



РЕПУБЛИКА СРБИЈА
ФАРМАЦЕУТСКА КОМОРА
The Pharmaceutical Chamber of Serbia

ПРИМЕНА СТАНДАРДА КРОЗ ПРИКАЗ ПРИМЕРА ИЗ ПРАКСЕ

МАГ. ФАРМ. СПЕЦ. ИВАНА ЈОКИЋ



МАГИСТАР ФАРМАЦИЈЕ КАО ДЕО ИСТРАЖИВАЧКОГ ТИМА



- упознавање са протоколом клиничког испитивања
- пријем испитиваног лека/ медицинског средства
- складиштење и чување испитиваног лека/ медицинског средства
- издавање испитиваног лека/ медицинског средства (када је потребно и када за то постоје могућности припрема) лека/ медицинског средства
- вођење евиденције о издавању и утрошку испитиваног лека/ медицинског средства
- складиштење и чување искоришћених остатака испитиваног лека/ медицинског средства
- повраћај неупотребљеног као и неискоришченог остатка лека/ медицинског средства спонзору

НА ПОЧЕТКУ

- Важећи GCP сертификат
- Упознавање са протоколом и начином вођења документације – потписани документи о извршеној обуци
- Уговор о учешћу у спровођењу клиничког испитивања



Investigator Site Personnel ICH GCP Training Certificate

Roche/Genentech certifies that Ivana Jokić has
Name of Trainee

completed Good Clinical Practice training meeting "Minimum Criteria for ICH E6 GCP Investigator Site Personnel Training*," identified by TransCelerate BioPharma, Inc., entitled

Good Clinical Practice (Investigator Version), version #2.1 on 21 JUN 2020
Date (dd-MON-yyyy)

This certificate reflects that Sponsor, not TransCelerate BioPharma, certifies that an investigator and/or trainee has completed training meeting the Minimum Criteria to facilitate mutual recognition of site training and qualification. This is not a legal document, and does not certify compliance with any applicable laws or regulations. A list of GCP Training Solutions meeting the minimum criteria is maintained on TransCelerate's website <http://transceleratebiopharma.com>.

*TransCelerate BioPharma, Inc. Operating Principles for ICH GCP Investigator Training 7 February 2013, version 1.1

ИСПОРУКА И ПРИЈЕМ



19. NOV 20.

- На основу захтева за испоруку испитиваног лека/ медицинског средства центру кроз IWRS систем

Drug Shipment Request: Gilead GS-US-417-0304
Notification Date/Time: 12 Nov 2020 4:12:00 PM CET
Date of Shipment Request: 12 Nov 2020
Drug Shipment Number: 263509

100557549

Protocol: Gilead GS-US-417-0304
Shipment Number: 263509
Requester: Bracket – IWRS

Shipment Type: Resupply
Total Quantity Requested: 12

Depot: Ireland
Site Name: Clinical Hospital Center Bezanijaska kosa
Investigator Name: Bogdanovic, Gordana
Site ID: 12844
Country: Serbia

Drug Delivery Contact Telephone Number: +381-692695071
Drug Delivery Contact Name: Alajbeg, Mirjana
Clinical Hospital Center Bezanijaska kosa
Bezanijaska kosa bb

Shipping Notes:

Belgrade, 11080
Serbia

This is a notification that a drug shipment containing the following study drug is required:

Part Number: FP-12763	Finished Lot Number: 417-0304/27	Material Description: Filgotinib Tablets, 200 mg or Placebo, 30 ct	Qty: 6		
8065110	8065113	8065115	8065117	8065119	8065123
Part Number: FP-13007	Finished Lot Number: 417-0304/40	Material Description: Filgotinib Tablets, 100 mg or Placebo, 30 ct	Qty: 6		
6110908	6110909	6110911	6110913	6110914	6110919

To be completed by site:

1. PLEASE CONFIRM RECEIPT BY CALLING IXRS OR BY LOGGING ONTO THE IXRS STUDY WEBSITE AT: <https://rxsm.bracketglobal.com/Sunlit/>
2. PLEASE RETAIN THIS FORM IN YOUR STUDY DRUG BINDER.
3. STORE STUDY DRUG IN SECURE LOCATION AND ACCORDING TO THE PRODUCT LABEL.

Notification Date/Time: 12 Nov 2020 4:12:00 PM CET

ИСПОРУКА И ПРИЈЕМ



Libero PDF Report No 22305811 (ALARM ALX0061_Temp_Site 381004 20180418102221 16025516.pdf)

ABLYNX Study ALX0061-C204 Temperature Report Site 381004

ALARM

Additional Information
 Trial Code: ALX0061-C204
 Site No: 381004
 Country: Serbia (SRB)

In case of ALARM, please complete Form for temperature excursion during storage.

Device Configuration

Type:	Libero Te1-N V1.36	Inspection Range:	Last Tr-Ar / Show all
Logger ID:	16025516	Current State:	Logging Arrived
Log Interval / Duration:	15 m / 168.7 d	Remaining Battery:	378 d
Log Mode:	Loop	Logger Start:	25.Jan.2018 14:35:06
Report Time Base:	GMT	Checksum:	AbE4 / 3.351.135.064
Configured by:	S1362, EC49/mulmer, 05.Jan.2018 15:39:15		

Alarm Zones

Alarm Zone	Allowed Time	Total Time	No. of violations	Status
Z1: over 25.4 °C	0 s (sin)	0 s	0 / unlim.	OK
Z2: over 15.4 °C	0 s (sin)	0 s	0 / unlim.	OK
Z3: over 8.4 °C	0 s (sin)	15 m.	1 / unlim.	ALARM
Z4: 1.5 to 8.4 °C	unlimited	14.1 d		
Z5: below 1.5 °C	0 s (sin)	0 s	0 / unlim.	OK
Z6: below -0.4 °C	0 s (sin)	0 s	0 / unlim.	OK

Logging Results

Highest Temperature:	8.8 °C; 18.Apr.2018 10:20:08	Transit Start at:	04.Apr.2018 08:36:15
Lowest Temperature:	4.0 °C; 16.Apr.2018 19:35:06	Arrived at:	18.Apr.2018 10:21:57
Average Temperature:	4.8 °C	Alarm at:	18.Apr.2018 10:20:06
MKT:	4.9 °C	File created:	18.Apr.2018 10:22:21

Evaluation report created by Libero, the PDF Logger®

Advise: Temperature-device data evaluation
 Shipping Order No. 10624440



Shipping item 10624440 / 00376401357909917153

LIBERO PDF Report No. 154212578 (OK Cold Chain Shipment 2-8 °C 2018112018 2208 72579001516.pdf)

Cold Chain Shipment 2-8 °C

Additional Information
 bestlibo-logs@libero-temp.com

LIBERO Configuration

Type:	LIBERO CH V4.31	Current State:	Stopped
Device ID:	72070001516	Start at:	16.Nov.2018 11:43:02
Log Interval:	15 m	Final Measurement:	16.Nov.2018 11:43:02
Report Time Base:	UTC	Checksum:	C: 18 / 732.310.156
Configured by:	81770, RRAMW08278/kebulam, 18.Nov.2018 13:11:44		

Alarm Zone

Alarm Zone	Allowed Time	Total Time	No. of Excursions	Largest Exc.	Status
H) over 8.0 °C	0 m (sin)	0 m	0 / unlimited	0 m.	OK
G) 2.0 to 8.0 °C	unlimited	3 d 23 h 16 m.			OK
L) below 2.0 °C	0 m (sin)	0 m	0 / unlimited	0 m.	OK

MKT Limits and Maximum Duration

Duration:	3 d 23 h 16 m.	Alarm Conditions:	none
MKT:	3.0 °C		

Logging Results

Highest Temperature:	8.0 °C; 16.Nov.2018 11:43:02	Stop at:	20.Nov.2018 00:57:12
Lowest Temperature:	3.9 °C; 16.Nov.2018 12:53:03	Alarm at:	none
Average Temperature:	3.8 °C	File created:	20.Nov.2018 11:27:08

Report created by LIBERO PDF Logger® Page 1 / 1 www.libero.com

ИСПОРУКА И ПРИЈЕМ



MERCK

Annex 3 to MBQ Quality Standard Procedure #20043481 "Definition and monitoring and Storage conditions of investigational products"

REPORTING, ASSESSMENT AND CLOSE OUT OF TEMPERATURE EXCURSIONS

Section 1 : Report (ALL excursions)

Protocol N°/Trial No (as applicable/if applicable):

Reporting Unit/Site/Depot/CMO:
(include Trial Site No/Country as applicable / if applicable):

Product (DS/DP/IMP/NIMP): Batch N°:

Order / Delivery / Shipment number
(as applicable, not requested in case of deviation at the site):

Assessment expected by:

Reason (e.g. patient to be treated by, kits to be shipped by):

Presentation:	Kit or patient N° (only IMP):
	Quantity of product affected:

Excursion occurred during:	Apparent Cause:
<input type="checkbox"/> Transport	<input type="checkbox"/> Temperature deviation during s
<input type="checkbox"/> Storage (CMO/Warehouse)	<input type="checkbox"/> Refrigerator, cold room, air-con
<input type="checkbox"/> Storage (CMO/Depot)	problems
<input type="checkbox"/> Storage (CRO/Clinical Trial site)	<input type="checkbox"/> Power failure
	<input type="checkbox"/> Other

Description of Excursion:	Documentation Attached
Date:	<input type="checkbox"/> No, justification.....
Temperature:	
Duration:	<input type="checkbox"/> Yes (please list)

Comments / Emergency Action Taken:

Datalogger no.:

Person reporting the temperature excursion event

Name/Function/Site:

Date: Signature:

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QUALITY FORM - ManGo # 20043484 v.3

MERCK

SECTION 4 - CLOSE OUT (Critical Temperature Excursions only)

Final Conclusion:

The product involved in the deviation is suitable for use: YES NO (Tick the relevant box)

Comment:

Qualified Person Close Out:

Name: Signature: Date(data):

Form Revision History

Version n°	Reason for and Description of the Change	Replaces Document
1	Creation	Not applicable
2		V1
3	Revision of main SOP, update Annex to current layout and SOP. Order / Delivery / Shipment number requested in section 1.	V2

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QUALITY FORM - ManGo # 20043484 v.3 Page 3 of 3

MERCK

SECTION 5 - ASSESSMENT (All excursions)

Appearance:	Data Assessment:
<input type="checkbox"/> s	<input type="checkbox"/> Complies with Transport and Storage Conditions
<input type="checkbox"/> g	<input type="checkbox"/> Data shows allowable excursion only
<input type="checkbox"/> ging	<input type="checkbox"/> Data shows critical excursion
	<input type="checkbox"/> No clear data of extension and/or duration of temperature excursion (go to section 4 to document not suitability for use)

nt by QP/Authorized/Delegate/QC:

ature Excursion – material can be confirmed for intended use, e.g. clinical use not applicable)

re Excursion - requires Assessment/Investigation and decision by QP

Visé reference:

ity, not relevant for Trial Sites/CROs)

gated/QC:

Signature: Date

able excursion, please send the close out to fax n°:

Section 6 (Critical Temperature Excursions only)

rackWide Deviation Reference (not relevant for CT site/CROs):

eference: Included: Yes No

on Reviewed:

istory: YES NO

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ManGo # 20043484 v.3 Page 2 of 3

ИСПОРУКА И ПРИЈЕМ



19. NOV 20.

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Notification Date/Time: 12 Nov 2020 4:12:00 PM CET
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Protocol: Gilead GS-US-417-0304
Shipment Number: 263509
Requester: Bracket – IWRS

Shipment Type: Resupply
Total Quantity Requested: 12

Depot: Ireland
Site Name: Clinical Hospital Center Bezanijska kosa
Investigator Name: Bogdanovic, Gordana
Site ID: 12814
Country: Serbia

Drug Delivery Contact Telephone Number: +381-692695071
Drug Delivery Contact Name: Alajbeg, Mirjana
Clinical Hospital Center Bezanijska kosa
Bezanijska kosa bb

Shipping Notes:

Belgrade, 11080
Serbia

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3. STORE STUDY DRUG IN SECURE LOCATION AND ACCORDING TO THE PRODUCT LABEL.

Notification Date/Time: 12 Nov 2020 4:12:00 PM CET

ИСПОРУКА И ПРИЈЕМ



VETPROM Export-Import D.O.O. BEOGRAD

PIB 100125088

Sponzor: **GILEAD SCIENCES INC** Dobavljač: **VETPROM Export - Import D.O.O. Beograd** Klinička studija: **GS-US-417-0304**

OTPREMNICA BR. **1957/404** Odgovorno lice: **Dipl. ph. Snezana Cvijic** Datum štampa otpremnice: **16.11.2020.**

Prevalac: KBC Bezanjska Kosa Gl. istraživač: Dr Ljudmila Stojanovic	Ulica i broj: Bezanjska kosa bb Kontakt: Gordana Bogdanovic 053213443 Tatjana Stojanovic 064112119 Jelena Hajder 0641480690 Jovanka Dragosevic 0648434838 Djevica Radovanovic 06412031514 Osvitana Katic 0641112108 Mirjana Alajbeg 0682856071	Mesto: BEOGRAD SITE 12844
--	--	---

Na osnovu: Gilead Proforma Invoice No: 263509 od 12.11.2020.
AWB 4394747542

R br	Serijski broj	NAZIV ROBE	Količina	Jedinica mere	Rok
1.	417-030427	Labelled Filgotinib (GS-9034) Film Tablets, 200mg, 30 ct Bottle or Matching Film Placebo Tablets 0mg Storage conditions: 15 - 30 C	6	KE	31.01.2022.
2.	417-030440	Labelled Filgotinib (GS-6034) Film Tablets, 100mg, 30 ct Bottle or Matching Film Placebo Tablets 0mg Storage conditions: 16 - 30 C	6	KE	30.04.2021.

Robu prima: **VETPROM Export-Import D.O.O. Beograd** Datum prijema: **19. NOV 2020** Temperatura Ambijentalna: **18,8°C**

Robu prima: *Mirjana Alajbeg* Kontrolisao: *Mirjana Alajbeg 19.11.2020: 8h*
 Robu otpremio: *Mirjana Alajbeg 19.11.2020: 8h*

11/16/2020

Bracke@RTSM



GILEAD
GS-US-417-0304

Welcome Mirjana Alajbeg | LOG OFF



REPORTS | INVESTIGATOR SITE

DRUG SHIPMENT RECEIPT

Site ID : 12844

Success

This transaction has been recorded. Shortly you will receive a notification confirming your entries.

Shipment Number : 263509

To record an additional transaction, please choose a menu option from the navigation panel.

СКЛАДИШТЕЊЕ



RESAL WIRELESS MONITORING MEASURING & CONTROL CALIBRATION

CALIBRATION REPORT

IQUIA RDS d.o.o. Beograd
Attn. Ms. V. Milkovic
Rudnicka 2
11000 Belgrade
Serbia

Report number: 214975

Data sensor under test		Data reference, device and surroundings	
Entry date	: 17-05-2018	Type reference	: MR-T433-PT100
Instrument	: Thermometer	Serial number	: 103-15-26/P0645
Model	: RT801B	Device	: Liquid thermostat bath
Measuring range	: -50°C - +70°C	Calibration certificate no.	: 18-1031526/01
Serial number	: F3576	Environmental conditions	: 23,0°C ± 3°C
Accuracy	: 0,5°C		

The thermometer was calibrated by comparison with a work standard based on the ITS-90. This was put together with the standard in a liquid thermostat bath on the same depth of 12-13cm.

Results calibration

Reference measurement ISO	Thermometer 1 datalogger 1	Difference ISO - 1
15,03 °C	14,90 °C	-0,13 °C
19,99 °C	19,80 °C	-0,19 °C
24,98 °C	24,80 °C	-0,18 °C
29,97 °C	29,70 °C	-0,27 °C

Start of calibration : 29-05-2018 Re-calibration date : 29-05-2019
End of calibration : 30-05-2018

The measurements have been executed using standards for which the traceability to (inter)national standards has been demonstrated.

Issue: 01-06-2018

M. Caspers
Calibration technician

Reproduction of the complete certificate is allowed. Parts of the certificate may only be produced with written approval of RESAL B.V.

Page 1 of 1

Metrix an (Dien 848) 2162 HC 1355E The Netherlands www.resal.nl info@resal.nl t +31(0)65 422 4490
BTW NL 027450980.801 R.v.a. 20278883 IBAN NL38 0480 0505 0034 70 BIC: RABO NL33 Member of Haringh Streekl



Temperature Log
GB-118 417-0364
Effective Date: 25 May 2016

Temperature Log Filgotinib

MONTH/YEAR: April 2019
LOCATION: Minsk, 1244/1919G
MAKE/MODELNO: G20-2014W
SERIALNO.: 181053251
DEVICE / TYPE: Digital thermometer

Temperature Range
Room Temperature
25°C (77°F)

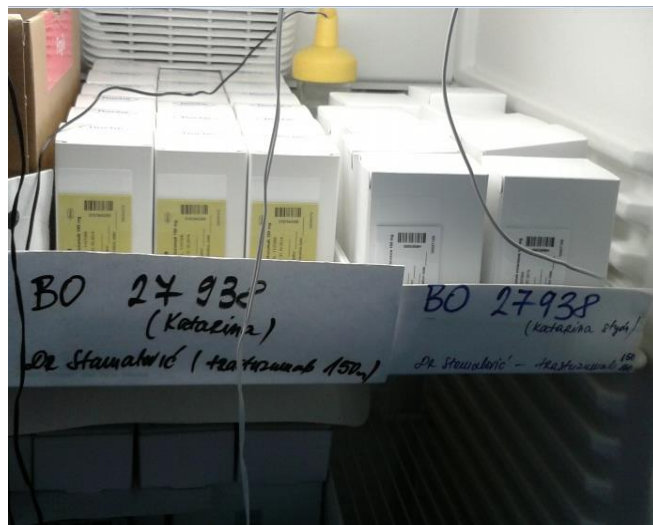
DAY	TIME	TEMP		DEVIATIONS	REPORTED		COMMENTS / RECOMMENDATIONS	INITIALS
		F (Min)	F (Max)		*YES/NO	*YES/NO		
				(If yes, comment)	(If yes, comment)			
1	08:54	22,3	25,0	N	NA	NA	NA	llc
2	09:25	21,0	25,0	N	NA	NA	NA	llc
3				N	NA	NA	WCECMB	llc
4				N	NA	NA	WCECMB	llc
5	09:48	22,0	24,8	N	NA	NA	NA	llc
6	09:00	22,3	25,0	N	NA	NA	NA	llc
7	09:50	22,4	24,5	N	NA	NA	NA	llc
8	09:35	25,0	24,9	N	NA	NA	NA	llc
9	08:00	21,6	23,0	N	NA	NA	NA	llc
10				N	NA	NA	WCECMB	llc
11				N	NA	NA	WCECMB	llc
12	09:30	22,3	25,0	N	NA	NA	NA	llc
13	09:42	21,6	24,9	N	NA	NA	NA	llc
14	09:40	21,0	25,0	N	NA	NA	NA	llc
15	08:45	22,0	25,0	N	NA	NA	NA	llc
16	09:20	21,8	24,8	N	NA	NA	NA	llc
17				N	NA	NA	WCECMB	llc
18				N	NA	NA	WCECMB	llc
19	09:45	21,9	25,0	N	NA	NA	NA	llc
20	09:00	22,1	24,8	N	NA	NA	NA	llc
21	09:45	24,0	24,0	N	NA	NA	NA	llc
22	09:40	21,8	24,3	N	NA	NA	NA	llc
23	09:10	21,8	25,0	N	NA	NA	NA	llc
24				N	NA	NA	WCECMB	llc
25				N	NA	NA	WCECMB	llc
26	09:15	22,1	25,0	N	NA	NA	NA	llc
27	08:10	23,0	25,0	N	NA	NA	NA	llc
28	09:00	24,0	24,3	N	NA	NA	NA	llc
29	09:20	22,1	25,0	N	NA	NA	NA	llc
30				N	NA	NA	HOLIDAY	llc
31				N	NA	NA		llc

(*COMPLETE ALL COLUMNS WITH A VALUE OR N/A)

SUPSRV 004 T 04 D

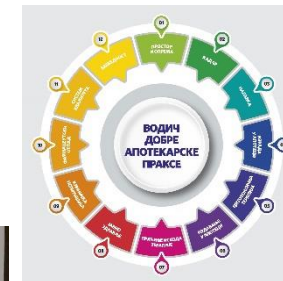
Page 2 of 2

СКЛАДИШТЕЊЕ



ИЗДАВАЊЕ

- лек/ медицинско средство се издаје на основу електронске потврде о издавању из IWRS базе података
- при издавању се врши провера исправности достављене документације
- издавање се врши по пацијенту сходно протоколу



3/16/22, 8:06 AM Gmail Ivana Jokic <ivjokic@gmail.com>

Fwd: Gilead GS-US-417-0304: Study Visit Confirmation (Blinded): Site 12844, Subject Number: 41732
1 message

Gordana Bogdanović <boggoca@gmail.com> Tue, Sep 1, 2020 at 7:44 AM
To: Ivana Jokic <ivjokic@gmail.com>

----- Forwarded message -----
From: **Signant Health** <noreply.irt@signanthealth.com>
Date: Tue, Sep 1, 2020 at 7:28 AM
Subject: Gilead GS-US-417-0304: Study Visit Confirmation (Blinded): Site 12844, Subject Number: 41732
To: <agupta@klinera.com>, <Alejandra.Zacapa@gilead.com>, <alonsojulia@prahs.com>, <asuka-yoshioka.sc@cmic.co.jp>, <ChanPinky@prahs.com>, <chiharu-takahashi.hy@cmic.co.jp>, <ChiuMichelle@prahs.com>, <FrancoisWadeline@prahs.com>, <heathrainya@prahs.com>, <hinakobori.gc@cmic.co.jp>, <Hiroki.Ueda@gilead.com>, <hrathod@klinera.com>, <kroshinaimna@prahs.com>, <KusAgnes@prahs.com>, <LiuPeiYing@prahs.com>, <LopezFernando@prahs.com>, <MarelliCristina@prahs.com>, <Mark.Hu@gilead.com>, <muzychenkostyantyn@prahs.com>, <Natasha.OrzeckByrnes@gilead.com>, <Nathan.Wong@gilead.com>, <OrtaSosaJulian@prahs.com>, <osipenkovadim@prahs.com>, <PilkertonDevin@prahs.com>, <PjevacNikola@prahs.com>, <popovigor@prahs.com>, <Priyanka.Shele@klinera.com>, <rooneykevin@prahs.com>, <saima.shaikh@klinera.com>, <sjaiswal@klinera.com>, <smithathana@prahs.com>, <sochio.ikeda@cmic.co.jp>, <VaughanNatalie@prahs.com>, <VolkonEniko@prahs.com>, <WangLucille@prahs.com>, <WangsinmongkolChuta@prahs.com>, <WolfSnip@prahs.com>, <yuki-Onchi.hs@cmic.co.jp>, <boggoca@gmail.com>

Protocol: Gilead GS-US-417-0304
Visit: Study Visit

Site Name: Clinical Hospital Center Bezanijska kosa
Investigator Name: Stojanovic, Ljudmila
Site ID: 12844
Country: Serbia

Subject Number: 41732
Subject Date of Birth: 23 Jun 1966
Subject Initials: S-J
Subject Gender: Female
Subject Requires Dose Reduction: No

Day -1 Date: 16 Apr 2019

Visit Number: 09
Visit Type: Week 72
Visit Date: 01 Sep 2020

Study Drug Dispensed:
Filgotinib Tablets, 100 mg or Placebo, 30 ct 6087832, 6087833, 6087834
Filgotinib Tablets, 200 mg or Placebo, 30 ct 8061704, 8061706, 8061707

Transaction Recorded Date: 31 Aug 2020
Notification Date/Time: 01 Sep 2020 7:28:00 AM CET
User Name: Bogdanovic, Gordana

*Bogdanovic
01. sep 2020.*

This is a notification that a study visit was recorded in the Gilead GS-US-417-0304 study.

For study-related questions, please consult your study contact. If you have system technical questions, please contact Bracket Technical Support. Country-specific Technical Support access numbers are noted in your worksheet packet or instruction material. For non-urgent issues, you may also send an email to support@bracketglobal.com

<https://mail.google.com/mail/u/0/?ik=2232710314&view=pt&search=all&permthid=thread-f%3A1676609178606432482&siml=msg-f%3A167660...> 1/2

ЕВИДЕНТИРАЊЕ



Master Investigational Product Inventory Log
GIL41702-417304
Version Date: 25-Oct-2016

Master Investigational Product Inventory Log

PRA PROJECT ID: GIL41702-417304	SPONSOR: Gilead Sciences, Inc.	PROTOCOL NUMBER: GS-US-417-0304	INVESTIGATOR NAME: G. Bogdanovic	SIT
SITE ADDRESS: ЧКЦ "Београдска комора" 11080 Београд, Србија		ITEM DESCRIPTION: Filgotinib (100 mg) / PTM (Placebo-to-match) Bottles with 30 tablets each, Regimen dose: 1 tablet/day		

Kit Receipt Information					IP Condition	IP Dispensing				Verified by CRA		IP Return Information	
Date Received (dd-Mmm-yyyy)	Kit Number	Expiry Date (dd-Mmm-yyyy)	Batch Number	Received By (initials)	*Enter a, b, c or d as appropriate (see below)	Date Dispensed (dd-Mmm-yyyy)	Subject Number	Dispensed by (initials)	Date dispensed (dd-Mmm-yyyy)	Verified By (initials)	Date (dd-Mmm-yyyy)	U	D
25.Feb.2019	6028.536	31/01/21	417-0304/17	ME	A	16.Feb.2019	41732	ME	26.JUN.2019	VB	31.MAY.2021		
25.Feb.2019	6028.539	31/01/21	417-0304/17	ME	A	17.Feb.2019	41733	ME	26.JUN.2019	VB	31.MAY.2021		
21.Feb.2019	6028.540	31/01/21	417-0304/17	ME	B	20.Feb.2019	41732	ME	26.JUN.2019	VB	N/A		
21.Feb.2019	6028.541	31/01/21	417-0304/17	ME	A	20.Feb.2019	41733	ME	26.JUN.2019	VB			
21.Feb.2019	6029.233	31/01/21	417-0304/17	ME	N/A	N/A	N/A	N/A	31.MAY.2021	VB			
21.Feb.2019	6029.242	31/01/21	417-0304/17	ME	N/A	N/A	N/A	N/A	31.MAY.2021	VB			
21.Feb.2019	6029.243	31/01/21	417-0304/17	ME	N/A	N/A	N/A	N/A	31.MAY.2021	VB			
21.Feb.2019	6029.244	31/01/21	417-0304/17	ME	N/A	N/A	N/A	N/A	31.MAY.2021	VB			

*For the IP Condition column, enter the appropriate corresponding letter: a) IP is in good condition at time of dispensing b) IP is Temperature Excursion. If IP has been quarantined, indicate in the comments section the date the IP was quarantined and the date of COV: ALL IPs PACKED/CHECKED ON IMV#6 (31 MAY 2021) & IMV#7 (29 JUL 2021) WE BY LOCAL VENDOR VETFROM ON 19 AUG 2021. FILGOTINIB 100mg/PTM - 55 used kits + 4 WERE INCLUDED IN THE SHIPMENT (1 kit NOT RETURNED TO SITE/LOST BY SUBJECT - 602854)

PRS 070 T 69 A

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Subject Investigational Product Accountability Log
GIL41702-417304
Version Date: 25-Oct-16

Subject Investigational Product Accountability Log

PRA PROJECT ID: GIL41702-417304	SPONSOR: Gilead Sciences, Inc.	PROTOCOL NUMBER: GS-US-417-0304	INVESTIGATOR NAME: G. Bogdanovic	SITE NUMBER: 112844
SITE ADDRESS: ЧКЦ "Београдска комора" 11080 Београд, Србија		ITEM DESCRIPTION: Filgotinib (100 mg) / PTM (Placebo-to-match) Bottles with 30 tablets each, Regimen dose: 1 tablet/day		
SUBJECT ID NUMBER: 41732				

IP Dispensing Information					IP Returned by Subject Information					Verified by CRA		IP Return to Supplier Info		Comments	
Visit	Kit #	Expiry Date (dd-Mmm-yyyy)	Batch Number	# Units Dispensed	Date Dispensed (dd-Mmm-yyyy)	By (initials)	Date Received (dd-Mmm-yyyy)	# Units Returned	% Compliance	Returned To (initials)	Date (dd-Mmm-yyyy)	By (initials)	Unused Units		Core (dd-Mmm-yyyy)
W60	6028537	31/01/21	417-0304/17	30	15 JUN 2020	ME	01 SEP 2020	12	100%	J	16 OCT 2020	VB	12		VB
W72	602852	31/01/22	417-0304/17	30	01 SEP 20	J	30 NOV 2020	0	100%	J	29 APR 2021	VB	0		VB
W72	602853	31/01/22	417-0304/17	30	01 SEP 20	J	30 NOV 2020	0	100%	J	29 APR 2021	VB	0		VB
W72	602854	21/01/22	417-0304/17	30	01 SEP 20	J	30 NOV 2020	0	100%	J	29 APR 2021	VB	0		VB
W72	602855	31/01/21	417-0304/17	30	30 NOV 2020	J	18 FEB 2021	0	100%	J	29 APR 2021	VB	0		VB
W72	602856	31/01/21	417-0304/17	30	30 NOV 2020	J	18 FEB 2021	0	100%	J	29 APR 2021	VB	0		VB

COMMENTS:

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ОТПАД И УНИШТАВАЊЕ



- Морају постојати обезбеђени услови за прописно чување и складиштење искоришћених остатака испитиваног лека/ медицинског средства
- Студијски монитор организује и одобрава процес уништавања лека
- Врши се уништавање неискоришћеног лека/ медицинског средства, испитивани лек/ медицинско средство са истеклим роком употребе, амбалажа као и остатак коришћеног испитиваног лека/ медицинског средства
- Све мора бити евидентирано на IMP RETURN FORM формулару
- Уколико се уништавање врши према интерној процедури у самој здравственој установи то се мора навести у протоколу о клиничком испитивању



ХВАЛА НА ПАЖЊИ