



Gilead Sciences Ireland UC,
IDA Business & Technology Park,
Carrigrohilly, Co. Cork,
Ireland.
VAT Reg Number: IE8259755V

Invoice

Page No. 1 of 1
Invoice No. 3531042906
Invoice Date 28-Jun-19
Order No. 3531042906
PO No. 017179
L/C No. N/A

Buyer:

LEPL SOCIAL SERVICE AGENCY,
144 TSERETELI AVE,
TBILISI 0159,
GEORGIA

Consignee:

WAREHOUSE OF LEPL CENTRE FOR MENTAL HEALTH
AND PREVENTION OF ADDICTION,
21A KAVTARADZE STREET,
TBILISI 0186,
GEORGIA

Distribution Center

Gilead Sciences Ireland UC
Eagle House Elm Road
Dublin Airport Logistics Park
St. Margarets, Co. Dublin

Contact: Tata Sirbiladze

Email: tsirbiladze@ssa.gov.ge

Country of Origin		Country of Destination		Port/airport of loading		Place of delivery		Transport Information		
CANADA		GEORGIA		DUBLIN		LEPL SOCIAL SERVICE AGENCY, GEORGIA		CIP TBILISI INTERNATIONAL AIRPORT		
Line#	Item Number	Lot Number	Mfg Date	Exp Date	Description	Commodity Code number	UOM	Quantity	Unit Price	Total Amount
1.00	61958-2202-3	YPPGD	26-Jul-17	31-Jul-21	Epclusa, Tablets, 28ct, Access Program, Standard Shared Pack (GS-004A)	3004 90 0000	bt	3734	1.00	3734
2.00	61958-2202-3	YNHHD	03-Jul-17	31-Jul-21	Epclusa, Tablets, 28ct, Access Program, Standard Shared Pack (GS-004A)	3004 90 0000	bt	6837	1.00	6837
1.00	61958-2202-3	YPPH	16-Aug-17	31-Aug-21	Epclusa, Tablets, 28ct, Access Program, Standard Shared Pack (GS-004A)	3004 90 0000	bt	205	1.00	205
1.00	61958-2202-3	YNHHA	03-Jul-17	31-Jul-21	Epclusa, Tablets, 28ct, Access Program, Standard Shared Pack (GS-004A)	3004 90 0000	bt	200	1.00	200
Packing Details & Shipping marks										

Packing Details & Shipping marks

5 pallets 1180*1050*1110

1035 kg

THESE GOODS ARE FREE OF CHARGE.

THE AMOUNT SHOWN IS FOR CUSTOMS PURPOSES ONLY.

Any unused or expired Product is not eligible for credit, refund or exchange.

Note: FCA Dublin

Buyers are responsible at their own expense for carriage of goods, purchasing insurance and obtaining customs clearance of goods from Dublin to final destination. Gilead does not provide insurance coverage. All risks coverage, insurance, and clearance through customs up to last destination will be the buyer's responsibility.

MEDICINAL PRODUCT FOR HUMAN USE

Please Remit to Address Below:

Bank: Bank of America N.A.

Bank Address: 2 Park Place, Hatch Street, Dublin 2

Account: Gilead Sciences Ireland UC

Account Number: 53601021

IBAN: IE44 BOFA 9900 6153 6010 21

BIC: BOFAIE3X

Correspondent Bank: Bank of America N.A., New York, BOFAUS33

Under 21 CFR 314.510 and Section 505(b) of the U.S. Food and Drug Cosmetic Act.

NON-HAZARDOUS/NOT RESTRICTED/DOES NOT CONTAIN ANIMAL PRODUCTS/SYNTHETICALLY (CHEMICALLY) DERIVED

Maintain 15-30°C (59-86°F), protect from extreme heat or freezing. *Ambient

NDAP 21-356

These commodities for ultimate destination Division contrary to U.S. law prohibited. I/We hereby certify that the information on this invoice is true and correct and that the contents of this shipment are as stated above. I/We hereby authorize Wells Fargo Bank, Palo Alto, California, USA to execute any additional documents necessary for the export of merchandise described herein on my/our behalf.

Total Customs Value

3734.00

Currency:

USD

Name of Signatory:

Ben Dunne

Place and Date of Issue:

Dublin 28-Jun-19

Signature:

Ben Dunne



Gilead Sciences Ireland UC
Eagle House, Elm Road, Dublin AirPort Logistics Park
St. Margaret's
Dublin
Ireland
Tel: +353 1 291 3580 Fax: +353 21 4825518
VAT Reg Number: IE8259755V

Packing Slip

127-909794

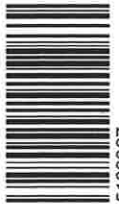
3531042906



Customer Information		Investigator Name/Investigator #:
Customer Name	LEPL Social Service Agency	Contact / Investigator Phone Number:
Customer Number	19905	
Bill to Address: LEPL Social Service Agency LEPL Social Service Agency 144 Tsereteli Ave. Tbilisi 0159 Georgia		Ship to Address: LEPL Social Service Agency Warehouse of LEPL Centre for Mental Health and Prevention of Addiction 21A Kavtaradze Street Tbilisi 0186 Georgia
Deliver to Address: LEPL Social Service Agency Warehouse of LEPL Centre for Mental Health and Prevention of Addiction 21A Kavtaradze Street Tbilisi 0186 Georgia		

Sales Order	3531042906
Customer PO/DSR#	01/7179
Order Date	23-APR-2019
Order Status	BOOKED
Entered by	Dunne, Bernard Francis
Page Number	1 of 1
Inventory Org	IE-207-DIST-DUBLIN
Warehouse #	127
Delivery Note#	5108627
Study #	
Recipient Name	
Recipient Phone #	

Scheduled Ship Date		Carrier	Ship Method	Incoterms		Packing Instructions		Shipping Instructions	
28-JUN-2019		EXPEDITOR	EXPEDITOR-AIR	S		Carriage and insurance paid to			
Line #	Item Number	Lot #	Location	Expiry Date	Description	Sales Order Line #	Quantity	UOM	Shipping Conditions
1	61958-2202-3	YNHHD	MAIN D 05 15	31-JUL-2021	Epclusa, Tablets, 28ct, Access Program, Standard Shared Pack (GS-004A)	1.1	1920	bt	
2	61958-2202-3	YNHHD	MAIN D 05 13	31-JUL-2021	Epclusa, Tablets, 28ct, Access Program, Standard Shared Pack (GS-004A)	1.1	537	bt	
3	61958-2202-3	YPPHD	MAIN C 03 06	31-AUG-2021	Epclusa, Tablets, 28ct, Access Program, Standard Shared Pack (GS-004A)	1.1	205	bt	
4	61958-2202-3	YNHHD	MAIN D 04 07	31-JUL-2021	Epclusa, Tablets, 28ct, Access Program, Standard Shared Pack (GS-004A)	1.1	1077	bt	
5	61958-2202-3	YNHHD	MAIN D 04 14	31-JUL-2021	Epclusa, Tablets, 28ct, Access Program, Standard Shared Pack (GS-004A)	1.1	1920	bt	
6	61958-2202-3	YNHHAD	MAIN D 05 09	31-JUL-2021	Epclusa, Tablets, 28ct, Access Program, Standard Shared Pack (GS-004A)	1.1	200	bt	
7	61958-2202-3	YNHHD	MAIN D 05 13	31-JUL-2021	Epclusa, Tablets, 28ct, Access Program, Standard Shared Pack (GS-004A)	1.1	1383	bt	
RECEIPT CONFIRMATION FOR CLINICAL TRIAL PURPOSE ONLY STORAGE CONDITIONS: REFER TO PRODUCT LABELS						Shippable Weight 0kg			
For IVR/IVRS orders please confirm receipt in system. For non-IVRS orders, please complete section below, return a copy to the study CRA. Maintain the original in the study files. Please select one:						Pack Slip Date/ Time 28.06.2019 02:11:44			
1. ALL PRODUCTS LISTED ON THE PACKING SLIP HAVE BEEN RECEIVED IN GOOD CONDITION									
2. SOME ITEMS ARE MISSING OR DAMAGED, PLEASE EXPLAIN:									
Received by:						Date:			



5108627



Packing Slip

3531042906



Sales Order	3531042906
Customer PO/DSR#	01/7179
Order Date	23-APR-2019
Order Status	BOOKED
Entered by	Dunne, Bernard Francis
Page Number	1 of 1
Inventory Org	IE-207-DIST-DUBLIN
Warehouse #	127
Delivery Note#	5122936
Study #	
Recipient Name	
Recipient Phone #	

Scheduled Ship Date	Carrier	Ship Method	Incoterms	Packing Instructions	Shipping Instructions
28-JUN-2019	EXPEDITOR S	EXPEDITORS-AIR	Carriage and insurance paid to		
Line # Item Number	Lot #	Location	Expiry Date	Description	Sales Order Line #
1 61958-2202-3	YPPGD	ASAP SHIP	31-JUL-2021	Eplusa, Tablets, 28ct, Access Program, Standard Shared Pack (GS-004A)	1.1
				Quantity	UOM Shipping Conditions
				3734	bt

RECEIPT CONFIRMATION FOR CLINICAL TRIAL PURPOSE ONLY STORAGE CONDITIONS: REFER TO PRODUCT LABELS

For IVR/IWRS orders please confirm receipt in system. For non-IVRS orders, please complete section below. return a copy to the study CRA.
Maintain the original in the study files. Please select one:

1. ALL PRODUCTS LISTED ON THE PACKING SLIP HAVE BEEN RECEIVED IN GOOD CONDITION

2. SOME ITEMS ARE MISSING OR DAMAGED, PLEASE EXPLAIN:

Received by: _____ Date: _____

Shippable Weight 0kg

Pack Slip Date/ Time 28.06.2019 02:11:44

Gilead Sciences Ireland, UC
CERTIFICATE OF ANALYSIS - Access Georgia

PRODUCT:		Epclusa Access		MANUFACTURE DATE:		03 Jul 2017	
LOT NUMBER:		YNHHA		EXPIRY DATE:		07 2021	
SPECIFICATION:		GSPEC-274-98		MANUFACTURING SITE:		Patheon TRO	
REVISION NUMBER:		2.0		TESTING SITE:		GSIUC, Cork Ireland, Patheon TRO	

TESTS	TESTING SITE	RESULTS		LOWER LIMIT	UPPER LIMIT	PASS/FAIL
		SOF	VEL			
Appearance	GSIUC, Cork Ireland	Complies		SOF/VEL Tablets are red, diamond-shaped tablets, debossed with "GSI" on one side and "7916" on the other side.		PASS
Identification (Chromatographic Retention Time)	Patheon TRO	Complies		The retention times of the main peaks of the sample are consistent with those of the reference standards of each active ingredient.		PASS
Identification (UV Spectrum)	GSIUC, Cork Ireland	Complies		The ultraviolet spectrum of the sample confirms the presence of sofosbuvir and velpatasvir when assessed against the reference standard, similarly measured		PASS
Water Content (%)	Patheon TRO	2.1		None	5.5	PASS
Strength by HPLC Assay (% of label claim)		100.6	100.6	95.0	105.0	PASS
Degradation Product Content (SOF)						
Total SOF-related degradation products (%)		0.0		None	0.6	PASS
GS-607669 (%)		Not Detected		None	0.30	PASS
GS-607670 (%)		Not Detected		None	0.30	PASS
GS-606965 (%)		Not Detected		None	0.30	PASS
GS-331007 (%)		Not Detected		None	0.30	PASS
Phenol (%)		Not Detected		None	0.30	PASS
Each of any Unspecified SOF-related degradation product (%)		Complies		None	0.20	PASS
Degradation Product Content (VEL)						
Total VEL-related degradation products (%)			0.5	None	3.0	PASS
GS-642273/GS-642269 (%)			0.38	None	1.90	PASS
GS-607685/GS-627174 (%)			0.10	None	0.90	PASS
GS-598740 (%)			Trace	None	0.90	PASS
GS-650350 (%)			Not Detected	None	0.60	PASS
GS-645999 (%)			Not Detected	None	0.60	PASS
GS-695896 (%)			Not Detected	None	0.40	PASS
Each of any Unspecified VEL-related degradation product (%)			Complies	None	0.20	PASS
Uniformity of Dosage Units		Complies		Meets USP and Ph.Eur. requirements		PASS
Dissolution (% at 20 min for SOF and VEL)		99	97	75	None	PASS
Microbial Limits						
Aerobic microbial count (cfu/g)		<0.05 x 10 ³		None	10 ³ CFU/g	PASS
Yeasts and Molds (cfu/g)		<0.1 x 10 ²		None	10 ² CFU/g	PASS
Absence of <i>E. coli</i>		Absent		Absent		PASS

GENERATED BY:

[Signature]
GSIUC QC DEPARTMENT

DATE: *31 May 19*

REVIEWED BY:

[Signature]
GSIUC QC DEPARTMENT

DATE: *31 May 19*

APPROVED BY:

NAME:

[Signature]
Qualified Person

Mary Fitzgerald

DATE:

06 Jun 19

Gilead Sciences Ireland UC

IDA Business & Technology Park, Carrigrohilly, Co. Cork, Ireland
Tel: + 353 (0)21 482 5500 • Fax: + 353 (0)21 482 5518 • www.gilead.com

Registered in Ireland 259755

Directors: David Cadogan, Taiyin Yang (USA), Brett Pletcher (USA), Robin Washington (USA)

Gilead Sciences Ireland, UC
CERTIFICATE OF ANALYSIS - Access Georgia

PRODUCT:	Eplusa Access	MANUFACTURE DATE:		16 Aug 2017	
LOT NUMBER:	YPPH	EXPIRY DATE:		08 2021	
SPECIFICATION:	GSPEC-274-98	MANUFACTURING SITE:		Patheon TRO	
REVISION NUMBER:	2.0	TESTING SITE:		GSIUC, Cork Ireland, Patheon TRO	

TESTS	TESTING SITE	RESULTS		LOWER LIMIT	UPPER LIMIT	PASS/FAIL
		SOF	VEL			
Appearance	GSIUC, Cork Ireland	Complies		SOF/VEL Tablets are red, diamond-shaped tablets, debossed with "GSI" on one side and "7916" on the other side.		PASS
Identification (Chromatographic Retention Time)	Patheon TRO	Complies		The retention times of the main peaks of the sample are consistent with those of the reference standards of each active ingredient.		PASS
Identification (UV Spectrum)	GSIUC, Cork Ireland	Complies		The ultraviolet spectrum of the sample confirms the presence of sofosbuvir and velpatasvir when assessed against the reference standard, similarly measured		PASS
Water Content (%)	Patheon TRO	2.3		None	5.5	PASS
Strength by HPLC Assay (% of label claim)		99.6	100.6	95.0	105.0	PASS
Degradation Product Content (SOF)						
Total SOF-related degradation products (%)		0.0		None	0.6	PASS
GS-607669 (%)		Not Detected		None	0.30	PASS
GS-607670 (%)		Not Detected		None	0.30	PASS
GS-606965 (%)		Not Detected		None	0.30	PASS
GS-331007 (%)		Not Detected		None	0.30	PASS
Phenol (%)		Not Detected		None	0.30	PASS
Each of any Unspecified SOF-related degradation product (%)		Complies		None	0.20	PASS
Degradation Product Content (VEL)						
Total VEL-related degradation products (%)			0.4	None	3.0	PASS
GS-642273/GS-642269 (%)			0.40	None	1.90	PASS
GS-607685/GS-627174 (%)			Trace	None	0.90	PASS
GS-598740 (%)			Not Detected	None	0.90	PASS
GS-650350 (%)			Not Detected	None	0.60	PASS
GS-645999 (%)			Not Detected	None	0.60	PASS
GS-695896 (%)			Not Detected	None	0.40	PASS
Each of any Unspecified VEL-related degradation product (%)			Complies	None	0.20	PASS
Uniformity of Dosage Units		Complies		Meets USP and Ph.Eur. requirements		PASS
Dissolution (% at 20 min for SOF and VEL)		100	101	75	None	PASS
Microbial Limits						
Aerobic microbial count (cfu/g)		<0.05 x 10 ³		None	10 ³ CFU/g	PASS
Yeasts and Molds (cfu/g)		<0.1 x 10 ²		None	10 ³ CFU/g	PASS
Absence of <i>E. coli</i>		Absent		Absent		PASS

GENERATED BY:

Eian Moroney
GSiUC QC DEPARTMENT

DATE: 21 May 17

REVIEWED BY:

Paul W. Kern
GSiUC QC DEPARTMENT

DATE: 21 May 2019

APPROVED BY:

NAME:

M. Fitzgerald
Qualified Person

Mary Fitzgerald

DATE:

23 May 19

Gilead Sciences Ireland UC

IDA Business & Technology Park, Carrigrohilly, Co. Cork, Ireland
Tel: + 353 (0)21 482 5500 • Fax: + 353 (0)21 482 5518 • www.gilead.com

Registered in Ireland 259755

Directors: David Cadogan, Taiyin Yang (USA), Brett Fletcher (USA), Robin Wastington (USA)

Gilead Sciences Ireland, UC
CERTIFICATE OF ANALYSIS - Access Georgia

PRODUCT:	Eclusa Access	MANUFACTURE DATE:		26 Jul 2017	
LOT NUMBER:	YPPG	EXPIRY DATE:		07 2021	
SPECIFICATION:	GSPEC-274-98	MANUFACTURING SITE:		Patheon TRO	
REVISION NUMBER:	2.0	TESTING SITE:		GSIUC, Cork Ireland, Patheon TRO	

TESTS	TESTING SITE	RESULTS		LOWER LIMIT	UPPER LIMIT	PASS/FAIL
		SOF	VEL			
Appearance	GSIUC, Cork Ireland	Complies		SOF/VEL Tablets are red, diamond-shaped tablets, debossed with "GSI" on one side and "7916" on the other side.		PASS
Identification (Chromatographic Retention Time)	Patheon TRO	Complies		The retention times of the main peaks of the sample are consistent with those of the reference standards of each active ingredient.		PASS
Identification (UV Spectrum)	GSIUC, Cork Ireland	Complies		The ultraviolet spectrum of the sample confirms the presence of sofosbuvir and velpatasvir when assessed against the reference standard, similarly measured		PASS
Water Content (%)	Patheon TRO	2.4		None	5.5	PASS
Strength by HPLC Assay (% of label claim)		101.7	102.4	95.0	105.0	PASS
Degradation Product Content (SOF)		0.0		None	0.6	PASS
Total SOF-related degradation products (%)		Not Detected		None	0.30	PASS
GS-607669 (%)		Not Detected		None	0.30	PASS
GS-607670 (%)		Not Detected		None	0.30	PASS
GS-606965 (%)		Not Detected		None	0.30	PASS
GS-331007 (%)		Not Detected		None	0.30	PASS
Phenol (%)		Not Detected		None	0.30	PASS
Each of any Unspecified SOF-related degradation product (%)		Complies		None	0.20	PASS
Degradation Product Content (VEL)		0.4		None	3.0	PASS
Total VEL-related degradation products (%)		0.39		None	1.90	PASS
GS-642273/GS-642269 (%)		Trace		None	0.90	PASS
GS-607685/GS-627174 (%)		Not Detected		None	0.90	PASS
GS-598740 (%)		Not Detected		None	0.60	PASS
GS-650350 (%)		Not Detected		None	0.60	PASS
GS-645999 (%)		Not Detected		None	0.40	PASS
GS-695896 (%)		Not Detected		None	0.20	PASS
Each of any Unspecified VEL-related degradation product (%)		Complies		None	0.20	PASS
Uniformity of Dosage Units		Complies		Meets USP and Ph.Eur. requirements		PASS
Dissolution (% at 20 min for SOF and VEL)		99	99	75	None	PASS
Microbial Limits		<0.05 x 10 ³		None	10 ³ CFU/g	PASS
Aerobic microbial count (cfu/g)		<0.1 x 10 ²		None	10 ² CFU/g	PASS
Yeast and Molds (cfu/g)		Absent		Absent		PASS
Absence of <i>E. coli</i>		Absent		Absent		PASS

GENERATED BY:

REVIEWED BY:

Evan Maroney
GSIUC QC DEPARTMENT
Das (SLOV)
GSIUC QC DEPARTMENT

DATE: 21 May 19

DATE: 21 MAY 19

APPROVED BY:

NAME: *M Fitzgerald*
Mary Fitzgerald
Qualified Person

DATE: 23 May 19

Gilead Sciences Ireland UC

IDA Business & Technology Park, Carrigrohilly, Co. Cork, Ireland
Tel: +353 (0)21 482 5500 • Fax: +353 (0)21 482 5518 • www.gilead.com

Registered in Ireland 259755
Directors: David Cardogan, Taiyin Yang (USA), Brett Plancher (USA), Robin Washington (USA)

Gilead Sciences Ireland, UC
CERTIFICATE OF ANALYSIS - Access Georgia

PRODUCT:	Epclusa Access	MANUFACTURE DATE:		03 Jul 2017	
LOT NUMBER:	YNHH	EXPIRY DATE:		07 2021	
SPECIFICATION:	GSPEC-274-98	MANUFACTURING SITE:		Patheon TRO	
REVISION NUMBER:	2.0	TESTING SITE:		GSUIC, Cork Ireland, Patheon TRO	

TESTS	TESTING SITE	RESULTS		LOWER LIMIT	UPPER LIMIT	PASS/FAIL
		SOF	VEL			
Appearance	GSUIC, Cork Ireland	Complies		SOF/VEL Tablets are red, diamond-shaped tablets, debossed with "GSI" on one side and "7916" on the other side.		PASS
Identification (Chromatographic Retention Time)	Patheon TRO	Complies		The retention times of the main peaks of the sample are consistent with those of the reference standards of each active ingredient.		PASS
Identification (UV Spectrum)	GSUIC, Cork Ireland	Complies		The ultraviolet spectrum of the sample confirms the presence of sofosbuvir and velpatasvir when assessed against the reference standard, similarly measured		PASS
Water Content (%)	Patheon TRO	2.1		None	5.5	PASS
Strength by HPLC Assay (% of label claim)		100.6	100.6	95.0	105.0	PASS
Degradation Product Content (SOF)		0.0		None	0.6	PASS
Total SOF-related degradation products (%)		Not Detected		None	0.30	PASS
GS-607669 (%)		Not Detected		None	0.30	PASS
GS-607670 (%)		Not Detected		None	0.30	PASS
GS-606965 (%)		Not Detected		None	0.30	PASS
GS-331007 (%)		Not Detected		None	0.30	PASS
Phenol (%)		Not Detected		None	0.30	PASS
Each of any Unspecified SOF-related degradation product (%)		Complies		None	0.20	PASS
Degradation Product Content (VEL)		0.5		None	3.0	PASS
Total VEL-related degradation products (%)		0.38		None	1.90	PASS
GS-642273-GS-642269 (%)		0.10		None	0.90	PASS
GS-607685-GS-627174 (%)		Trace		None	0.90	PASS
GS-598740 (%)		Not Detected		None	0.60	PASS
GS-650350 (%)		Not Detected		None	0.60	PASS
GS-645999 (%)		Not Detected		None	0.40	PASS
GS-695896 (%)		Complies		None	0.20	PASS
Each of any Unspecified VEL-related degradation product (%)		Complies		Meets USP and Ph.Eur. requirements		PASS
Uniformity of Dosage Units		99	97	75	None	PASS
Dissolution (% at 20 min for SOF and VEL)		99		75	None	PASS
Microbial Limits		<0.05 x 10 ¹		None	10 ¹ CFU/g	PASS
Aerobic microbial count (cfu/g)		<0.1 x 10 ²		None	10 ² CFU/g	PASS
Yeast and Molds (cfu/g)		Absent		Absent		PASS
Absence of E. coli		Absent		Absent		PASS

GENERATED BY:

Cian Monaghan
GSUIC QC DEPARTMENT

DATE: 22 May 17

REVIEWED BY:

David L. Kelly
GSUIC QC DEPARTMENT

DATE: 22 MAY 2019

APPROVED BY:

NAME:

Brendan Duloher
Qualified Person

Brendan Duloher

DATE:

23rd MAY 2019

Gilead Sciences Ireland UC

IDA Business & Technology Park, Carrington Hill, Co. Cork, Ireland
Tel: +353 (0)21 482 5500 • Fax: +353 (0)21 482 5515 • www.gilead.com

Registered in Ireland 259755

Directors: David Carlogan, Taimin Yang (USA), Brad Pleicher (USA), Robin Washington (USA)