

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 75-100

CHEMISTRY REVIEW(S)

SEP 22 1998

38. Chemistry Comments to be Provided to the Applicant

ANDA: 75-100 APPLICANT: Lek Pharmaceutical and Chemical Co. d.d.

DRUG PRODUCT: Bromocriptine Mesylate Capsules USP, 5 mg

The deficiencies presented below represent Facsimile deficiencies.

Rashmikant M. Patel, Ph.D.  
Director  
Division of Chemistry I  
Office of Generic Drugs  
Center for Drug Evaluation and Research

1. CHEMISTRY REVIEW NO. 3

2. ANDA # 75-100

3. NAME AND ADDRESS OF APPLICANT

Lek Pharmaceutical and Chemical Co.  
Verovškova 57  
1526 Ljubljana, Slovenia

U.S. Representative:

Lek USA, Inc  
Englewood Cliffs, NJ 07632

4. LEGAL BASIS FOR SUBMISSION

505(j)(2)(a).

5. SUPPLEMENT(s)

N/A

6. PROPRIETARY NAME

N/A

7. NONPROPRIETARY NAME

Bromocriptine Mesylate  
Capsules U.S.P., 5 mg

8. SUPPLEMENT(s) PROVIDE(s) FOR:

N/A

9. AMENDMENTS AND OTHER DATES:

DOS 3/25/97; RTF Letter 5/8/97; Amend 5/12/97; Acceptance Letter for 3/25/97, 5/27/97; Memo 5/21/97; NA (Major) 9/25/97; Amend (Major) 4/9/98; Label review 5/21/98; NA (FAX) 9/22/98. \*Amend (FAX) 10/20/98; Label review 11/4/98.

10. PHARMACOLOGICAL CATEGORY

1. Hyperprolactinemia  
2. Acromegaly  
3. Parkinson's Disease

11. Rx or OTC

Rx

12. RELATED IND/NDA/DMF(s)

17-962 - Sandoz's Parlodel® Capsules 5 mg.  
- Lek's Bromocriptine Mesylate U.S.P.  
ANDA 74-631 - Lek's 2.5 mg Bromocriptine Mesylate Tablets USP  
was Approved 1/13/98.

13. DOSAGE FORM

Opaque Pink Capsules,  
Imprinted "BCT 5" on both  
cap and body

14. POTENCY

5 mg as Bromocriptine (base).

15. CHEMICAL NAME AND STRUCTURE

Not found in CDER's formula files. See U.S.P. 23 monograph, pages 217-218.

16. RECORDS AND REPORTS

N/A

17. COMMENTS

No chemistry deficiencies remain.

Labeling approved with revisions needed post-approval, 11/4/98.

Bioequivalence data found adequate on 12/97.

EER still pending.

18. CONCLUSIONS AND RECOMMENDATIONS

Approve ANDA 75-100 pending acceptable EER.

19. REVIEWER:

DATE COMPLETED:

Stephen Sherken

11/5/98

cc: ANDA 75-100

Endorsements:

**/S/**

RV3

Page(s) 2

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releasable.

Chemistry Review # 3

#20-#37

1. CHEMISTRY REVIEW NO. 2

2. ANDA # 75-100

3. NAME AND ADDRESS OF APPLICANT

Lek Pharmaceutical and Chemical Co.  
Verovškova 57  
1526 Ljubljana, Slovenia

U.S. Representative:

Lek USA, Inc  
Englewood Cliffs, NJ 07632

4. LEGAL BASIS FOR SUBMISSION

505(j)(2)(a).

5. SUPPLEMENT(s)

N/A

6. PROPRIETARY NAME

N/A

7. NONPROPRIETARY NAME

Bromocriptine Mesylate  
Capsules U.S.P., 5 mg

8. SUPPLEMENT(s) PROVIDE(s) FOR:

N/A

9. AMENDMENTS AND OTHER DATES:

DOS 3/25/97; RTF Letter 5/8/97; Amend 5/15/97; Acceptance Letter  
for 3/25/97, 5/27/97; Memo 5/21/97; NA (Major) 9/25/97; Amend  
(Major) 4/9/98; Label review 5/21/98.

10. PHARMACOLOGICAL CATEGORY

1. Hyperprolactinemia  
2. Acromegaly  
3. Parkinson's Disease

11. Rx or OTC

Rx

12. RELATED IND/NDA/DMF(s)

17-962 - Sandoz's Parlodel® Capsules 5 mg.  
- Lek's Bromocriptine Mesylate U.S.P.  
ANDA 74-631 - Lek's 2.5 mg Bromocriptine Mesylate Tablets USP  
was Approved 1/13/98.

13. DOSAGE FORM

Opaque Pink Capsules,  
Imprinted "BCT 5" on both  
cap and body

14. POTENCY

5 mg as Bromocriptine (base).

15. CHEMICAL NAME AND STRUCTURE

Not found in CDER's formula files. See U.S.P. 23 monograph, pages  
217-218.

16. RECORDS AND REPORTS

N/A

17. COMMENTS

Facsimile chemistry deficiencies remain.

Labeling deficiencies remain.

Bioequivalence data found adequate on 12/97.

EER still pending.

18. CONCLUSIONS AND RECOMMENDATIONS

Send Facsimile fax to Lek. Include labeling deficiencies.

19. REVIEWER:DATE COMPLETED:

Stephen Sherken

August 17, 1998

Page (s) 12

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releasable.

*Chemistry Review #2*

*#20 - #38*



CHEMISTRY REVIEW NO. 1

2. ANDA # 75-100

3. NAME AND ADDRESS OF APPLICANT

Lek Pharmaceutical and Chemical Co.  
Verovškova 57  
1526 Ljubljana, Slovenia

U.S. Representative:

Lek USA, Inc  
Englewood Cliffs, NJ 07632

4. LEGAL BASIS FOR SUBMISSION

505(j)(2)(a), same as Sandsoz's Parlodel® Capsules 5 mg.

5. SUPPLEMENT(s)

N/A

6. PROPRIETARY NAME

N/A

7. NONPROPRIETARY NAME

Bromocriptine Mesylate  
Capsules U.S.P. 5 mg

8. SUPPLEMENT(s) PROVIDE(s) FOR:

N/A

9. AMENDMENTS AND OTHER DATES:

DOS 3/25/97; RTF Letter 5/8/97; Amend 5/15/97; Acceptance Letter  
5/27/97; Memo 5/21/97.

10. PHARMACOLOGICAL CATEGORY

1. Hyperprolactinemia
2. Acromegaly
3. Parkinson's Disease

11. Rx or OTC

Rx

12. RELATED IND/NDA/DMF(s)

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- Lek's Bromocriptine Mesylate U.S.P.

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14. POTENCY

5 mg as Bromocriptine (base).

15. CHEMICAL NAME AND STRUCTURE

Not found in CDER's formula files. See U.S.P. 23 monograph, pages  
217-218.

16. RECORDS AND REPORTS

N/A

17. COMMENTS

18. CONCLUSIONS AND RECOMMENDATIONS

19. REVIEWER:

DATE COMPLETED:

Stephen Sherken

9/15/97

Page (s) 22

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*Security Review #1*

*#20 - #30*