

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

208341Orig1s000

CHEMISTRY REVIEW(S)

Recommendation: Approval

NDA 208341

Review 2

Drug Name/Dosage Form	Epclusa (Sofosbuvir and Velpatasvir) Tablets
Strength	400mg / 100 mg
Route of Administration	Oral
Rx/OTC Dispensed	Rx
Applicant	Gilead
US agent, if applicable	NA

SUBMISSION(S) REVIEWED	DOCUMENT DATE	DISCIPLINE(S) AFFECTED
Presubmission	09-Oct-2015	Presubmission
Original	28-Oct-2015	Original
Amendment	06-Jan-2016	Amendment
Amendment	05-Feb-2016	Amendment
Amendment	23-Mar-2016	Amendment
Amendment	13-Apr-2016	Amendment
Amendment	08-Jun-2016	Labeling
Amendment	15-Jun-2016	Amendment

Quality Review Team

Discipline	Reviewer	Secondary Reviewer
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Table of Contents

Table of Contents	2
Quality Review Data Sheet.....	3
Executive Summary	5
Primary Quality Review.....	9
ASSESSMENT OF THE DRUG SUBSTANCE	9
2.3.S DRUG SUBSTANCE:	9
ASSESSMENT OF THE DRUG PRODUCT	59
2.3.P DRUG PRODUCT.....	59
R.2 Comparability Protocols.....	95
ASSESSMENT OF THE PROCESS.....	96
2.3.P DRUG PRODUCT.....	96
ASSESSMENT OF THE FACILITIES.....	116
2.3.S DRUG SUBSTANCE	116
2.3.P DRUG PRODUCT.....	121
ASSESSMENT OF THE BIOPHARMACEUTICS	128
ASSESSMENT OF MICROBIOLOGY.....	144
ASSESSMENT OF ENVIRONMENTAL ANALYSIS	145
I. Review of Common Technical Document-Quality (Ctd-Q) Module 1	146
Labeling & Package Insert.....	146
II. List of Deficiencies To Be Communicated.....	157
III. Attachments	158

Quality Review Data Sheet

1. RELATED/SUPPORTING DOCUMENTS:
A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	STATUS ²	DATE REVIEW COMPLETED	COMMENTS
(b) (4)	III		(b) (4)	Adequate.	3/17/16	
	III		Adequate.	3/17/16		
	III		Adequate.	3/17/16		
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	III		Adequate.	3/17/16		



CHEMISTRY REVIEW



(b) (4)	III	(b) (4)	Adequate	3/17/16	
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B. Other Documents: *IND, RLD, or sister applications*

DOCUMENT	APPLICATION NUMBER	DESCRIPTION
IND 118605		Sofosbuvir & Valpatasvir studies

2. CONSULTS:

DISCIPLINE	STATUS	RECOMMENDATION	DATE	REVIEWER
Biostatistics	NA			
Pharmacology/Toxicology	NA	Separate review		
CDRH	NA			
Clinical	NA			
Other				

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