

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

75-237

CHEMISTRY REVIEW(S)



Food and Drug Administration
Center for Drug Evaluation and Research
Office of Generic Drugs
Chemistry Division II - Branch VIII
Abbreviated New Drug Application Review

- ✓ 1. **CHEMISTRY REVIEW NO 4**
2. **ANDA # 75-237**
3. **NAME AND ADDRESS OF APPLICANT**
GENPHARM INC.
Attention: Tirtho Uppal
37 Advance Road
Etobicoke, Ontario
Canada
4. **LEGAL BASIS FOR SUBMISSION**
The listed drug is BETAPACE® Tablets, 80 mg, 160, mg and 240 mg of Berlex Laboratories. The applicant certified that in their opinion and to the best of their knowledge patent information has not been filed with the FDA. The exclusivity for BETAPACE® Tablets expires October 30, 1999 and the applicant states that to the best of their knowledge no extension has been registered.
The applicant states that the drug product will not be made available for sale until the expiration of Orphan Drug Exclusivity on October 30, 1999.

See pp. 22 and 24 for patent and exclusivity statements.
5. **SUPPLEMENT (s): N/A**
6. **PROPRIETARY NAME: N/A**
7. **NONPROPRIETARY NAME: Sotalol Tablets**
8. **SUPPLEMENT (s) PROVIDE FOR: N/A**

9. AMENDMENTS AND OTHER DATES:

Firm:

Original	October 30, 1997
Amendment	October 21, 1998
Fax Amendment	July 14, 1999
Amendment	8/23/1999
Labeling Amendment	9/13/1999
Telephone Amendment	10/08/1999
Minor Amendment	
for the final approval	02/29/2000
	Subject of this review

FDA:

Telecon:	November 19, 1997
Acknowledgement:	November 26, 1997
Deficiency letter:	August 7, 1998
Deficiency letter:	June 14, 1999
Telecon:	July 1, 1999
Labeling Approval:	September 15, 1999
Telecon:	October 7, 1999
Approval letter:	October 21, 1999

10. PHARMACOLOGICAL CATEGORY:

Antiarrhythmic

11. Rx or OTC

Rx

12. RELATED IND/NDA/DMF(s)

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13. **DOSAGE FORM**

Tablets

14. **POTENCIES:**

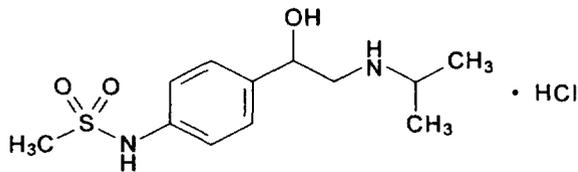
80 mg, 120 mg

160 mg and 240 mg

15: **CHEMICAL NAME AND
STRUCTURE**

Sotalol Hydrochloride. Methanesulfonamide, N-[4-[1-hydroxy-2-[(1-methylethyl)amino]ethyl]phenyl]-, monohydrochloride.

$C_{12}H_{20}N_2O_3S \cdot HCl$. 308.82. 959-24-0. Anti-adrenergic (beta-receptor).



16. **RECORDS AND REPORTS:** N/A

17. **COMMENTS:**

This amendment provides for the changes made in the conditions under which the drug product was tentatively approved. These changes include the raw material specifications of all the excipients as follows:

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- 1



Finished product In-House method for related substances by
has been submitted on page 45 and it is satisfactory.
Technical information, on packaging components were
acceptable.

18. CONCLUSIONS AND RECOMMENDATIONS:

This Application is acceptable for final approval.

19. REVIEWER:

Mouna P. Selvam, Ph.D.,

DATE COMPLETED:

03/29/2000

1. CHEMISTRY REVIEW NO. 1

2. ANDA # 75-237

3. NAME AND ADDRESS OF APPLICANT

GENPHARM INC.
37 Advance Road
Etobicoke, Ontario
Canada

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5. SUPPLEMENT(s): N/A

6. PROPRIETARY NAME: N/A

7. NONPROPRIETARY NAME: Sotalol Tablets

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

9. AMENDMENTS AND OTHER DATES:

Firm:

Submitted: October 30, 1997

FDA:

Telecon: November 19, 1997

Acknowledgement: November 26, 1997

10. PHARMACOLOGICAL CATEGORY

Antiarrhythmic

11. Rx or OTC

Rx

12. RELATED IND/NDA/DMF(s)

... (Tablets - Caps)

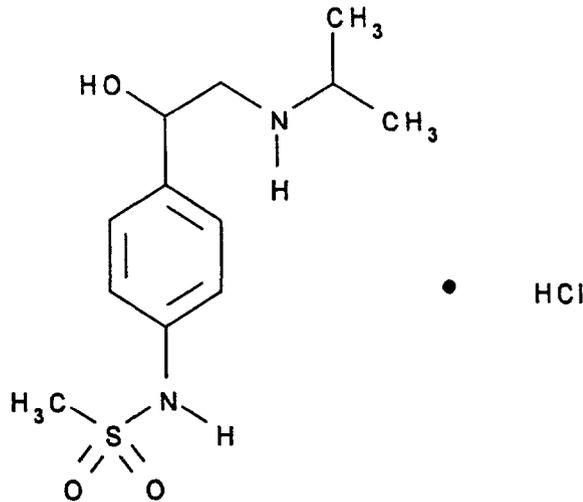
13. DOSAGE FORM

Tablets

14. POTENCIES: 80 mg, 160 mg and 240 mg

15: CHEMICAL NAME AND STRUCTURE

Sotalol
 $C_{12}H_{20}N_2O_3S \cdot HCl$;



Hydrochloride
 M.W. = 308.82

4'-[1-Hydroxy-2-(isopropylamino)ethyl]methanesulfonanilide
 monohydrochloride. CAS [959-24-0]

16. RECORDS AND REPORTS: N/A

17. COMMENTS

- a. The ANDA contains CMC deficiencies.
- b. The bio review is pending.

- c. Methods validation is deferred until the issues noted in item 28 are resolved and the Div. Of Bioequivalence accepts the dissolution method and specification.
- d. The label review is pending as of 4/13/98.
- e. The EIR for Genpharm is pending as of 4/9/98.

18. CONCLUSIONS AND RECOMMENDATIONS

This ANDA is NOT APPROVABLE. The amendment will be MAJOR.

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| 19. | <u>REVIEWER:</u> | <u>DATE COMPLETED:</u> |
| | Donald Shostak | April 13, 1998 |

Page(s)

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Contain Trade Secret,
Commercial/Confidential
Information and are not
releasable.

Chem Rev 1

4/13/98