

CERTIFICATE OF ANALYSIS- ACCESS PROGRAM
PRODUCT: Sovaldi (SOF 400mg) Access Tablets

LOT NUMBER: TZDND

SPECIFICATION: GSPEC-204-97.00

MANUFACTURE DATE: 26 September 2015

EXPIRY DATE: 09 2017

MANUFACTURING SITE: Patheon Inc., Toronto Region Operations, Canada

PRIMARY PACKAGING SITE: Patheon Inc., Toronto Region Operations, Canada

SECONDARY PACKAGING SITE: Gilead Sciences Ireland UC, Ireland

RELEASE SITE: Gilead Sciences Ireland UC, Ireland

TESTS	ACCEPTANCE CRITERIA	RESULTS
APPEARANCE	Sofosbuvir Tablets, 400 mg, are white, capsule-shaped, film-coated tablets debossed with "GSI" on one side and "7977" on the other side.	Conforms
IDENTIFICATION		
LC Retention Time		
Chromatographic Retention Time	The retention time of the main peak from Sofosbuvir Tablets, 400 mg, is consistent with that of the sofosbuvir reference standard.	Conforms
IDENTIFICATION UV		
UV Spectrum	The UV spectrum of Sofosbuvir Tablets, 400 mg, is consistent with that of the sofosbuvir reference spectrum.	Conforms
WATER CONTENT	NMT 3.5 %	1.8 %
ASSAY		
Sofosbuvir	NLT 95.0 and NMT 105.0 %	100.8 %
DEGRADATION PRODUCT CONTENT		
Total Deg. Products	NMT 0.6 %	0.0 %
GS-606985	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

Printed By: Gillian Guiney Date Printed: 08-Dec-2015

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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Catherine May
 09 Dec 2015

CERTIFICATE OF ANALYSIS- ACCESS PROGRAM

PRODUCT:	Sovaldi (SOF 400mg) Access Tablets		
LOT NUMBER:	TZDND		
SPECIFICATION:	GSPEC-204-97.00		
MANUFACTURE DATE:	26 September 2015	EXPIRY DATE:	09 2017
MANUFACTURING SITE:	Patheon Inc., Toronto Region Operations, Canada		
PRIMARY PACKAGING SITE:	Patheon Inc., Toronto Region Operations, Canada		
SECONDARY PACKAGING SITE:	Gilead Sciences Ireland UC, Ireland		
RELEASE SITE:	Gilead Sciences Ireland UC, Ireland		

TESTS	ACCEPTANCE CRITERIA	RESULTS
GS-607670	NMT 0.30 %	Not Detected
Phenol	NMT 0.30 %	Not Detected
Each of any unspecified degradation product	NMT 0.20%	Conforms
UNIFORMITY OF DOSAGE UNITS		
Weight Variation	Meet the harmonized USP, Ph. Eur. requirements for weight variation.	Conforms
AV (SOF)		1.4
DISSOLUTION (Stage 1)		
Dissolution Summary	Meet the USP and Ph. Eur. criteria for the amount of sofosbuvir dissolved at 20 minutes when Q is 80%.	Conforms
Mean SOF @ 20 mins		99 %
Max SOF @ 20 mins		100 %
Min SOF @ 20 mins		98 %

QC Released by: Clare Bartley

Date: 03-Dec-2015

Approved by:

Qualified Person

Catherine P. Maye

Date:

09 Dec 2015

Cathy Maye

Printed By: Gillian Guiney Date Printed: 08-Dec-2015

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CERTIFICATE OF ANALYSIS- ACCESS PROGRAM

PRODUCT: Sovaldi (SOF 400mg) Access Tablets
LOT NUMBER: TZDPD
SPECIFICATION: GSPEC-204-97.00

MANUFACTURE DATE: 27 September 2015 **EXPIRY DATE:** 09 2017
MANUFACTURING SITE: Patheon Inc., Toronto Region Operations, Canada
PRIMARY PACKAGING SITE: Patheon Inc., Toronto Region Operations, Canada
SECONDARY PACKAGING SITE: Gilead Sciences Ireland UC, Ireland

RELEASE SITE: Gilead Sciences Ireland UC, Ireland

TESTS	ACCEPTANCE CRITERIA	RESULTS
APPEARANCE		
	Sofosbuvir Tablets, 400 mg, are white, capsule-shaped, film-coated tablets debossed with "GSI" on one side and "7977" on the other side.	Conforms
IDENTIFICATION		
LC Retention Time		
Chromatographic Retention Time	The retention time of the main peak from Sofosbuvir Tablets, 400 mg, is consistent with that of the sofosbuvir reference standard.	Conforms
IDENTIFICATION UV		
UV Spectrum	The UV spectrum of Sofosbuvir Tablets, 400 mg, is consistent with that of the sofosbuvir reference spectrum.	Conforms
WATER CONTENT	NMT 3.5 %	1.8 %
ASSAY		
Sofosbuvir	NLT 95.0 and NMT 105.0 %	101.0 %
DEGRADATION PRODUCT CONTENT		
Total Deg. Products	NMT 0.6 %	0.0 %
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

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Catherine Smyth
 09 Dec 2015

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LOT NUMBER: TZDPD

SPECIFICATION: GSPEC-204-97.00

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GS-607670	NMT 0.30 %	Not Detected
Phenol	NMT 0.30 %	Not Detected
Each of any unspecified degradation product	NMT 0.20%	Conforms
UNIFORMITY OF DOSAGE UNITS		
Weight Variation	Meet the harmonized USP, Ph. Eur. requirements for weight variation.	Conforms
AV (SOF)		1.6
DISSOLUTION (Stage 1)		
Dissolution Summary	Meet the USP and Ph. Eur. criteria for the amount of sofosbuvir dissolved at 20 minutes when Q is 80%.	Conforms
Mean SOF @ 20 mins		100 %
Max SOF @ 20 mins		101 %
Min SOF @ 20 mins		97 %

QC Released by: Clare Bartley

Date: 03-Dec-2015

Approved by:

Qualified Person

Date:

09 Dec 2015

Cathy Maye

Printed By: Gillian Guiney Date Printed: 08-Dec-2015

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