

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 74-754

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO 3
2. ANDA 74-754
3. NAME AND ADDRESS OF APPLICANT
Lemmon Company
Attention: Deborah A. Jaskot
650 Cathill Road
Sellersville, PA 18960
4. LEGAL BASIS FOR SUBMISSION
Toradol® (Syntex) NDAs 19645 (10 mg tablets) & 19698 (injection). Patent expires 05/16/97
5. SUPPLEMENT(s) N/A
6. PROPRIETARY NAME N/A
7. NONPROPRIETARY NAME Ketorolac Tromethamine Tablets, USP
8. SUPPLEMENT(s) PROVIDE(s) FOR: N/A
9. AMENDMENTS AND OTHER DATES: see next page

10. PHARMACOLOGICAL CATEGORY Nonsteroidal anti-inflammatory

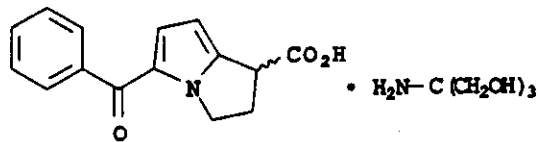
11. Rx or OTC
Rx

12. RELATED IND/NDA/DMF(s) see DMF checklist

13. DOSAGE FORM
Tablets

14. POTENCY
10 mg

15. CHEMICAL NAME AND STRUCTURE
(±)-5-Benzoyl-2,3-dihydro-1H-pyrrolizine-1-carboxylic acid, compound with 2-amino-2-(hydroxymethyl)-1,3-propanediol (1:1)



$C_{15}H_{13}NO_3 \cdot C_4H_{11}NO_3$

M.W. = 376.41 CAS [74103-07-4]

16. RECORDS AND REPORTS N/A

17. COMMENTS Tentative approval to full approval; firm reports no changes in the application since the tentative approval. Therefore this review document merely summarizes previous reviews.

18. CONCLUSIONS AND RECOMMENDATIONS
Recommend: **APPROVAL.**

19. REVIEWER: J. L. Smith DATE COMPLETED: 04/08/97
Endorsements: HFD-623/J.Smith/ Jc
HFD-623/V.Sayeed/4-

/S/

110/27.

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4/8/97

Chemistry Review
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Addendum to the Chemistry Review

ANDA 74-754

Lemmon

Ketorolac Tromethamine Tablets USP, 10 mg

Addendum Items:

1. New submissions since chemistry review:

Date: November 22, 1996
Type: New Correspondence. (Change in patent certification.)
Action: None. (Not a chemistry issue.)

Date: September 30, 1996
Type: Chemistry Amendment. (New contract lab to perform X-ray diffraction testing on the active drug substance.)
Action: EER was amended to include Oneida Research Services, Inc.

2. Labeling:

Pending at the time of the chemistry review. Labeling is now satisfactory (review dated 09/27/96).

3. Bio:

Pending at the time of the chemistry review. Bio is now satisfactory (review dated 07/19/96).

4. EER:

Still pending as of 12/02/96.

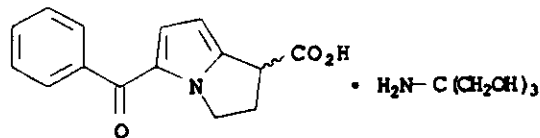
Reviewer: John Smith

Date of Addendum: December 2, 1996

1. CHEMISTRY REVIEW NO 2
2. ANDA 74-754
3. NAME AND ADDRESS OF APPLICANT
 Lemmon Company
 Attention: Deborah A. Jaskot
 650 Cathill Road
 Sellersville, PA 18960
6. PROPRIETARY NAME N/A
7. NONPROPRIETARY NAME Ketorolac Tromethamine Tablets, USP
10. PHARMACOLOGICAL CATEGORY Nonsteroidal anti-inflammatory
11. Rx or OTC
Rx

13. DOSAGE FORM Tablets
14. POTENCY 10 mg

15. CHEMICAL NAME AND STRUCTURE
 (±)-5-Benzoyl-2,3-dihydro-1H-pyrrolizine-1-carboxylic acid, compound with 2-amino-2-(hydroxymethyl)-1,3-propanediol (1:1)



$C_{15}H_{13}NO_3 \cdot C_4H_{11}NO_3$

M.W. = 376.41 CAS [74103-07-4]

18. CONCLUSIONS AND RECOMMENDATIONS
 Recommend: APPROVAL (Tentative).

19. REVIEWER: J. L. Smith DATE COMPLETED: 06/28/96

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6/28/98

Chemistry Review
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1. CHEMISTRY REVIEW NO 1

2. ANDA 74-754

3. NAME AND ADDRESS OF APPLICANT

Lemmon Company
Attention: Deborah A. Jaskot
650 Cathill Road
Sellersville, PA 18960

6. PROPRIETARY NAME N/A

7. NONPROPRIETARY NAME Ketorolac Tromethamine Tablets, USP

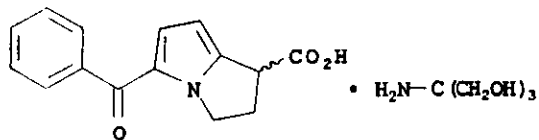
10. PHARMACOLOGICAL CATEGORY
Nonsteroidal anti-inflammatory

11. RX or OTC
Rx

13. DOSAGE FORM
Tablets

14. POTENCY
10 mg

15. CHEMICAL NAME AND STRUCTURE
(±)-5-Benzoyl-2,3-dihydro-1H-
pyrrolizine-1-carboxylic acid,
compound with 2-amino-2-
(hydroxymethyl)-1,3-propane-
diol (1:1)



C₁₅H₁₃NO₃ · C₄H₁₁NO₃

M.W. = 376.41

CAS [74103-07-4]

18. CONCLUSIONS AND RECOMMENDATIONS

Recommend: NOT APPROVABLE. Minor Amendment.

19. REVIEWER: J. L. Smith

DATE COMPLETED: 01/30/96

Page (s)

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Chemistry

1/30/96

Review # 1