

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
22-276

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

25 MARCH 2008

NDA: 22-276

Drug Product Name

Proprietary: N/A

Non-proprietary: Nicardipine Hydrochloride Injection

Drug Product Priority Classification: S

Review Number: 1

Dates of Submission(s) Covered by this Review

Letter	Stamp	Review Request	Assigned to Reviewer
9/28/2007	10/1/2007	10/28/2007	10/16/2007

Submission History (for amendments only): N/A

Applicant/Sponsor

Name: Teva Parenteral Medicines, Inc.

Address: 19 Hughes, Irvine, CA 92618-1902

Representative: Susan O'Brien

Telephone: 949-455-4724

Name of Reviewer: Bryan S. Riley, Ph.D.

Conclusion: Recommend Approval

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUBMISSION:** Original NDA [505(b)(2)]
 2. **SUBMISSION PROVIDES FOR:** A sterile parenteral drug product
 3. **MANUFACTURING SITE:** Teva Parenteral Medicines, Inc.
19 Hughes
Irvine, CA 92618-1902
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** Sterile aqueous solution in a 10 mL single-use vial for intravenous administration, 2.5 mg/mL
 5. **METHOD(S) OF STERILIZATION:** _____ b(4)
 6. **PHARMACOLOGICAL CATEGORY:** Calcium Channel Blocker
- B. **SUPPORTING/RELATED DOCUMENTS:** N/A
- C. **REMARKS:** This application was submitted electronically in the CTD format (not eCTD).

filename: N022276R1.doc

Executive Summary

I. Recommendations

- A. **Recommendation on Approvability** – This submission is recommended for approval from the standpoint of product quality microbiology.
- B. **Recommendations on Phase 4 Commitments and/or Agreements, if Approvable** – N/A

II. Summary of Microbiology Assessments

- A. **Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology** – The drug product is **b(4)**
- B. **Brief Description of Microbiology Deficiencies** – N/A
- C. **Assessment of Risk Due to Microbiology Deficiencies** – N/A

III. Administrative

- A. **Reviewer's Signature** _____
Bryan S. Riley, Ph.D.
- B. **Endorsement Block** _____
James L. McVey
Microbiology Team Leader
- C. **CC Block**
N/A

8 Page(s) Withheld

Trade Secret / Confidential (b4)

Draft Labeling (b4)

Draft Labeling (b5)

Deliberative Process (b5)

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/s/

Bryan Riley
3/31/2008 09:10:44 AM
MICROBIOLOGIST

James McVey
3/31/2008 10:51:14 AM
MICROBIOLOGIST
I concur.

PRODUCT QUALITY MICROBIOLOGY FILING CHECKLIST

NDA Number: 22-276

Applicant: Teva Parenteral
Medicines

Letter Date: 28 September
2007

Drug Name: Nicardipine HCl
Injection

NDA Type: S

Stamp Date: 1 October 2007

The following are necessary to initiate a review of the NDA application:

	Content Parameter	Yes	No	Comments
1	Is the product quality microbiology information described in the NDA and organized in a manner to allow substantive review to begin? Is it legible, indexed, and/or paginated adequately?	X		A separate product quality microbiology table of contents was provided.
2	Has the applicant submitted an overall description of the manufacturing processes and microbiological controls used in the manufacture of the drug product?	X		The drug product is <u> </u> b(4)
3	Has the applicant submitted protocols and results of validation studies concerning microbiological control processes used in the manufacture of the drug product?	X		
4	Are any study reports or published articles in a foreign language? If yes, has the translated version been included in the submission for review?		X	
5	Has the applicant submitted preservative effectiveness studies (if applicable) and container-closure integrity studies?	X		
6	Has the applicant submitted microbiological specifications for the drug product and a description of the test methods?	X		
7	Has the applicant submitted the results of analytical method verification studies?	X		
8	Has the applicant submitted all special/critical studies/data requested during pre-submission meetings and/or discussions?	X		
9	Is this NDA fileable? If not, then describe why.	X		

Additional Comments: none

Bryan S. Riley, Ph.D.
Senior Review Microbiologist

Date

James L. McVey
OPS/NDMS/Team Leader

Date

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/s/

Bryan Riley
11/8/2007 02:21:38 PM
MICROBIOLOGIST

James McVey
11/8/2007 02:32:34 PM
MICROBIOLOGIST