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RESEARCH**

APPLICATION NUMBER:
201655Orig1s000

CHEMISTRY REVIEW(S)

NDA 201655

**OPANA® ER (oxymorphone hydrochloride)
Extended Release Tablets**

Endo Pharmaceuticals Inc.

**Craig M. Bertha, Ph.D.
Office of New Drug Quality Assessment/Division III/Branch
VIII**

for

Division of Anesthetics and Analgesics Products

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Chemistry Review Data Sheet

1. NDA 201655
2. REVIEW #:3
3. REVIEW DATE: 18-JUL-2011
4. REVIEWER: Craig M. Bertha, Ph.D.

5. PREVIOUS DOCUMENTS:

<u>Document Date(s)</u>	<u>Previous Document</u>
07-JUL-2010	Original Submission
23-JUL-2010	Updated labeling
14-SEP-2010	Amendment (response to filing letter)
29-SEP-2010	Amendment (response to CMC DR letter)
01-OCT-2010	Amendment (stability data DP [REDACTED] (b) (4))
06-OCT-2010	Amendment (updated package insert labeling)

6. SUBMISSION(S) BEING REVIEWED:

<u>Document Date(s)</u>	<u>Submission(s) Reviewed</u>
13-JUN-2011	Amendment (response to complete response action letter; stability update; label/labeling update)

7. NAME & ADDRESS OF APPLICANT:

Name: Endo Pharmaceuticals Inc.
Address: 100 Endo Boulevard
Chadds Ford, PA 19317
Representative: Robert A. Barto, MBA, Vice President, Reg. Affairs



CHEMISTRY REVIEW



Chemistry Review Data Sheet

Telephone: 484-840-4262

8. DRUG PRODUCT NAME/CODE/TYPE:

- a) Proprietary Name: N/A
- b) Non-Proprietary Name (USAN): oxymorphone hydrochloride
- c) Code Name/# (ONDQA only): EN3288
- d) Chem. Type/Submission Priority (ONDQA only):
 - Chem. Type: 3
 - Submission Priority: P

9. LEGAL BASIS FOR SUBMISSION: 505(b)(1)

10. PHARMACOL. CATEGORY: analgesic; oxymorphone hydrochloride is a centrally acting opioid compound and is proposed for the relief of moderate to severe pain in patients requiring continuous opioid therapy for an extended period

11. DOSAGE FORM: extended release tablets

12. STRENGTH/POTENCY: 5, 7.5, 10, 15, 20, 30, 40 mg oxymorphone hydrochloride/tablet

13. ROUTE OF ADMINISTRATION: oral

14. Rx/OTC DISPENSED: Rx OTC

15. [SPOTS \(SPECIAL PRODUCTS ON-LINE TRACKING SYSTEM\)](#):

SPOTS product – Form Completed

Not a SPOTS product

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