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RESEARCH**

APPLICATION NUMBER:
202788Orig1s000

CHEMISTRY REVIEW(S)

NDA 202788

**Subsys™ (Fentanyl)
Sublingual Spray**

Insys Therapeutics, Inc

**Julia C. Pinto, Ph.D.
Office of New Drug Quality Assessment, Division III**

Division of Anesthesia, Analgesia and Addiction Products

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CHEMISTRY REVIEW



Chemistry Review Data Sheet

Chemistry Review Sheet

1. NDA 202788
2. REVIEW #: 2
3. REVIEW DATE: Dec 28, 2011
4. REVIEWER: Julia C. Pinto, Ph.D.

5. PREVIOUS DOCUMENTS:

<u>Previous Documents</u>	<u>Document Date</u>
Original	March 4, 2011
Amendment	April 5, 2011
Amendment	April 15, 2011
Amendment	April 29, 2011
Amendment	May 18, 2011
Amendment	May 20, 2011
Amendment	May 27, 2011
Amendment	June 3, 2011
Amendment	June 29, 2011
Amendment	July 7, 2011
Amendment	July 11, 2011

6. SUBMISSIONS BEING REVIEWED:

<u>Submission(s) Reviewed</u>	<u>Document Date</u>
Original	March 4, 2011
Amendment	April 5, 2011
Amendment	April 15, 2011
Amendment	April 29, 2011
Amendment	May 18, 2011
Amendment	May 20, 2011
Amendment	May 27, 2011
Amendment	June 3, 2011
Amendment	June 29, 2011
Amendment	July 7, 2011
Amendment	July 11, 2011
Amendment	Dec. 21, 2011

7. NAME AND ADDRESS OF APPLICANT:

Name: Insys Therapeutics, Inc
Address: 10220 South 51st Street
Suite 2
Phoenix, AZ 85044

Chemistry Review Data Sheet

8. Product Drug Code and Name:

- a) Proprietary Name: None
- b) Non-Proprietary Name (USAN): Fentanyl
- c) Code name/#(ONDQA only):
- d) Chem. Type/Submission Priority (ONDQA only):
 - Chem. Type: Type 3
 - Submission Priority: S

9. LEGAL BASIS FOR SUBMISSION: FD&C ACT 505(b)(2)

10. PHARMACOLOGICAL CATEGORY:

Treatment of break through pain in patients with malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain.

11. DOSAGE FORM: Sublingual Spray

12. STRENGTH/POTENCY: 100, 200, 400, 600 and 800mcg in (b) (4) of solution

13. ROUTE OF ADMINISTRATION: Sublingual

14. Rx/OTC DISPENSED: Rx OTC15. SPOTS (SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM):

SPOTS product – Form Completed

Not a SPOTS product

16. CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA, MOLECULAR WEIGHT:

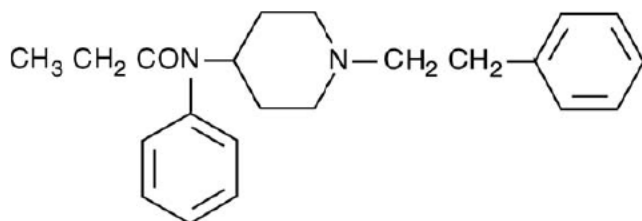
INN Name: Fentanyl

USAN name: Fentanyl [p]

IUPAC name: *N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl] propanamide

Molecular formula: C₂₂H₂₈N₂O

Relative molecular weight 336.47 (base):



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