

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

022272Orig1s027

CHEMISTRY REVIEW(S)

OFFICE OF LIFE CYCLE PRODUCTS
DPMA I, BRANCH I

Review of Chemistry, Manufacturing, and Controls

Clinical Review Division: Analgesic, Anesthesia and Addiction Products (HFD-510)

NDA#: 22-272	REVIEW#: 1	REVIEW DATE: 5/10/2015
SUBMISSION TYPE S-027 (Efficacy)	DOCUMENT DATE 12/10/2014	CDER DATE 12/10/2014
AMENDMENT 04/02/2015 05/06/2015	PDUFA GOAL 06/10/2015	ASSIGNED 05/08/2015

NAME & ADDRESS OF APPLICANT:

Purdue Pharma L.P.
201 Tresser Blvd
Stamford, CT 06901-3431

Beth Connelly, Associate Director, Regulatory Affairs
Phone: 203-588-7289
FAX: 203-588-6229

DRUG PRODUCT NAME

Proprietary: OxyContin® Tablets
Nonproprietary/USAN: oxycodone HCl extended release tablets

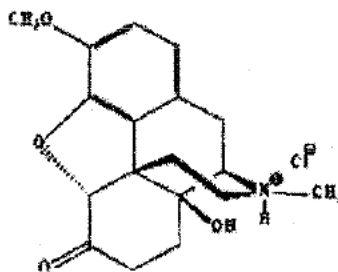
PHARMACOLOGICAL CATEGORY/INDICATION: Management of severe pain

DOSAGE FORM: Extended Release Tablet
STRENGTH: 10, 15, 20, 30, 40, 60 and 80 mg

ROUTE OF ADMINISTRATION: Oral
DISPENSED: Rx OTC
SPECIAL PRODUCTS: Yes No

**CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA,
MOL. WT:**

Chemical Name: 4,5-epoxy-14-hydroxy-3-methoxy-17-methylmorphinan-6-one hydrochloride
Molecular Formula: C₁₈H₂₁NO₄·HCl
Molecular Weight: 351.82



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OxyContin® Extended Release Tablets (10, 15, 20, 30, 40, 60 and 80 mg Oxycodone HCl)
Purdue Pharma L.P.

PROVIDES FOR: (1) Labeling changes based on the pediatric studies to fulfill the Pediatric Written Request #3, Amendment #2; [REDACTED] (b) (4)

REMARKS/COMMENTS:

In the supplement, the applicant submitted the Pediatric Study Reports to support the requested pediatric exclusivity. The supplement also provides for the labeling changes based on the clinical studies in accordance with the November 14, 2011 Written Request #3, Amendment #2.

The focus of this CMC review is [REDACTED]

(b) (4)

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(b) (4)

CONSULT REVIEWS: N/A

COMMENTS/REQUESTS TO BE CONVEYED TO APPLICANT: N/A

CONCLUSIONS & RECOMMENDATIONS:

Based on the information provided by the applicant, it appears that Purdue Pharma has made

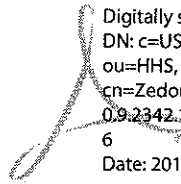
(b) (4)

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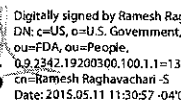
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Zedong Dong, Ph.D.
Quality Assessment Lead (Acting)

Ramesh
Raghavachari -S



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Ramesh Raghavachari, Ph.D.
Chief, Branch I

cc: Orig. NDA#22272
OLDP/DPMA I/RRAGHAVACHARI
OLDP/DPMA I/ZDONG

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