



**ДЕРЖАВНА СЛУЖБА З ЛІКАРСЬКИХ ЗАСОБІВ ТА КОНТРОЛЮ ЗА
НАРКОТИКАМИ У КИЇВСЬКІЙ ОБЛАСТІ**

пров. Світличної Надії, 3, м.Київ, 02099, тел/факс: (044) 576-40-41
E-mail: dls.ko@dls.gov.ua, Код ЄДРПОУ 37078774

**ВИСНОВОК
про якість ввезеного в Україну лікарського засобу**

14.10.2026

№ 50012/26/10

ЛІТФУЛО

(найменування лікарського засобу згідно з реєстраційним посвідченням)

**капсули тверді по 50 мг по 10 капсул твердих у блістері, по 3 блістери у картонній
коробці**

(форма випуску, дозування, вид пакування лікарського засобу)

Номер реєстраційного посвідчення UA/20751/01/01 строк дії реєстраційного посвідчення 28.01.2030

Серія лікарського засобу № **RM7227**

Кількість ввезеного лікарського засобу 40

Виробник

Пфайзер Ментофекчуринг Дойчленд ГмбХ, Німеччина

(найменування виробника лікарського засобу, країна походження)

Ввезено в Україну

**Спільне українсько-єстонське підприємство у формі товариства
з обмеженою відповідальністю "Оптіма-Фарм, ЛТД", ідент. код:
21642228**

(найменування та код за ЄДРПОУ юридичної особи або прізвище, ім'я, по батькові фізичної
особи - підприємця, її місце проживання та реєстраційний номер облікової картки платника
податків або серія та номер паспорта)

Протокол візуального контролю від 13.10.2026 № 2917/15.

За результатами державного контролю встановлено, що лікарський засіб ввезено в Україну з
дотриманням вимог законодавства щодо забезпечення якості лікарських засобів.

В.о. начальника служби

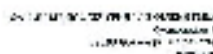
(підпис особи органу державного контролю)



(підпис)

Ольга СЕРБОМЕНКО

(підпис та прізвище)



CONCLUSIONS

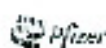
DOI: 10.1002/anie.200500049

Материалы: 72000404
 Дата: 2011-07-04
 Дата окончания: 2011-07-04
 Дата проведения: 2011-07-04
 Место проведения: М.П. 72000404-000001

[illegible]

1. *Journal of the American Medical Association*, 1997; 278: 100-104.

Вх.ак № 09-17 Глг 04.10.2026. Илгг/Б



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RECEIVED: 1994 JANUARY 10; REVISED: 1994 JULY 10; ACCEPTED: 1994 SEPTEMBER 10

[illegible][illegible]

Table 1. Values of parameters for the three different models used in the present study

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12345678910111213141516171819202122232425262728293031323334353637383940414243444546474849505152535455565758596061626364656667686970717273747576777879808182838485868788899091929394959697989910010110210310410510610710810911011111211311411511611711811912012112212312412512612712812913013113213313413513613713813914014114214314414514614714814915015115215315415515615715815916016116216316416516616716816917017117217317417517617717817918018118218318418518618718818919019119219319419519619719819920020120220320420520620720820921021121221321421521621721821922022122222322422522622722822923023123223323423523623723823924024124224324424524624724824925025125225325425525625725825926026126226326426526626726826927027127227327427527627727827928028128228328428528628728828929029129229329429529629729829930030130230330430530630730830931031131231331431531631731831932032132232332432532632732832933033133233333433533633733833934034134234334434534634734834935035135235335435535635735835936036136236336436536636736836937037137237337437537637737837938038138238338438538638738838939039139239339439539639739839940040140240340440540640740840941041141241341441541641741841942042142242342442542642742842943043143243343443543643743843944044144244344444544644744844945045145245345445545645745845946046146246346446546646746846947047147247347447547647747847948048148248348448548648748848949049149249349449549649749849950050150250350450550650750850951051151251351451551651751851952052152252352452552652752852953053153253353453553653753853954054154254354454554654754854955055155255355455555655755855956056156256356456556656756856957057157257357457557657757857958058158258358458558658758858959059159259359459559659759859960060160260360460560660760860961061161261361461561661761861962062162262362462562662762862963063163263363463563663763863964064164264364464564664764864965065165265365465565665765865966066166266366466566666766866967067167267367467567667767867968068168268368468568668768868969069169269369469569669769869970070170270370470570670770870971071171271371471571671771871972072172272372472572672772872973073173273373473573673773873974074174274374474574674774874975075175275375475575675775875976076176276376476576676776876977077177277377477577677777877978078178278378478578678778878979079179279379479579679779879980080180280380480580680780880981081181281381481581681781881982082182282382482582682782882983083183283383483583683783883984084184284384484584684784884985085185285385485585685785885986086186286386486586686786886987087187287387487587687787887988088188288388488588688788888989089189289389489589689789889990090190290390490590690790890991091191291391491591691791891992092192292392492592692792892993093193293393493593693793893994094194294394494594694794894995095195295395495595695795895996096196296396496596696796896997097197297397497597697797897998098198298398498598698798898999099199299399499599699799899910001001100210031004100510061007100810091010101110121013101410151016101710181019102010211022102310241025102610271028102910301031103210331034103510361037103810391040104110421043104410451046104710481049105010511052105310541055105610571058105910601061106210631064106510661067106810691070107110721073107410751076107710781079108010811082108310841085108610871088108910901091109210931094109510961097109810991100110111021103110411051106110711081109111011111112111311141115111611171118111911201121112211231124112511261127112811291130113111321133113411351136113711381139114011411142114311441145114611471148114911501151115211531154115511561157115811591160116111621163116411651166116711681169117011711172117311741175117611771178117911801181118211831184118511861187118811891190119111921193119411951196119711981199120012011202120312041205120612071208120912101211121212131214121512161217121812191220122112221223122412251226122712281229123012311232123312341235123612371238123912401241124212431244124512461247124812491250125112521253125412551256125712581259126012611262126312641265126612671268126912701271127212731274127512761277127812791280128112821283128412851286128712881289129012911292129312941295129612971298129913001

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215. KLEF, M.

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4. *How do you estimate the number of people who will be affected by the proposed project?*

[illegible]

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

Certificate of Analysis

Material Number: F03C063404
Description: LITFULO 80mg CNP 3x10 BLS UA
Batch: RM7227
Specification Reference Number: H000022558-08
Manufacture Date: 10 Mar 2028
Expiration Date: 28 Feb 2029
Test Result Source Lab: VIC00037597 - NFB2426

| Test | Specification | Test Method | Result |
|--|--|-------------------|----------------|
| Appearance | Size #5 opaque capsule containing a white to off-white powder with "R08 50" radial printed in black ink on a yellow body and "Pfizer" radial printed in black ink on a blue cap. | Visual Inspection | Conforms |
| Identify | | TM-8218A | |
| Identify (LC) | Retention time of the main peak in the test chromatogram is comparable to that of the reference standard. | | Conforms |
| Identify (UV) | UV spectrum of the main peak in the test chromatogram is comparable to that of the reference standard. | | Conforms |
| Assay and Degradation Products (LC) | | TM-8218A | |
| Assay (LC) | 95.0 - 105.0% of label claim | | 99.7 % I.C. |
| Each Specified Degradation Product / PF-08787444 | NMT 0.8% | | <0.1 % |
| Each Specified Degradation Product / PF-07287081 | NMT 0.3% | | ≤ 0.05 percent |
| Unspecified degradation product | NMT 0.2% (each) | | ≤ 0.05 percent |
| Total degradation products | NMT 1.5% | | <0.1 % |

Requested By: CARVER ZWOTIN

Date of Issue: 15-Jul-2025 08:24:00

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

Report Number: gLUMPS-180489

Page 1 of 5



PFIZER MANUFACTURING
DEUTSCHLAND GMBH
MOOSWALDALLEE 1
79109 FREIBURG IM BREISGAU, GERMANY

Certificate of Analysis

Material Number: F000063404
Description: LITFULO 60mg CHP 3x10 BLS UA
Batch: RM7227

| Test | Specification | Test Method | Result |
|----------------------------|---|-----------------|---------|
| Dissolution (UV) | | TM9217A | |
| Result | Conforms to Ph. Eur. 2.9.3 requirements (Q = 80% in 30 minutes) | | Pass |
| Average | - | | 94 % |
| Minimum | - | | 87 % |
| Maximum | - | | 98 % |
| RSD | - | | 4.5 % |
| Stage | - | | 1 |
| Uniformity of dosage units | | Ph. Eur. 2.9.40 | |
| Weight Variation | | | |
| Result | Conforms to Ph. Eur. 2.9.40 requirements | | Pass |
| Average | - | | 99.7 % |
| Minimum | - | | 98.9 % |
| Maximum | - | | 100.7 % |
| RSD | - | | 0.50 % |
| Acceptance value | - | | 1.2 % |
| Stage | - | | 1 |
| Water Activity | NMT 0.47 | Ph. Eur. 2.9.36 | 0.27 mw |

This 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
Betriebsstelle Freiburg
Mooswaldallee 1
79109 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: CARMEN ZWGTN

Date of MCL: 16-JUL-2024 09:34:06

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Report Number: gLWSFD-136488

Page 2 of 6



PFIZER MANUFACTURING
DEUTSCHLAND GMBH
MOOSWALDALLEE 5
79108 FREIBURG IM BREISGAU, GERMANY

Certificate of Analysis

Material Number: P000063404
Description: UTFULO 60mg CHP 3x10 BLS UA
Batch: RM7227

Microbiological testing is not performed routinely, merely when tested. If no results are listed on the CoA, testing was not performed.

Issued By: CARMEN ZWITTM

Control Date: 15-Jul-2020 08:24:58

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Report Number: gLWSPS-126486

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PFIZER MANUFACTURING
DEUTSCHLAND GMBH
MOOSWALDALLEE 1
78103 FREIBURG IM BREISGAU, GERMANY

Certificate of Compliance

| | |
|------------------------|------------------------------|
| Material Number: | F000063404 |
| Description: | LITFULO 50mg OHP 3x10 BLS UA |
| Destination: | Ukraine |
| Batch: | RM7227 |
| Manufacture Date: | 10-Mar-2026 |
| Expiration Date: | 28-Feb-2029 |
| Quantity Manufactured: | 478 Each |
| Date of Release: | 16 Jul 2026 |
| Registration Number: | UA/20761/01/01 |
| API Name: | Ribociclib |
| Packaging Type: | Blister |
| Dosage Type: | Capsules |

Name, address and number of manufacturing authorization licensee of all manufacturing and quality control sites

Bulk Manufacture and QS Testing: Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 78103 Freiburg im Breisgau, Germany; DE_BW_01_MIA_2025_0076;

Microbiological testing: total aerobic microbial count (TAMC), method: Ph. Eur. 2.6.12, limit: not more than 10^6 CFU/g; total combined yeasts moulds count (TYMC), method: Ph. Eur. 2.6.12, limit: not more than 10^6 CFU/g; specified microorganisms, absence of E. coli (1 g), method: Ph. Eur. 2.6.13, limit: conforms.
This testing is not performed routinely, occurs when tested. If no results are listed on the CoA, testing was not performed.

Certificate of Quality

To the Health Authorities of Ukraine

GUARANTEE LETTER

I, the undersigned, qualified person for the Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 78103 Freiburg im Breisgau, Germany confirm that this product was manufactured for the Ukrainian market.

We guarantee the quality of this product was manufactured according to the rules of Good Manufacturing Practice and the appropriate Certificate of Analysis was issued.

This certificate may not be reproduced and is solely destined to the Governmental Authorities of Ukraine.

Issued By: CARVEN ZIVOTIN

Date of issue: 15-Jul-2026 08:24:26

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

Report Number: pLMS75-135486

Page 4 of 5



PFIZER MANUFACTURING
DEUTSCHLAND GMBH
MOOSWALDALLEE 1
79106 FREIBURG IM BREISGAU, GERMANY

Certificate of Compliance

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
Betriebsstraße Freiburg
Mooswaldallee 1
79000 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: Christian Koltner
Disposition Date: 15-Jul-2025 08:28:17

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

Issued By: CARMEN ZWARTEN

Date of Issue: 15-Jul-2025 08:24:05

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

Headline: C:\MSD\DOC\JUN\SP9-152405

Page 3 of 5



**ДЕРЖАВНА СЛУЖБА З ЛІКАРСЬКИХ ЗАСОБІВ ТА КОНТРОЛЮ ЗА
НАРКОТИКАМИ У КИЇВСЬКІЙ ОБЛАСТІ**

пров. Світличної Надії, 3, м.Київ, 02099, тел/факс: (044) 576-40-41
E-mail: dls.ko@dls.gov.ua, Код ЄДРПОУ 37078774

**ВИСНОВОК
про якість ввезеного в Україну лікарського засобу**

14.10.2026

№ 50012/26/10

ЛІТФУЛО

(найменування лікарського засобу згідно з реєстраційним посвідченням)

**капсули тверді по 50 мг по 10 капсул твердих у блістері, по 3 блістери у картонній
коробці**

(форма випуску, дозування, вид пакування лікарського засобу)

Номер реєстраційного посвідчення UA/20751/01/01 строк дії реєстраційного посвідчення 28.01.2030

Серія лікарського засобу № **RM7227**

Кількість ввезеного лікарського засобу 40

Виробник

Пфайзер Ментофекчурінг Дойчленд ГмбХ, Німеччина

(найменування виробника лікарського засобу, країна походження)

Ввезено в Україну

**Спільне українсько-єстонське підприємство у формі товариства
з обмеженою відповідальністю "Оптіма-Фарм, ЛТД", ідент. код:
21642228**

(найменування та код за ЄДРПОУ юридичної особи або прізвище, ім'я, по батькові фізичної
особи - підприємця, її місце проживання та реєстраційний номер облікової картки платника
податків або серія та номер паспорта)

Протокол візуального контролю від 13.10.2026 № 2917/15.

За результатами державного контролю встановлено, що лікарський засіб ввезено в Україну з
дотриманням вимог законодавства щодо забезпечення якості лікарських засобів.

В.о. начальника служби

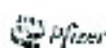
(підпис особи органу державного контролю)



(підпис)

Ольга СЕРБОМЕНКО

(підпис та прізвище)



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RECEIVED: 1994 JANUARY 10; REVISED: 1994 JULY 10; ACCEPTED: 1994 SEPTEMBER 10

[illegible][illegible][illegible]

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12345678910111213141516171819202122232425262728293031323334353637383940414243444546474849505152535455565758596061626364656667686970717273747576777879808182838485868788899091929394959697989910010110210310410510610710810911011111211311411511611711811912012112212312412512612712812913013113213313413513613713813914014114214314414514614714814915015115215315415515615715815916016116216316416516616716816917017117217317417517617717817918018118218318418518618718818919019119219319419519619719819920020120220320420520620720820921021121221321421521621721821922022122222322422522622722822923023123223323423523623723823924024124224324424524624724824925025125225325425525625725825926026126226326426526626726826927027127227327427527627727827928028128228328428528628728828929029129229329429529629729829930030130230330430530630730830931031131231331431531631731831932032132232332432532632732832933033133233333433533633733833934034134234334434534634734834935035135235335435535635735835936036136236336436536636736836937037137237337437537637737837938038138238338438538638738838939039139239339439539639739839940040140240340440540640740840941041141241341441541641741841942042142242342442542642742842943043143243343443543643743843944044144244344444544644744844945045145245345445545645745845946046146246346446546646746846947047147247347447547647747847948048148248348448548648748848949049149249349449549649749849950050150250350450550650750850951051151251351451551651751851952052152252352452552652752852953053153253353453553653753853954054154254354454554654754854955055155255355455555655755855956056156256356456556656756856957057157257357457557657757857958058158258358458558658758858959059159259359459559659759859960060160260360460560660760860961061161261361461561661761861962062162262362462562662762862963063163263363463563663763863964064164264364464564664764864965065165265365465565665765865966066166266366466566666766866967067167267367467567667767867968068168268368468568668768868969069169269369469569669769869970070170270370470570670770870971071171271371471571671771871972072172272372472572672772872973073173273373473573673773873974074174274374474574674774874975075175275375475575675775875976076176276376476576676776876977077177277377477577677777877978078178278378478578678778878979079179279379479579679779879980080180280380480580680780880981081181281381481581681781881982082182282382482582682782882983083183283383483583683783883984084184284384484584684784884985085185285385485585685785885986086186286386486586686786886987087187287387487587687787887988088188288388488588688788888989089189289389489589689789889990090190290390490590690790890991091191291391491591691791891992092192292392492592692792892993093193293393493593693793893994094194294394494594694794894995095195295395495595695795895996096196296396496596696796896997097197297397497597697797897998098198298398498598698798898999099199299399499599699799899910001001100210031004100510061007100810091010101110121013101410151016101710181019102010211022102310241025102610271028102910301031103210331034103510361037103810391040104110421043104410451046104710481049105010511052105310541055105610571058105910601061106210631064106510661067106810691070107110721073107410751076107710781079108010811082108310841085108610871088108910901091109210931094109510961097109810991100110111021103110411051106110711081109111011111112111311141115111611171118111911201121112211231124112511261127112811291130113111321133113411351136113711381139114011411142114311441145114611471148114911501151115211531154115511561157115811591160116111621163116411651166116711681169117011711172117311741175117611771178117911801181118211831184118511861187118811891190119111921193119411951196119711981199120012011202120312041205120612071208120912101211121212131214121512161217121812191220122112221223122412251226122712281229123012311232123312341235123612371238123912401241124212431244124512461247124812491250125112521253125412551256125712581259126012611262126312641265126612671268126912701271127212731274127512761277127812791280128112821283128412851286128712881289129012911292129312941295129612971298129913001

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12. 4. 2008

1984年4月—1986年12月

215. KLEF, M.

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4. *How do you estimate the number of people who will be affected by the project?*

19. 1995年10月1日起, 凡在我国境内销售货物的单位和个人, 均须依法缴纳增值税。

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

Certificate of Analysis

Material Number: F03C063404
Description: LITFULO 80mg CNP 3x10 BLS UA
Batch: RM7227
Specification Reference Number: H000022558-08
Manufacture Date: 10 Mar 2028
Expiration Date: 28 Feb 2029
Test Result Source Lab: VIC00037597 - NR2426

| Test | Specification | Test Method | Result |
|--|--|-------------------|----------------|
| Appearance | Size #5 opaque capsule containing a white to off-white powder with "R08 50" radial printed in black ink on a yellow body and "Pfizer" radial printed in black ink on a blue cap. | Visual Inspection | Conforms |
| Identify | | TM-8218A | |
| Identify (LC) | Retention time of the main peak in the test chromatogram is comparable to that of the reference standard. | | Conforms |
| Identify (UV) | UV spectrum of the main peak in the test chromatogram is comparable to that of the reference standard. | | Conforms |
| Assay and Degradation Products (LC) | | TM-8218A | |
| Assay (LC) | 95.0 - 105.0% of label claim | | 99.7 % I.C. |
| Each Specified Degradation Product / PF-08787444 | NMT 0.8% | | <0.1 % |
| Each Specified Degradation Product / PF-07287081 | NMT 0.3% | | ≤ 0.05 percent |
| Unspecified degradation product | NMT 0.2% (each) | | ≤ 0.05 percent |
| Total degradation products | NMT 1.5% | | <0.1 % |

Requested By: CARVER ZWOTIN

Date of Issue: 15-Jul-2025 08:24:00

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

Report Number: gLUMPS-180489

Page 1 of 5



PFIZER MANUFACTURING
DEUTSCHLAND GMBH
MOOSWALDALLEE 1
79109 FREIBURG IM BREISGAU, GERMANY

Certificate of Analysis

Material Number: F000063404
Description: LITFULO 60mg CHP 3x10 BLS UA
Batch: RM7227

| Test | Specification | Test Method | Result |
|----------------------------|---|-----------------|---------|
| Dissolution (UV) | | TM9217A | |
| Result | Conforms to Ph. Eur. 2.9.3 requirements (Q = 80% in 30 minutes) | | Pass |
| Average | - | | 94 % |
| Minimum | - | | 87 % |
| Maximum | - | | 98 % |
| RSD | - | | 4.5 % |
| Stage | - | | 1 |
| Uniformity of dosage units | | Ph. Eur. 2.9.40 | |
| Weight Variation | | | |
| Result | Conforms to Ph. Eur. 2.9.40 requirements | | Pass |
| Average | - | | 99.7 % |
| Minimum | - | | 98.9 % |
| Maximum | - | | 100.7 % |
| RSD | - | | 0.50 % |
| Acceptance value | - | | 1.2 % |
| Stage | - | | 1 |
| Water Activity | NMT 0.47 | Ph. Eur. 2.9.36 | 0.27 mw |

This 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
Betriebsstelle Freiburg
Mooswaldallee 1
79109 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: CARMEN ZWGTN

Date of MCL: 16-JUL-2024 09:34:06

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

Report Number: gLWSFO-136488

Page 2 of 6



PFIZER MANUFACTURING
DEUTSCHLAND GMBH
MOOSWALDALLEE 5
79108 FREIBURG IM BREISGAU, GERMANY

Certificate of Analysis

Material Number: P000063404
Description: UTFULO 60mg CHP 3x10 BLS UA
Batch: RM7227

Microbiological testing is not performed routinely, merely when tested. If no results are listed on the CoA, testing was not performed.

Issued By: CARMEN ZWITTM

Control Date: 15-Jul-2020 08:24:58

This certificate was created by a validated system and is not subject to manual signature.

Report Number: gLWSPS-126486

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PFIZER MANUFACTURING
DEUTSCHLAND GMBH
MOOSWALDALLEE 1
78103 FREIBURG IM BREISGAU, GERMANY

Certificate of Compliance

| | |
|------------------------|------------------------------|
| Material Number: | F000063404 |
| Description: | LITFULO 50mg OHP 3x10 BLS UA |
| Destination: | Ukraine |
| Batch: | RM7227 |
| Manufacture Date: | 10-Mar-2026 |
| Expiration Date: | 28-Feb-2029 |
| Quantity Manufactured: | 478 Each |
| Date of Release: | 16 Jul 2026 |
| Registration Number: | UA/20761/01/01 |
| API Name: | Ribociclib |
| Package Type: | Blister |
| Dosage Type: | Capsules |

Name, address and number of manufacturing authorization licensee of all manufacturing and quality control sites

Bulk Manufacture and QS Testing: Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 78103 Freiburg im Breisgau, Germany; DE_BW_01_MIA_2025_0076;

Microbiological testing: total aerobic microbial count (TAMC), method: Ph. Eur. 2.6.12, limit: not more than 10^2 CFU/g; total combined yeasts moulds count (TYMC), method: Ph. Eur. 2.6.12, limit: not more than 10^2 CFU/g; specified microorganisms, absence of E. coli (1 g), method: Ph. Eur. 2.6.13, limit: conforms.
This testing is not performed routinely, occurs when tested. If no results are listed on the CoA, testing was not performed.

Certificate of Quality

To the Health Authorities of Ukraine

GUARANTEE LETTER

I, the undersigned, qualified person for the Pfizer Manufacturing Deutschland GmbH, Mooswaldallee 1, 78103 Freiburg im Breisgau, Germany confirm that this product was manufactured for the Ukrainian market.

We guarantee the quality of this product was manufactured according to the rules of Good Manufacturing Practice and the appropriate Certificate of Analysis was issued.

This certificate may not be reproduced and is solely destined to the Governmental Authorities of Ukraine.

Issued By: CARVEN ZIVOTIN

Date of issue: 15-Jul-2026 08:24:26

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

Report Number: pLMS75-135486

Page 4 of 5



PFIZER MANUFACTURING
DEUTSCHLAND GMBH
MOOSWALDALLEE 1
79106 FREIBURG IM BREISGAU, GERMANY

Certificate of Compliance

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
Betriebsstraße Freiburg
Mooswaldallee 1
79000 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: Christian Koltner
Disposition Date: 15-Jul-2025 08:28:17

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

Issued By: CARMEN ZWARTEN

Date of Issue: 15-Jul-2025 08:34:05

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

Headline: C:\MSD\DOC\JUN\SP9-1524\MS

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