

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

205029Orig1s000

CHEMISTRY REVIEW(S)



NDA 205029

**Epinephrine Injection
1 mg/mL**

Belcher Pharmaceuticals

Division of Cardiology and Renal Products, HFD 110

**Shastri Bhamidipati, Ph.D.
Division of New Drug Quality Assessment I
Office of New Drug Quality Assessment**

**Submission Date : 29-JAN-2014
PDUFA Goal Date: 28-JUL-2014**

Chemistry Review Data Sheet

1. NDA 205029
2. REVIEW #: 3
3. REVIEW DATE: 10-July-2014
4. REVIEWER: Shastri Bhamidipati, Ph.D.

5. PREVIOUS DOCUMENTS:

Previous Documents

IND (b) (4)

Document Date

01-Feb-2012

6. SUBMISSION(S) BEING REVIEWED:

Submission(s) ReviewedNDA 205029 SD#9
NDA 205029(SD#10)
NDA 205029(SD#11)
NDA 205029(SD#12)Document Date29-JAN-2014
13-JUN-2014
01-JUL-2014
09-JUL-2014

7. NAME & ADDRESS OF APPLICANT:

Name: Belcher Pharmaceuticals
Mihir Taneja
Vice President,
Regulatory Affairs & Compliance
Representative: 6911 Bryan Dairy Road
Largo, FL 33777 USA

Telephone: (727) 471-0850 Ext 250

Chemistry Review Data Sheet

8. DRUG PRODUCT NAME/CODE/TYPE:

- a) Proprietary Name: N/A
- b) Non-Proprietary Name (USAN): Epinephrine
- c) Code Name/# (ONDQA only): N/A
- d) Chem. Type/Submission Priority (ONDQA only):
 - Chem. Type: 7
 - Submission Priority: S

9. LEGAL BASIS FOR SUBMISSION: 21 CFR 314.50, 505(b)(2)

10. PHARMACOL. CATEGORY: Cardiology, Septic Shock

11. DOSAGE FORM: Injection

12. STRENGTH/POTENCY: 1.0 mg/mL (1:1000)

13. ROUTE OF ADMINISTRATION: Intravenous

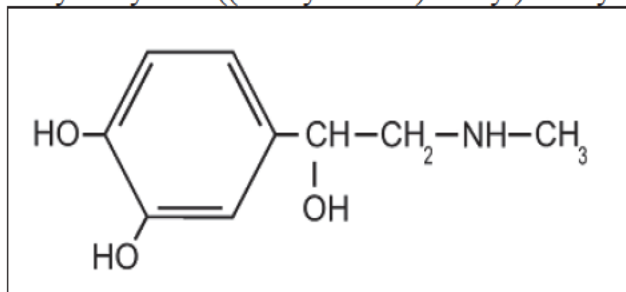
14. Rx/OTC DISPENSED: Rx OTC15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM): SPOTS product – Form Completed Not a SPOTS product

Chemistry Review Data Sheet

1. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:

Chemical Name(s):

1. Chemical Name: (R)-1-(3,4-dihydroxyphenyl)-2-methylaminoethanol 1,2-Benzenediol, 4-(1-hydroxy-2-(methylamino)ethyl)-, (R)-(-)-3,4-Dihydroxy- IX -((methylamino)methyl)-benzyl alcohol



Synonym: (-)-Adrenaline

(-)- Epinephrine

(b) (4)

CAS-No: 51 - 43 - 4

Molecular Formula: C₉H₁₃NO₃

Molecular Mass: 183.20

17. RELATED/SUPPORTING DOCUMENTS:

A. DMFs:

DMF #	TYPE	HOLDER	ITEM REFERENCED	CODE ¹	STATUS ²	DATE REVIEW COMPLETE D	COMMENTS
(b) (4)	II	(b) (4)	(b) (4)	1	Adequate	06/24/2014	S. Bhamidipati
	III			4			

¹ Action codes for DMF Table:

1 – DMF Reviewed.

Other codes indicate why the DMF was not reviewed, as follows:

2 – Type 1 DMF

3 – Reviewed previously and no revision since last review

4 – Sufficient information in application

5 – Authority to reference not granted

6 – DMF not available

7 – Other (explain under "Comments")

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