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RESEARCH**

*APPLICATION NUMBER:*

**202832Orig1s000**

**MICROBIOLOGY REVIEW(S)**

# Product Quality Microbiology Review

26 October 2011

**NDA:** 202-832/N-000

**Drug Product Name**

**Proprietary:**

(b) (4)

**Non-proprietary:** Sodium Chloride Injection

**Review Number:** 1

## **Dates of Submission(s) Covered by this Review**

<b>Submit</b>	<b>Received</b>	<b>Review Request</b>	<b>Assigned to Reviewer</b>
31 January 2011	31 January 2011	15 February 2011	17 February 2011
19 October 2011	20 October 2011	N/A	N/A

**Submission History (for amendments only)** Not applicable

### **Applicant/Sponsor**

**Name:** Medefil, Inc.

**Address:** 250 Windy Point Drive  
Glendale Heights, IL 60139

**Representative:** Pradeep Agarwal

**Telephone:** 630-682-4600

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

**Conclusion:** Recommended for approval

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## Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUBMISSION:** Original NDA
  2. **SUBMISSION PROVIDES FOR:** Sterility assurance information for a new drug product.
  3. **MANUFACTURING SITE:** Medefil Inc.  
250 Windy Point Drive  
Glendale Heights, IL 60139  
FEI 3001677091
  4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
    - Sterile solution
    - I.V., sub-Q, I.M.
    - 9 mg/mL (0.9%)
  5. **METHOD(S) OF STERILIZATION:** (b) (4)
  6. **PHARMACOLOGICAL CATEGORY:** Drug product diluent
- B. **SUPPORTING/RELATED DOCUMENTS:** Not applicable
- C. **REMARKS:** The application was provided by the project manager in a series of PDF documents. The application was arranged in CTD format.

**filename:** N202832R1.doc

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## **Executive Summary**

### **I. Recommendations**

- A. Recommendation on Approvability -**  
NDA 208-832 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 -**  
The drug product will be (b) (4) processed for bioburden reduction (b) (4).
- B. Brief Description of Microbiology Deficiencies -**  
No product quality microbiology 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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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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STEPHEN E LANGILLE  
10/28/2011

JAMES L MCVEY  
10/31/2011  
I concur.