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APPLICATION NUMBER:
202788Orig1s000

MICROBIOLOGY REVIEW(S)

Product Quality Microbiology Review

7 SEPTEMBER 2011

NDA: 202788

Drug Product Name

Proprietary: N/A

Non-proprietary: Fentanyl Sublingual Spray

Review Number: 1

Dates of Submission(s) Covered by this Review

Submit	Received	Review Request	Assigned to Reviewer
4 March 2011	4 March 2011	18 April 2011	21 April 2011
5 August 2011	5 August 2011	N/A	N/A

Submission History (for amendments only): N/A

Applicant/Sponsor

Name: Insys Therapeutics, Inc.

Address: 10220 S. 51st Street, Suite 2, Phoenix, AZ 85044



Representative: Lauren H. Wind, MPH, Senior Consultant (The Weinberg Group Inc.)

Telephone: 202-730-4101

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

Conclusion: Recommended for Approval

Product Quality Microbiology Data Sheet

- A.
1. **TYPE OF SUBMISSION:** 505(b)(2) NDA
 2. **SUBMISSION PROVIDES FOR:** A sublingual drug product
 3. **MANUFACTURING SITE:**  (b) (4)
 4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:**  (b) (4) solution in a glass vial with rubber stopper, in a single-dose sublingual spray apparatus, 100, 200, 400, 600, and 800 mcg/dose.
 5. **METHOD(S) OF STERILIZATION:** N/A
 6. **PHARMACOLOGICAL CATEGORY:** Opioid analgesic
- B. **SUPPORTING/RELATED DOCUMENTS:** N/A
- C. **REMARKS:** This was an eCTD submission. The following IR was sent to the applicant on 1 August 2011 – “Provide descriptions of the test methods used for microbial limits. Also provide a summary of the microbiological method suitability testing with the drug product.” The response to the IR was provided in an amendment dated 5 August 2011. The amendment was reviewed in section P.5 of this review.

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Executive Summary

I. Recommendations

- A. Recommendation on Approvability** – This submission is recommended for approval on the basis 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** – (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.
Senior Review Microbiologist, OPS/NDMS
- B. Endorsement Block** _____
Stephen E. Langille, Ph.D.
Senior Review 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.

/s/

BRYAN S RILEY
09/07/2011

STEPHEN E LANGILLE
09/07/2011

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