

**CENTER FOR DRUG
EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

76-168

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO. 1
2. ANDA # 76-168
3. NAME AND ADDRESS OF APPLICANT
Teva Pharmaceuticals USA
Attention: Phillip Erickson R.Ph.
1090 Horsham Road
P.O. Box 1090
North Wales PA 19454
4. LEGAL BASIS FOR SUBMISSION
The reference listed drug is Oxycontin. The NDA holder is
Purdue Pharma L.P.
5. SUPPLEMENT(s) N/A
6. PROPRIETARY NAME
N/A
7. NONPROPRIETARY NAME
Oxycodone Hydrochloride
8. SUPPLEMENT PROVIDE FOR: N/A
9. AMENDMENTS AND OTHER DATES:
Orig. Submission May 8, 2001
New Correspondence July 3, 2001
Gratuitous Amendment
for New Strength July 25, 2001
10. PHARMACOLOGICAL CATEGORY
Analgesic
11. Rx or OTC
Rx
12. RELATED IND/NDA/DMF(s)

13. DOSAGE FORM
Extended release tablet
14. POTENCIES
80 mg
15. CHEMICAL NAME AND STRUCTURE
4,5-epoxy-14-hydroxy-3-methoxy-17-methylmorphinan-6-One-
hydrochloride
16. RECORDS AND REPORTS
N/A
17. COMMENTS
FIRST GENERIC.

18. CONCLUSIONS AND RECOMMENDATIONS

Not approvable; Major

19. REVIEWER:

A.Langowski

DATE COMPLETED:

09/04/01

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1. CHEMISTRY REVIEW NO. 2
2. ANDA 76-168
3. NAME AND ADDRESS OF APPLICANT
Teva Pharmaceuticals USA
Attention: Phillip Erickson R.Ph.
1090 Horsham Road
P.O. Box 1090
North Wales, PA 19454
4. LEGAL BASIS FOR SUBMISSION
The reference listed drug is Oxycontin. The NDA holder is
Purdue Pharma L.P.
5. SUPPLEMENT(s) N/A
6. PROPRIETARY NAME
N/A
7. NONPROPRIETARY NAME
Oxycodone Hydrochloride
8. SUPPLEMENT PROVIDE FOR: N/A
9. AMENDMENTS AND OTHER DATES:
Orig. Submission May 8, 2001
New Correspondence July 3, 2001
Gratuitous Amendment
for New Strength July 25, 2001
Amendment Jan 11, 2002
10. PHARMACOLOGICAL CATEGORY
Analgesic
11. Rx or OTC
Rx
12. RELATED IND/NDA/DMF(s)

13. DOSAGE FORM
Extended release tablet
14. POTENCIES
80 mg and 160 mg
15. CHEMICAL NAME AND STRUCTURE
4,5-epoxy-14-hydroxy-3-methoxy-17-methylmorphinan-6-One-
hydrochloride
16. RECORDS AND REPORTS
N/A
17. COMMENTS
FIRST GENERIC.

18. CONCLUSIONS AND RECOMMENDATIONS
Not approvable; pending Bio.

19. REVIEWER: DATE COMPLETED:
A.Langowski 02/13/02

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1. CHEMISTRY REVIEW NO. 3
2. ANDA 76-168
3. NAME AND ADDRESS OF APPLICANT
Teva Pharmaceuticals USA
Attention: Phillip Erickson R.Ph.
1090 Horsham Road
P.O. Box 1090
North Wales, PA 19454
4. LEGAL BASIS FOR SUBMISSION
The reference listed drug is Oxycontin. The NDA holder is
Purdue Pharma L.P.
5. SUPPLEMENT(s) N/A
6. PROPRIETARY NAME
N/A
7. NONPROPRIETARY NAME
Oxycodone Hydrochloride
8. SUPPLEMENT PROVIDE FOR: N/A
9. AMENDMENTS AND OTHER DATES:

Orig. Submission	May 08, 2001
New Correspondence	Jul 03, 2001
Gratuitous Amendment for New Strength	Jul 25, 2001
Amendment	Jan 11, 2002
Amendment	May 07, 2002
Amendment	Jun 25, 2002
Amendment	Dec 04, 2002
10. PHARMACOLOGICAL CATEGORY
Analgesic
11. Rx or OTC
Rx
12. RELATED IND/NDA/DMF(s)

13. DOSAGE FORM
Extended release tablet
14. POTENCIES
80 mg and 160 mg
15. CHEMICAL NAME AND STRUCTURE
4,5-epoxy-14-hydroxy-3-methoxy-17-methylmorphinan-6-One-
hydrochloride
16. RECORDS AND REPORTS
N/A

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1. CHEMISTRY REVIEW NO. 4
2. ANDA 76-168
3. NAME AND ADDRESS OF APPLICANT
Teva Pharmaceuticals USA
Attention: Phillip Erickson R.Ph.
1090 Horsham Road
P.O. Box 1090
North Wales, PA 19454
4. LEGAL BASIS FOR SUBMISSION
The reference listed drug is Oxycontin. The NDA holder is
Purdue Pharma L.P.
5. SUPPLEMENT(s) N/A
6. PROPRIETARY NAME
N/A
7. NONPROPRIETARY NAME
Oxycodone Hydrochloride
8. SUPPLEMENT PROVIDE FOR: N/A
9. AMENDMENTS AND OTHER DATES:

Orig. Submission	May 08, 2001
New Correspondence	Jul 03, 2001
Gratuitous Amendment for New Strength	Jul 25, 2001
Amendment	Jan 11, 2002
Amendment	May 07, 2002
Amendment	Jun 25, 2002
Amendment	Dec 04, 2002
Amendment	May 05, 2003
Amendment	July 2, 2003
10. PHARMACOLOGICAL CATEGORY
Analgesic
11. Rx or OTC
Rx
12. RELATED IND/NDA/DMF(s)

13. DOSAGE FORM
Extended release tablet
14. POTENCIES
80 mg
15. CHEMICAL NAME AND STRUCTURE
4,5-epoxy-14-hydroxy-3-methoxy-17-methylmorphinan-6-One-
hydrochloride

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1. CHEMISTRY REVIEW NO. 5
2. ANDA 76-168
3. NAME AND ADDRESS OF APPLICANT
Teva Pharmaceuticals USA
Attention: Phillip Erickson R.Ph.
1090 Horsham Road
P.O. Box 1090
North Wales, PA 19454
4. LEGAL BASIS FOR SUBMISSION
The reference listed drug is Oxycontin. The NDA holder is
Purdue Pharma L.P.
5. SUPPLEMENT(s) N/A
6. PROPRIETARY NAME
N/A
7. NONPROPRIETARY NAME
Oxycodone Hydrochloride
8. SUPPLEMENT PROVIDE FOR: N/A
9. AMENDMENTS AND OTHER DATES:

Orig. Submission	May 08, 2001
New Correspondence	Jul 03, 2001
Gratuitous Amendment for New Strength	Jul 25, 2001
Amendment	Jan 11, 2002
Amendment	May 07, 2002
Amendment	Jun 25, 2002
Amendment	Dec 04, 2002
Amendment	May 05, 2003
Amendment	July 2, 2003
Amendment (minor)	Dec 19, 2003
Amendment (tele)	Jan 16, 2004
10. PHARMACOLOGICAL CATEGORY
Analgesic
11. Rx or OTC
Rx
12. RELATED IND/NDA/DMF(s)
13. DOSAGE FORM
Extended release tablet
14. POTENCIES
80 mg

(u) 3-25-04

14

15. CHEMICAL NAME AND STRUCTURE
4,5-epoxy-14-hydroxy-3-methoxy-17-methylmorphinan-6-one-
hydrochloride
16. RECORDS AND REPORTS
N/A
17. COMMENTS
~~FIRST GENERIC~~ *uv*
18. CONCLUSIONS AND RECOMMENDATIONS
Approvable
19. REVIEWER: A.Langowski DATE COMPLETED: 01/08/04; 01/20/04

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