 184-1-4: Не более 15 ppm					
	1)	<3 ppm				
	2)	<3 ppm				
	Средн.:	<3 ppm				

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ПАТЕОН ИНК.
Производство, Упаковка, Маркировка и Выпускающий контроль
Региональное подразделение Торонто (100074-А)
2100 Синтекс Корт, Миссиссога, Онтарио,
L5N 7K9, Канада
(905) 821-4001

СЕРТИФИКАТ АНАЛИЗА
НЕРАСФАСОВАННЫЙ (БАЛК) ПРОДУКТ

ПРОДУКТ: КАБОЗАНТИНИБ 40 МГ, ТАБЛЕТКИ, ПОКРЫТЫЕ ПЛЕНОЧНОЙ ОБОЛОЧКОЙ (EU/ROW)

КЛИЕНТ: ЭКСЕЛИКС	**№ МАТЕРИАЛА БАЛКА ПРОДУКТА: 3000003084**
НОМЕРА МАТЕРИАЛОВ: 3000003084, 3000003114	**№ СЕРИИ БАЛКА ПРОДУКТА: CWDFD**
	ДАТА ПРОИЗВОДСТВА: 31 марта 2025
ARF FP Вер. 2	
Сертификат анализа Вер. 2	Дата вступления в силу: 22 марта 2018

Испытание	Спецификация	Результат
Микробиологическая чистота		
Согласуется с Фарм.США <61> и <62> и Евр.Фарм. 2.6.12 и 2.6.13 (ММ-1381)		
Общее количество аэробных микроорганизмов	Не более 1000 КОЕ/г	< 100 КОЕ/г
Общее количество плесневых и дрожжевых грибов	Не более 100 КОЕ/г	< 50 КОЕ/г
Отсутствие *P. aeruginosa*	Отсутствует	Отсутствует
Отсутствие *E. Coli*	Отсутствует	Отсутствует
Отсутствие *S. aureus*	Отсутствует	Отсутствует
Отсутствие *Salmonella spp.*	Отсутствует	Отсутствует

Просмотрено и утверждено: подпись
(Менеджер контроля качества)

Дата: 14 мая 2025

СЛУЖБА ОБЕСПЕЧЕНИЯ КАЧЕСТВА ПАТЕОН
14 мая 2025
(Подпись)
ВЫПУЩЕНО

«ИПСЕН» ГУБЕР 1000

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ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ

«Сведения, внесенные в автоматизированную информационную систему Росздравнадзора перед вводом в гражданский оборот серий, партий лекарственных средств/ Информация о выданных Росздравнадзором разрешениях на ввод в гражданский оборот в Российской Федерации серии или партии иммунобиологического лекарственного препарата, по состоянию на 06.02.2026 18:57»

Дата внесения в АИС Росздравнадзора	Торговое наименование	Производитель (выпускающий контроль)	Страна	Сведения о стадиях производства	Нормативная документация	Организация, выпустившая в гражданский оборот	Номер серии, партии	Номер, дата разрешения на ИЛП	Письма об изъятии ЛС (номер, дата)
18.12.2025	Кабометикс®; таблетки, покрытые пленочной оболочкой 40 мг 30 шт., флаконы (1), пачки картонные/ ~	Патеон Франция	Франция	Патеон Инк., Канада (Производитель (готовой ЛФ)); Патеон Инк., Канада (Упаковщик/фасовщик (в первичную упаковку)); Патеон Инк., Канада (Упаковщик/фасовщик (вторичная/третичная упаковка))	ЛП-№(008475)-(РГ-RU)-170125	ООО "ИПСЕН"	CWNXD	-	

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Документ подписан и передан через оператора ЭДО АО «ПФ «СКБ Контур»

	Организация, сотрудник	Доверенность: рег. номер, период действия и статус	Сертификат: серийный номер, период действия	Дата и время подписания
Подписи отправителя:	АКЦИОНЕРНОЕ ОБЩЕСТВО "Р-ФАРМ" Ларькина Анна Олеговна Доверитель: АКЦИОНЕРНОЕ ОБЩЕСТВО "Р-ФАРМ"	efc4dace-a286-4288-8a4e-1f48363a8398 с 07.08.2024 00:00 по 30.07.2027 23:59 GMT+03:00 Доверенность прошла проверку	06B002840040B34CB64328F324349AED80 с 21.08.2025 10:55 по 21.08.2026 11:00 GMT+03:00	27.02.2026 15:54 GMT+03:00 Подпись соответствует файлу документа