



GILEAD

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

Invoice

Page No. 1 of 1
Invoice No. 3531032957
Invoice Date 18-Jan-18
Order No. 3531032957
PO No. 01/68852
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 Ltd
Unit 92 Bracken Road
Sandyford Industrial Estate
Dublin 18, Ireland

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	61958-1502-2	5589102V2D	08-Dec-15	31-Dec-19	Harvoni, Tablets, 28ct, Access Program, Standard Shared Pack	3004 90 0000	bt	10423	1.00	10423
2.00	61958-1802-5	5589102V2D1	08-Dec-15	31-Dec-19	Harvoni, Tablets, 28ct, Access Program, Standard Shared Pack		bt	10000	1.00	10000
3.00	61958-1802-5	5589103V3D	09-Dec-15	31-Dec-19	Harvoni, Tablets, 28ct, Access Program, Standard Shared Pack		bt	19577	1.00	19577

Packing Details & Shipping marks

17 Pallet Boxes @ 1180 X 1050 X 1110 - 253 Kgs (each)
1 Pallet Box 1180 X 1050 X 1110 by 100 Kgs
Total 18 pallets - Gross Weight 4,401.00 Kgs

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"
ND# 21-356

Total Customs Value

40000.00

Currency:

USD

Name of Signatory:

Ben Dunne

Place and Date of Issue:

Dublin 18-Jan-18

Signature:

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.



Packing Slip

127-725993

3531032957



Gilead Sciences Ireland UC
IDA Business & Technology Park
Carrigrohilly
Co. Cork
Ireland
Tel: +353 21 4825500 Fax: +353 21 4825518
VAT Reg Number: IE8259755V

Customer Information			
Customer Name	LEPL Social Service Agency		Customer Contact
Customer Number	19905		Customer Ph No
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	3531032957
Customer PO	01/68852
Order Date	07-NOV-2017
Order Status	BOOKED
Entered by:	Dunne, Bernard Francis
Page Number	1 of 1
Inventory Org	IE-207-DIST-DUBLIN
Warehouse #	127
Delivery Note#	4186295
Study #	
Recipient Name	
Recipient Phone #	

Scheduled Ship date		Carrier	Ship Method	Incoterms	Packing Instructions	Shipping Instructions	
19-JAN-2018		EXPEDITORS	EXPEDITORS-AIR	Carriage and insurance paid to			
Line #	Item Number	Lot #	Serial #	Expiry Date	Description	Sales Order Line #	UOM
1	61958-1802-5	5589102V2D		31-DEC-2019	Harvoni,Tablets,28ct,Access Program,Standard Shared Pack (Updated PI GS-005 A)	1.1	bt
2	61958-1802-5	5589102V2D1		31-DEC-2019	Harvoni,Tablets,28ct,Access Program,Standard Shared Pack (Updated PI GS-005 A)	1.1	bt
3	61958-1802-5	5589103V3D		31-DEC-2019	Harvoni,Tablets,28ct,Access Program,Standard Shared Pack (Updated PI GS-005 A)	1.1	bt
							Quantity
							10423
							10000
							19577
Gilead User				Dunne, Bernard Francis			kg
				Pack Slip Date/ Time			15.01.2018 11:25:34

Gilead Sciences Ireland UC

CERTIFICATE OF ANALYSIS- ACCESS PROGRAM GEORGIA

PRODUCT: Harvoni (SOF 400 mg/LDV 90 mg) Access Tablets

LOT NUMBER: 5589102V2D1

SPECIFICATION: GSPEC-216-98.02

MANUFACTURE DATE: 08 December 2015

EXPIRY DATE: 12 2019

TESTS	ACCEPTANCE CRITERIA	RESULTS
APPEARANCE	SOF/LDV Tablets are white, diamond-shaped, film-coated tablets, debossed with "GSI" on one side and "7985" on the other side.	Conforms
IDENTIFICATION		
LC Retention Time		
Chromatographic Retention Time	The retention times of the main peaks in SOF/LDV Tablets are consistent with the reference standard of each active ingredient.	Conforms
IDENTIFICATION UV		
UV Spectrum	The ultraviolet absorption spectrum of SOF/LDV Tablets is consistent with that of sofosbuvir and ledipasvir reference standard solution.	Conforms
WATER CONTENT	NMT 5.0 %	2.1 %
ASSAY		
Sofosbuvir	NLT 95.0 and NMT 105.0 %	101.0 %
Ledipasvir	NLT 95.0 and NMT 105.0 %	101.7 %
DEGRADATION PRODUCT CONTENT		
Total SOF-related degradation products	NMT 0.6 %	0.0 %
Total LDV-related degradation products	NMT 1.4 %	0.1 %
GS-606965	NMT 0.30 %	Not Detected
GS-331007	NMT 0.30 %	Not Detected
GS-566500	NMT 0.30 %	Not Detected
GS-607669	NMT 0.30 %	Not Detected
GS-607670	NMT 0.30 %	Not Detected
phenol	NMT 0.30 %	Not Detected

Printed By: John-Paul Ivers Date Printed: 28-Nov-2017

29th Nov 2017

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, John Milligan (USA), Brett Fletcher (USA), Kevin Young (UK)

R-0214 (6.0)

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CERTIFICATE OF ANALYSIS- ACCESS PROGRAM GEORGIA

PRODUCT: Harvoni (SOF 400 mg/LDV 90 mg) Access Tablets

LOT NUMBER: 5589102V2D1

SPECIFICATION: GSPEC-216-98.02

MANUFACTURE DATE: 08 December 2015

EXPIRY DATE: 12 2019

TESTS	ACCEPTANCE CRITERIA	RESULTS
GS-459666	NMT 1.25 %	0.13 %
Each of any SOF-related unspecified degradation products	NMT 0.20%	Conforms
Each of any LDV-related unspecified degradation products	NMT 0.20%	Conforms
UNIFORMITY OF DOSAGE UNITS		
Content Uniformity	SOF/LDV Tablets meet the USP or Ph. Eur. requirements for content uniformity.	Conforms
DISSOLUTION (Stage 1)		
Dissolution Summary	SOF/LDV Tablets, meet the USP and Ph. Eur. criteria for the amount of sofosbuvir and ledipasvir dissolved at 30 minutes when Q= 80%.	Conforms
Mean SOF at 30 minutes		100 %
Mean LDV at 30 minutes		98 %

QC Released by: John-Paul Ivers

Date: 12-Aug-2016

Approved by: Brendan Dulchery
Qualified Person

Brendan Dulchery

Date: 29th Nov 2017

Printed By: John-Paul Ivers Date Printed: 28-Nov-2017

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SPECIFICATION:	GSPEC-216-98.02	
MANUFACTURE DATE:	08 December 2015	EXPIRY DATE: 12 2019

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GS-566500	NMT 0.30 %	Not Detected
GS-607669	NMT 0.30 %	Not Detected
GS-607670	NMT 0.30 %	Not Detected
phenol	NMT 0.30 %	Not Detected

Printed By: John-Paul Ivers Date Printed: 28-Nov-2017

29 Nov 2017

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SPECIFICATION: GSPEC-216-98.02

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Mean SOF at 30 minutes		100 %
Mean LDV at 30 minutes		98 %

QC Released by: John-Paul Ivers

Date: 12-Aug-2016

Approved by:

Brendan Dulchery

Brendan Dulchery

Date:

29th Nov 2017

Qualified Person

Printed By: John-Paul Ivers Date Printed: 28-Nov-2017

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CERTIFICATE OF ANALYSIS- ACCESS PROGRAM GEORGIA

PRODUCT: Harvoni (SOF 400 mg/LDV 90 mg) Access Tablets

LOT NUMBER: 5589103V3D

SPECIFICATION: GSPEC-216-98.02

MANUFACTURE DATE: 09 December 2015

EXPIRY DATE: 12 2019

TESTS	ACCEPTANCE CRITERIA	RESULTS
APPEARANCE	SOF/LDV Tablets are white, diamond-shaped, film-coated tablets, debossed with "GSI" on one side and "7985" on the other side.	Conforms
IDENTIFICATION		
LC Retention Time		
Chromatographic Retention Time	The retention times of the main peaks in SOF/LDV Tablets are consistent with the reference standard of each active ingredient.	Conforms
IDENTIFICATION UV		
UV Spectrum	The ultraviolet absorption spectrum of SOF/LDV Tablets is consistent with that of sofosbuvir and ledipasvir reference standard solution.	Conforms
WATER CONTENT	NMT 5.0 %	2.2 %
ASSAY		
Sofosbuvir	NLT 95.0 and NMT 105.0 %	101.3 %
Ledipasvir	NLT 95.0 and NMT 105.0 %	101.9 %
DEGRADATION PRODUCT CONTENT		
Total SOF-related degradation products	NMT 0.6 %	0.0 %
Total LDV-related degradation products	NMT 1.4 %	0.1 %
GS-606965	NMT 0.30 %	Not Detected
GS-331007	NMT 0.30 %	Not Detected
GS-566500	NMT 0.30 %	Not Detected
GS-607669	NMT 0.30 %	Not Detected
GS-607670	NMT 0.30 %	Not Detected
phenol	NMT 0.30 %	Not Detected

Printed By: John-Paul Ivers Date Printed: 28-Nov-2017

(M) 29th Nov 2017

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Advancing Therapeutics.
Improving Lives.

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CERTIFICATE OF ANALYSIS- ACCESS PROGRAM GEORGIA

PRODUCT: Harvoni (SOF 400 mg/LDV 90 mg) Access Tablets

LOT NUMBER: 5589103V3D

SPECIFICATION: GSPEC-216-98.02

MANUFACTURE DATE: 09 December 2015

EXPIRY DATE: 12 2019

TESTS	ACCEPTANCE CRITERIA	RESULTS
GS-459666	NMT 1.25 %	0.13 %
Each of any SOF-related unspecified degradation products	NMT 0.20%	Conforms
Each of any LDV-related unspecified degradation products	NMT 0.20%	Conforms
UNIFORMITY OF DOSAGE UNITS		
Content Uniformity	SOF/LDV Tablets meet the USP or Ph. Eur. requirements for content uniformity.	Conforms
DISSOLUTION (Stage 1)		
Dissolution Summary	SOF/LDV Tablets, meet the USP and Ph. Eur. criteria for the amount of sofosbuvir and ledipasvir dissolved at 30 minutes when Q= 80%.	Conforms
Mean SOF at 30 minutes		102 %
Mean LDV at 30 minutes		99 %

QC Released by: John-Paul Ivers

Date: 12-Aug-2016

Approved by:

Brendan Duloher

Brendan Duloher

Date: 29th Nov 2017

Qualified Person

Printed By: John-Paul Ivers Date Printed: 28-Nov-2017

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