CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

208194Orig1s000

CHEMISTRY REVIEW(S)





Bendeka (bendamustine hydrochloride) injection Eagle Pharmaceuticals, Inc.



Recommendation: Approval, pending an acceptable recommendation from the Office of Study Integrity and Surveillance (OSIS) of the bioequivalence clinical site inspections

NDA 208194 Review #1

Drug Name/Dosage Form	Bendamustine hydrochloride injection
Strength	100 mg/4 mL (25 mg/mL)
Route of Administration	Intravenous
Rx/OTC Dispensed	Rx
Applicant	Eagle Pharmaceutical, Inc.
US agent, if applicable	N/A

SUBMISSION(S) REVIEWED	DOCUMENT DATE
0000	02/13/2015
0002	03/03/2015
0004	03/18/2015
0005	04/02/2015
0015	06/25/2015
0017	07/09/2015
0018	07/14/2015
0019	08/11/2015
0020	09/01/2015
0021	09/14/2015





Bendeka (bendamustine hydrochloride) injection Eagle Pharmaceuticals, Inc.



Quality Review Team

Quality Review			
DISCIPLINE	REVIEWER	BRANCH/DIVISION	REVIEW
			RECOMMENDATION
Drug Substance	Nina Ni	Branch II/DNDP1/ONDP	Approval
Drug Product	Nina Ni	Branch II/DNDP1/ONDP	Approval
Process	Vidya Pai	Branch VII/DPAIII/OPF	Approval
Microbiology	Vinayak	MABI/DMA/OPF	Approval
	Pawar		
Facility	Zhong Li	IABI/DIA/OPF	Approval
Biopharmaceutics	Jing Li	BBI/DB/ONDP	Approval pending an
			acceptable OSIS
			recommendation
Business Process	Rabiya Laiq	Branch1/DRBPMI/OPRO	NA
Manager			
Application	Janice Brown	Branch II/DNDP1/ONDP	Approval pending an
Technical Lead			acceptable OSIS
			recommendation
Laboratory (OTR)	N/A	N/A	N/A
ORA Lead	Paul Perdue Jr.	MDTP/DMPTPO/OMPTP	See facility review
			recommendation
Environmental	Janice Brown	Branch II/DNDP1/ONDP	Categorical exclusion
Assessment (EA)			accepted





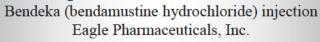




Table of Contents

Tal	ole of Cor	ntents	3
Qu	ality Rev	iew Data Sheet	4
Exe	ecutive Su	ummary	5
		ality Review	
ASS	SESSMENT	Γ OF THE DRUG SUBSTANCE	13
	2.3.S	DRUG SUBSTANCE	13
ASS	SESSMENT	F OF THE DRUG PRODUCT	37
	2.3.P R.2	DRUG PRODUCT Error! Bookmark not Comparability Protocols.	
ASS	SESSMENT	Γ OF THE PROCESS	38
	2.3.P R.2	DRUG PRODUCTComparability Protocols	
ASS	SESSMENT	Γ OF THE FACILITIES	60
	2.3.S 2.3.P	DRUG SUBSTANCE	
ASS	SESSMENT	Γ OF THE BIOPHARMACEUTICS INFORMATION	64
ASS	SESSMENT	「OF MICROBIOLOGY	72
	2.3.P.6	Reference Standards or Materials	85
A	APPEN	NDICES	85
	A.2	Adventitious Agents Safety Evaluation	85
I.	Review	of Common Technical Document-Quality (Ctd-Q) Module 1	88
Lab	eling & Pac	ckage Insert	88
II.	List of I	Deficiencies To Be CommunicatedError! Bookmark not	defined
III.	Attachn	nents	97
IV.	Admini	strative	99





Bendeka (bendamustine hydrochloride) injection Eagle Pharmaceuticals, Inc.



Quality Review Data Sheet

- 1. LEGAL BASIS FOR SUBMISSION: 505(b)(2)
- 2. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF#		HOLDER	ITEM REFERENCED	STATUS ¹	DATE REVIEW COMPLETED	COMMENTS
(b) (4)	II		(b) (4)	1	05/06/2014	Reviewed by Joyce
						Crich
	III			N/A	N/A	Adequate information
						provided in the NDA
	III			N/A	N/A	Adequate information
						provided in the NDA
	III			N/A	N/A	Adequate information
						provided in the NDA

Adequate, Adequate with Information Request, Deficient, or N/A (There is enough data in the application, therefore the DMF did not need to be reviewed)

B. Other Documents: IND, RLD, or sister applications

DOCUMENT	APPLICATION NUMBER	DESCRIPTION	
NDA	205580	(b) (4)	

3. CONSULTS: None

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



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