

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

208194Orig1s000

CHEMISTRY REVIEW(S)



QUALITY ASSESSMENT
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



QUALITY ASSSSMENT
Bendeka (bendamustine hydrochloride) injection
Eagle Pharmaceuticals, Inc.



Quality Review Team

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 Pawar	MABI/DMA/OPF	Approval
Facility	Zhong Li	IABI/DIA/OPF	Approval
Biopharmaceutics	Jing Li	BBI/DB/ONDP	Approval pending an acceptable OSIS recommendation
Business Process Manager	Rabiya Laiq	Branch1/DRBPMI/OPRO	NA
Application Technical Lead	Janice Brown	Branch II/DNDP1/ONDP	Approval pending an acceptable OSIS recommendation
Laboratory (OTR)	N/A	N/A	N/A
ORA Lead	Paul Perdue Jr.	MDTP/DMPTPO/OMPTP	See facility review recommendation
Environmental Assessment (EA)	Janice Brown	Branch II/DNDP1/ONDP	Categorical exclusion accepted



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Quality Review Data Sheet

1. LEGAL BASIS FOR SUBMISSION: 505(b)(2)

2. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	STATUS ¹	DATE REVIEW COMPLETED	COMMENTS
(b) (4)	II	[REDACTED]	(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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