

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

022485Orig1s000

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

21 December 2010

NDA: 22-485

Drug Product Name

Proprietary: Not applicable

Non-proprietary: Argatroban (in Sodium Chloride)

Review Number: 1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
16 March 2010	16 March 2010	22 March 2010	25 March 2010
17 December 2010	20 December 2010	N/A	N/A

Submission History (for amendments only): Not applicable

Applicant/Sponsor

Name: Sandoz Inc.

Address: 2555 W. Midway Blvd., P.O. Box 446
Broomfield, Colorado 80038

Representative: Alison Sherwood, Manager Regulatory Affairs

Telephone: (303) 438-4513

Name of Reviewer: Stephen E. Langille, Ph.D.

Conclusion: Recommended for approval

Product Quality Microbiology Data Sheet

- A.**
- 1. TYPE OF SUBMISSION:** Original NDA
 - 2. SUBMISSION PROVIDES FOR:** Manufacturing and terminal sterilization operations
 - 3. MANUFACTURING SITE:** Sandoz Canada Inc.
145 Jules-Léger Street
Boucherville, Canada
QC J4B 7K8
 - 4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
 - Sterile solution
 - Injection
 - 1 mg/mL
 - 125 mL
 - 5. METHOD(S) OF STERILIZATION:** (b) (4)
 - 6. PHARMACOLOGICAL CATEGORY:** Anticoagulant
- B. SUPPORTING/RELATED DOCUMENTS:** Not applicable
- C. REMARKS:** NDA 22-485 was submitted in eCTD format. An information request was sent to the applicant on 23 November 2010. The applicant responded on 17 December 2010.

filename: N022485r1.doc

Executive Summary

I. Recommendations

- A. Recommendation on Approvability -**
NDA 22-485 is recommended for approval from the standpoint of product quality microbiology.
- B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable -**
Not applicable

II. Summary of Microbiology Assessments

- A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology -**
Argatroban (in Sodium Chloride) will be (b) (4) at the (b) (4) manufacturing site.
- B. Brief Description of Microbiology Deficiencies -**
No deficiencies were identified based upon the information provided.
- C. Assessment of Risk Due to Microbiology Deficiencies -**
Not applicable

III. Administrative

- A. Reviewer's Signature** _____
Stephen E. Langille
- B. Endorsement Block**
James McVey – Team Leader
- C. CC Block**
N/A

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/s/

STEPHEN E LANGILLE
12/21/2010

JAMES L MCVEY
12/21/2010
I concur.

PRODUCT QUALITY MICROBIOLOGY FILING CHECKLIST

NDA Number: 22-485

Applicant: Sandoz

Letter Date: 16 March 2010

**Drug Name: Argatroban
Injection**

NDA Type: 505(b)(2)

Stamp Date: 16 March 2010

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		
2	Has the applicant submitted an overall description of the manufacturing processes and microbiological controls used in the manufacture of the drug product?	X		
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		The drug product is not preserved. Container closure integrity tests were provided in section P.2
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	No special studies were requested.
9	Is this NDA fileable? If not, then describe why.	X		

Additional Comments: The application was submitted in eCTD format. The drug product will be (b) (4). No additional information requests are necessary at this time.

Stephen E. Langille, Ph.D.
Reviewing Microbiologist

Date

Bryan Riley, Ph.D.
Microbiology Secondary Reviewer/Team Leader

Date

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22485	ORIG-1	SANDOZ CANADA INC	ARGATROBAN INJECTION 1 MG/ML

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/s/

STEPHEN E LANGILLE
05/03/2010

BRYAN S RILEY
05/03/2010
I concur.