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RESEARCH**

*APPLICATION NUMBER:*

**021876Orig1s000**

**MICROBIOLOGY REVIEW(S)**

# Product Quality Microbiology Review

05 August 2013

**NDA:** 021-876/S002

**Drug Product Name**

**Proprietary:**

(b) (4)

**Non-proprietary:**

Doxylamine Succinate and Pyridoxine  
Hydrochloride

**Review Number:** 1

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

Submit	Received	Review Request	Assigned to Reviewer
30 May 2013	30 May 2013	17 June 2013	20 June 2013

## Submission History – NA

### Applicant/Sponsor

**Name:**

Duchesnay, Inc.

**Address:**

950 boul Michele-Bohec  
Blainville PQ Canada J7C 5E2

**U. S. Agent:**

OptumInsight Life Sciences, Inc.  
131 Morristown Roads  
Basking Ridge NJ 07920

**Representative:**

John J. F. Killackey

**Telephone:**

1-866-722-6734

**Name of Reviewer:** Denise Miller

**Conclusion:** Recommended for Approval

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## Product Quality Microbiology Data Sheet

- A.**
- 1. TYPE OF SUBMISSION:** Prior Approval
  - 2. SUBMISSION PROVIDES FOR:** Removal of microbial limits testing from the release testing specifications.
  - 3. MANUFACTURING SITE:**  
<sup>(b) (4)</sup>  
Duchesnay Inc. (pending approval of Supplement 1)  
Blainsville, Quebec, Canada
  - 4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**
    - Dosage Form: Tablet, Delayed Release
    - Route of Administration: Oral
    - Strength/Potency: 10 mg/tablet
  - 5. METHOD(S) OF STERILIZATION:** Not sterile
  - 6. PHARMACOLOGICAL CATEGORY:** Treatment of nausea and vomiting of pregnancy

**B. SUPPORTING/RELATED DOCUMENTS:** NA

**C. REMARKS:**

Submission is an e-CTD formatted submission.

The original NDA was approved on 08 April 2013; a Quality Microbiology review was not located.

Information request was sent to the sponsor on 10 July 2013 for which a response was received on 26 July 2013.

**filename:** N021875S002R1.doc

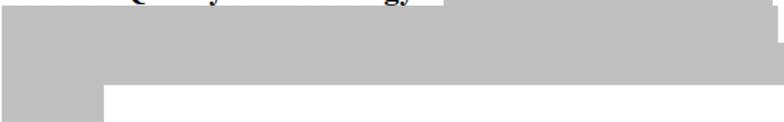
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## **Executive Summary**

### **I. Recommendations**

- A. Recommendation on Approvability** - Recommended for approval from a quality microbiology standpoint.
- B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable** - NA

### **II. Summary of Microbiology Assessments**

- A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology** – (b) (4)  

- B. Brief Description of Microbiology Deficiencies** – None identified in the information provided.
- C. Assessment of Risk Due to Microbiology Deficiencies** – NA
- D. Contains Potential Precedent Decision(s)**-  Yes  No

### **III. Administrative**

- A. Reviewer's Signature** \_\_\_\_\_  
Denise A. Miller  
Microbiologist, OPS/NDMS
- B. Endorsement Block** \_\_\_\_\_  
Bryan S. Riley, Ph.D.  
Senior Microbiologist, OPS/NDMS
- 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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DENISE A MILLER  
08/07/2013

BRYAN S RILEY  
08/07/2013  
I concur.