

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

ANDA 76-243

CHEMISTRY REVIEW(S)

1. CHEMISTRY REVIEW NO. 1

2. ANDA # 76-243

3. NAME AND ADDRESS OF APPLICANT

Westward Pharmaceutical Corporation
Attn: Elizabeth A. Marro
435/465 Industrial Way West
Eatontown, NJ 07724

4. LEGAL BASIS FOR SUBMISSION

Reference Listed Drug product: Now it is: Lithium Carbonate Capsules, USP, 600 mg manufactured by Roxanne approved in NDA #17-812. (It was previously Eskalith Capsules by SKB, but it has since changed).

The firm filed a Paragraph I certification indicating that there are no patents or exclusivities according to the Orange Book.

5. SUPPLEMENT(s) N/A

6. PROPRIETARY NAME

Lithium Carbonate Capsules, USP

7. NONPROPRIETARY NAME

NA

8. SUPPLEMENT(s) PROVIDE(s) FOR: N/A

9. AMENDMENTS AND OTHER DATES:

Original submission: 9-24-01
Accepted for Filing: 9-25-01
T-con: 2-27-02
Telephone amendment: 2/28/02

10. PHARMACOLOGICAL CATEGORY

Antimanic

11. Rx or OTC

Rx

12. RELATED IND/NDA/DMF(s)

DMF
DMF
DMF
DMF
DMF
DMF
DMF
DMF
DMF
DMF



13. DOSAGE FORM

Capsule

14. POTENCY

300 mg

15. CHEMICAL NAME AND STRUCTURE

Lithium Carbonate

Li₂CO₃ MW 73.89

16. RECORDS AND REPORTS

NA

17. COMMENTS

All chemistry deficiencies have been resolved satisfactorily by telephone.

Bioequivalence is pending.

Labeling is pending.

EER was submitted.

Methods validation is not needed. USP product.

DMF # — is adequate.

18. CONCLUSIONS AND RECOMMENDATIONS

The application is approvable.

19. REVIEWER:

Karen A. Bernard, Ph.D.

DATE COMPLETED:

3-5-02

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ON ORIGINAL**

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commercial

information

38. Chemistry Comments to be Provided to the Applicant

ANDA: 76-243

APPLICANT: Westward Pharmaceutical
Corporation

DRUG PRODUCT: Lithium Carbonate Capsule USP, 300 mg

The deficiencies presented below represent MINOR deficiencies.

Deficiencies:

1. The Division of Chemistry has no further questions at this time. However, Labeling deficiencies were sent to you on March 4, 2002 and have not been responded. Please provide a response to the labeling deficiencies. Your bioequivalence information is pending review. Deficiencies, if any, will be communicated separately.

Sincerely yours,

Florence Fang
Acting Director
Division of Chemistry II
Office of Generic Drugs
Center for Drug Evaluation and Research

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1. CHEMISTRY REVIEW NO. 2

2. ANDA # 76-243

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Westward Pharmaceutical Corporation
Attn: Elizabeth A. Marro
435/465 industrial Way West
Eatontown, NJ 07724

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cc: ANDA 76-243
DIV FILE
Field Copy

Endorsements:

HFD-640 /KBernard/3/5/02 *KBernard 6/24/02*
HFD-645/BArnwine/6/19/02 *(B⁷) Arnwine 6/25/02*
HFD-617/NPark/6/18/02 *Man 6/24/02*

F/T by: rad6/20/02

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APPROVE

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