

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
75-429

CORRESPONDENCE



Deborah A. Jaskot
Sr. Director, Regulatory Affairs

Corporate Headquarters:
TEVA PHARMACEUTICALS USA
650 Cathill Road, Sellersville, PA 18960

Corresponding Address:
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Phone: (215) 256-8400
FAX: (215) 721-9669

Toll Free: (888) TEVA USA
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FAX: (215) 256-7855

January 31, 2000

ORIG AMENDMENT

NJ Am

Douglas Sporn, Director
Office of Generic Drugs
Food and Drug Administration
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, Maryland 20855-2773

90 DAY AMENDMENT

ANDA #75-429
SOTALOL HYDROCHLORIDE TABLETS, 80 mg, 120 mg, 160 mg and 240 mg
90 DAY AMENDMENT

Dear Mr. Sporn:

We submit herewith a 90 Day Amendment to the above referenced tentatively approved ANDA in accord with your tentative approval letter of November 16, 1999.

At this time we have no updates for this pending ANDA.

This information is submitted for your review and final approval of this application. If there are any further questions, please do not hesitate to contact me at (215) 256-8400 ext. 5249 or via facsimile at (215) 256-8105.

Sincerely,

Deborah Jaskot/PE

DAJ/mea
Enclosures



DW
2-3-00



Deborah A. Jaskot
Sr. Director, Regulatory Affairs

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NEW CORRESP
NC to
Fax

October 20, 1999

Douglas Sporn, Director
Office of Generic Drugs
Food and Drug Administration
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, Maryland 20855-2773

FACSIMILE AMENDMENT

ANDA # 75-429
SOTALOL HYDROCHLORIDE TABLETS, 80 mg, 120 mg, 160 mg and 240 mg
FACSIMILE AMENDMENT - RESPONSE TO REVIEW LETTER DATED OCTOBER 4, 1999

Dear Mr. Sporn:

We submit herewith a Facsimile Amendment to the above referenced pending ANDA in response to your letter of October 4, 1999. The deficiencies in the aforementioned letter are addressed in the order in which they were presented.

A. Chemistry, Manufacturing and Controls

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B. Notes and Acknowledgments

We acknowledge that we received a facsimile dated August 31, 1999 requesting changes to our package insert. We made the requested changes and submitted the final printed product insert in our labeling amendment on September 17, 1999.

The information provided herein represents, in our opinion, a complete response to your letter of October 4, 1999 and is submitted towards the review and final approval of this tentatively approved ANDA. If any additional information or clarification is needed, please do not hesitate to contact me at (215) 256-8400 ext. 5249 or by facsimile at (215) 256-8105.

Sincerely,



DAJ/mea
Enclosures

38. Chemistry Comments to be Provided to the Applicant

ANDA: 75-429

APPLICANT: Teva Pharmaceuticals USA

DRUG PRODUCT: Sotalol Hydrochloride Tablets, 80 mg, 120 mg, 160 mg and 240 mg.

The deficiencies presented below represent Facsimile deficiencies.

A. Chemistry Deficiencies:

Regarding method validation:

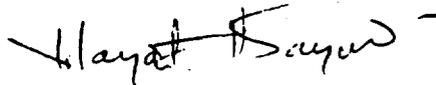
The following analyst's comments concerning the drug substance identification, the impurity testing, and the assay procedure should be addressed prior to approval:

1. The method for the Drug Substance specifies to follow the procedures in the Appendixes for the Identification, , Related Substances and Assay. These Appendixes are not copies of the British Pharmacopoeia. The method should specify that these appendixes are part of the British Pharmacopoeia.
2. The procedure for related substances also prepares solution #2 by diluting solution #1 by 1 to This would result in concentration of and the method uses this to determine the quantitation limit. The method refers to this solution as which is different than the actual In the calculation of the impurities it assumes a sample dilution of The method does not specify a set dilution. For the secondary impurities calculation this does not matter since it cancels out but in the Impurity III calculation the actual dilution used should be in the calculation. If a different dilution was used the formula would be wrong. The related substances procedure should also indicate a run time. This is to know how long to run the chromatogram to see all the impurities which may come out after the active ingredient.
2. The assay procedure uses a solution, however, it does not state the concentration to use. The copy of the British Pharmacopoeia did not include this either. This should be specified in the procedure.

B. In addition to responding to the deficiencies presented above, please note and acknowledge the following comments in your response:

Please note that final labeling update is also requested on 8-31-99 and pending for review.

Sincerely yours,



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



Deborah A. Jaskot
Sr. Director, Regulatory Affairs

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*AM noted
to me reviewer
for review
Deborah
8/10/99*

August 2, 1999

MINOR AMENDMENT

AM
90 DAY AMENDMENT

Douglas Sporn, Director
Office of Generic Drugs
Food and Drug Administration
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, Maryland 20855-2773

ANDA # 75-429
SOTALOL HYDROCHLORIDE TABLETS, 80 mg, 120 mg, 160 mg and 240 mg
90 DAY AMENDMENT

Dear Mr. Sporn:

We submit herewith a 90 Day Amendment to the above referenced tentatively approved ANDA in accord with your tentative approval letter of July 20, 1999.

At this time we have no updates for this pending ANDA.

This information is submitted for your review and final approval of this application. If there are any further questions, please do not hesitate to contact me at (215) 256-8400 ext. 5249 or via facsimile at (215) 256-8105.

Sincerely,

Deborah Jaskot
DAJ/mea
Enclosures



*Madame
8-4-99*



Deborah A. Jaskot
Sr. Director, Regulatory Affairs

Corporate Headquarters:
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July 6, 1999

Douglas Sporn, Director
Office of Generic Drugs
Food and Drug Administration
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, Maryland 20855-2773

TELEPHONE AMENDMENT

ANDA # 75-429

SOTALOL HYDROCHLORIDE TABLETS, 80 mg, 120 mg, 160 mg and 240 mg
TELEPHONE AMENDMENT - RESPONSE TO TELEPHONE CONVERSATION ON 6/25/99

Dear Mr. Sporn:

We submit herewith a Telephone Amendment to the above referenced pending ANDA in response to a telephone conversation between Dr. Ubrani Venkataram of your office and Deborah Jaskot of TEVA Pharmaceuticals USA on June 25, 1999. Dr. Venkataram requested that we revise the drug substance specification for total impurities to include the known impurity.

We have adopted the requested specification and the revised analytical method for the drug substance is provided as Attachment 1. A revised blank Certificate of Analysis indicating the revision is also contained herein as Attachment 2.

Additionally, Dr. Venkataram requested a modification to our stability commitment to include specifically that expiration dating extensions require the submission of stability data from three production batches.

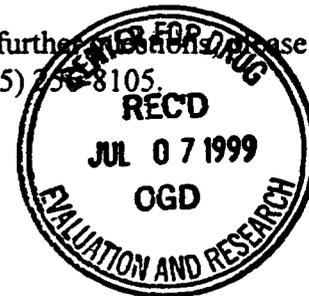
We have revised our stability commitment accordingly and it is provided as Attachment 3.

This information is submitted for your review and approval. If there are any further questions, please do not hesitate to contact me at (215) 256-8400 ext. 5249 or via facsimile at (215) 256-8105.

Sincerely,

Deborah Jaskot
DAJ/mea

Enclosures





Deborah A. Jaskot
Sr. Director, Regulatory Affairs

Corporate Headquarters:

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May 28, 1999

Douglas Sporn, Director
Office of Generic Drugs
Food and Drug Administration
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, Maryland 20855-2773

TELEPHONE AMENDMENT

ORIG AMENDMENT

FA

ANDA # 75-429

SOTALOL HYDROCHLORIDE TABLETS, 80 mg, 120 mg, 160 mg and 240 mg
TELEPHONE AMENDMENT - RESPONSE TO TELEPHONE CONVERSATION ON 5/14/99

Dear Mr. Sporn:

We submit herewith a Telephone Amendment to the above referenced pending ANDA in response to a telephone conversation between Mr. Tim Ames of your office and Philip Erickson of TEVA Pharmaceuticals USA on May 14, 1999. Mr. Ames requested that we revise the blend uniformity specification which appears on page 49 of our Facsimile Amendment dated April 22, 1999. Specifically, he requested that we change our specification of Individual), RSD

We have adopted the requested specification and revised the summary of drug product specifications page. The final blend specification pages for each strength are also contained herein.

This information is submitted for your review and approval. If there are any further questions, please do not hesitate to contact me at (215) 256-8400 ext. 5249 or via facsimile at (215) 256-8105.

Sincerely,

DAJ/mea
Enclosures





Deborah A. Jaskot
Sr. Director, Regulatory Affairs

Corporate Headquarters:
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*4/30/99 Reviewer, the
① 130 labels
② FA noted to CMC
Reviewer for review.
JLS PM*

April 22, 1999

Douglas Sporn, Director
Office of Generic Drugs
Food and Drug Administration
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, Maryland 20855-2773

FACSIMILE AMENDMENT

ANDA # 75-429
SOTALOL HYDROCHLORIDE TABLETS, 80 mg, 120 mg, 160 mg and 240 mg
FACSIMILE AMENDMENT - RESPONSE TO REVIEW LETTER DATED 3/22/99

Dear Mr. Sporn:

We submit herewith a Facsimile Amendment to the above referenced pending ANDA in response to your letter of March 22, 1999. The deficiencies in the aforementioned letter are addressed in the order in which they were presented.

I. Chemistry, Manufacturing and Controls

A. Deficiencies

1. a.

*s
f
#*

*Blc 11
sample*

Page(s) _____

Contain Trade Secret,

Commercial/Confidential

Information and are not
releasable.

4/22/99

d.

B. Notes and Acknowledgments

1. We note that, since our methods for the drug substance and drug product are non-USP, methods validation will be performed by an FDA laboratory.
2. We recognize that a change in bottle resin is permissible under 314.70 (d)(6), however, based on previous deficiency comments received when the bottle/cap resin had been or was soon to be discontinued and the alternate resin was not specified, we chose to include this information at the time of ANDA submission.

II. Labeling

Final printed labels, insert, and a side-by-side comparison of our proposed insert with that submitted in our original ANDA which incorporate revisions from deficiency comments are enclosed in Attachment 6.

With regard to comment 1., please note that different colors are used on the container labels for the different strengths in order to easily differentiate them.

Regarding comment 2.e., based on TEVA Pharmaceuticals USA format and recently approved labeling, "Rx only" has not been included in our insert.

The information provided herein represents, in our opinion, a complete response to your letter of March 22, 1999 and is submitted towards the review and approval of this pending ANDA. If any additional information or clarification is needed, please do not hesitate to contact me at (215) 256-8400 ext. 5249 or by facsimile at (215) 256-8105.

Sincerely,



DAJ/mea
Enclosures



Deborah A. Jaskot
Sr. Director, Regulatory Affairs

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July 31, 1998

Douglas Sporn, Director
Office of Generic Drugs
Food and Drug Administration
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

5050322a OK
(S) 8/20/98
Gregory S. Smith

ORIGINAL ABBREVIATED NEW DRUG APPLICATION
SOTALOL HYDROCHLORIDE TABLETS, 80 mg, 120 mg, 160 mg, and 240 mg

Dear Mr. Sporn:

We submit herewith an abbreviated new drug application for the drug product Sotalol Hydrochloride Tablets, 80 mg, 120 mg, 160 mg, and 240 mg.

Enclosed are archival and review copies assembled in accord with Office of Generic Drugs April 1997 Guidance for Industry: Organization of an Abbreviated New Drug Application and an Abbreviated Antibiotic Application. These copies are presented in a total of 19 volumes; 9 for the archival copy and 10 for the review copy.

The application contains a full report of two *in vivo* bioequivalence studies. These studies compared Sotalol Hydrochloride Tablets, 160 mg manufactured by TEVA Pharmaceuticals USA to the reference listed drug, BETAPACE[®], 160 mg under both fasting and post-prandial conditions.

Also contained herein, is a letter to your office concerning the change in bioequivalence requirements including a chronology of correspondence and key milestones in TEVA Pharmaceutical USA's development path. Telephone conversations between representatives of Office of Generic Drugs and representatives of TEVA Pharmaceuticals USA confirm the Office of Generic Drugs' agreement to accept the application for filing based on the performance of bioequivalence studies on the 160 mg strength.

RECEIVED

AUG 03 1998

GENERIC DRUGS

Two separately bound copies of the finished product and bulk drug analytical methodology and validation data are included in accord with 21 CFR 314.50(e)(2)(i).

We look forward to your review and comment.

Sincerely,



DAJ/mea
Enclosures

38. Chemistry Comments to be Provided to the Applicant

ANDA: 75-429

APPLICANT: TEVA Pharmaceutical, USA

DRUG PRODUCT: Sotalol Hydrochloride Tablets, 80 mg, 120 mg, 160 mg and 240 mg

The deficiencies presented below represent FACSIMILE deficiencies.

A. Chemistry Deficiencies:

1. In regard to the drug substance, we have the following comments:
 - a. Please describe any additional characterization tests performed on the material used as a reference standard for Sotalol Hydrochloride, which would further establish its suitability for use as a reference standard.
 - b. Please submit copies of all British Pharmacopeia methods used for the drug substance.
 - c. Please submit additional identification test besides the IR for drug substance.

2. In regard to the chemistry, manufacturing process and controls procedures, we have the following comments:
 - a. ... number "1060" for 120 mg.
 - b.
 - c. ... could
 - d.

- B. In addition to responding to the deficiencies presented above, please note and acknowledge the following comments in your response:
1. Since Sotalol Hydrochloride drug substance and Sotalol Hydrochloride Tablets are non-USP, methods validation will be performed by an FDA laboratory.
 2. Please note the provisions in 21 CFR 314.70(d)(6) regarding proposed packaging for which stability data is not available at present.

Sincerely yours,



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

BIOEQUIVALENCY COMMENTS TO BE PROVIDED TO THE APPLICANT

ANDA: 75-429

APPLICANT: Teva Pharmaceuticals

DRUG PRODUCT: Sotalol HCl Tablets
240 mg, 160 mg, 120 mg, 80 mg

The Division of Bioequivalence has completed its review and has no further questions at this time.

The following dissolution testing will need to be incorporated into your stability and quality control programs:

The dissolution testing should be conducted in 900 mL of water at 37° C using USP Apparatus (2) at 50 rpm. Based on the data submitted, the Agency recommends that the test product should meet the following specifications:

NLT 80% of the labeled amount of the drug in the dosage form in 30 minutes

Please note that the bioequivalency comments provided in this communication are preliminary. These comments are subject to revision after review of the entire application, upon consideration of the chemistry, manufacturing and controls, microbiology, labeling, or other scientific or regulatory issues. Please be advised that these reviews may result in the need for additional bioequivalency information and/or studies, or may result in a conclusion that the proposed formulation is not approvable.

Sincerely yours,



Dale P. Conner, Pharm. D.

Director

Division of Bioequivalence

Office of Generic Drugs

Center for Drug Evaluation and Research

2. The *in vivo* bioequivalence study conducted under non-fasting conditions by Teva Pharmaceuticals on its sotalol HCl tablets, 160 mg, lot # K-22947, comparing it to Berlex Laboratories' Betapace® tablets, 160 mg, lot # W70050, is acceptable.
3. The *in vitro* dissolution testing submitted by the firm on its sotalol HCl tablets (240 mg, 160 mg, 120 mg, 80 mg) is acceptable.
4. The waiver of requirements for *in vivo* bioequivalence testing on the 80 mg, 120 mg and 240 mg strengths can be granted per 21 CFR 320.22 (d) (2).
5. The dissolution testing should be incorporated into the firm's manufacturing controls and stability program. The dissolution should be conducted in 900 mL of water at 37° C using USP apparatus 2 (paddle) at 50 rpm. The test product should meet the following specifications:

Not less than () of the labeled amount of sotalol in the dosage form is dissolved in 30 minutes

Jahnavi S. Kharidia
 Jahnavi S. Kharidia, Ph.D.
 Review Branch III
 The Division of Bioequivalence

RD INITIALED BDAVIT
 FT INITIALED BDAVIT

BND 11/4/98
Barbara M Davis

Date 11/5/98

Concur: Dale P. Conner Date 11/5/98
 Dale P. Conner, Pharm.D.
 Director
 Division of Bioequivalence

cc:

FIGURE 1— . PLASMA sotalol LEVELS

3010 0 TABLETS, 160 MG, ANDA #75-429
UNDER FAST-VC COND.ONS
DOSE= X 160 MG

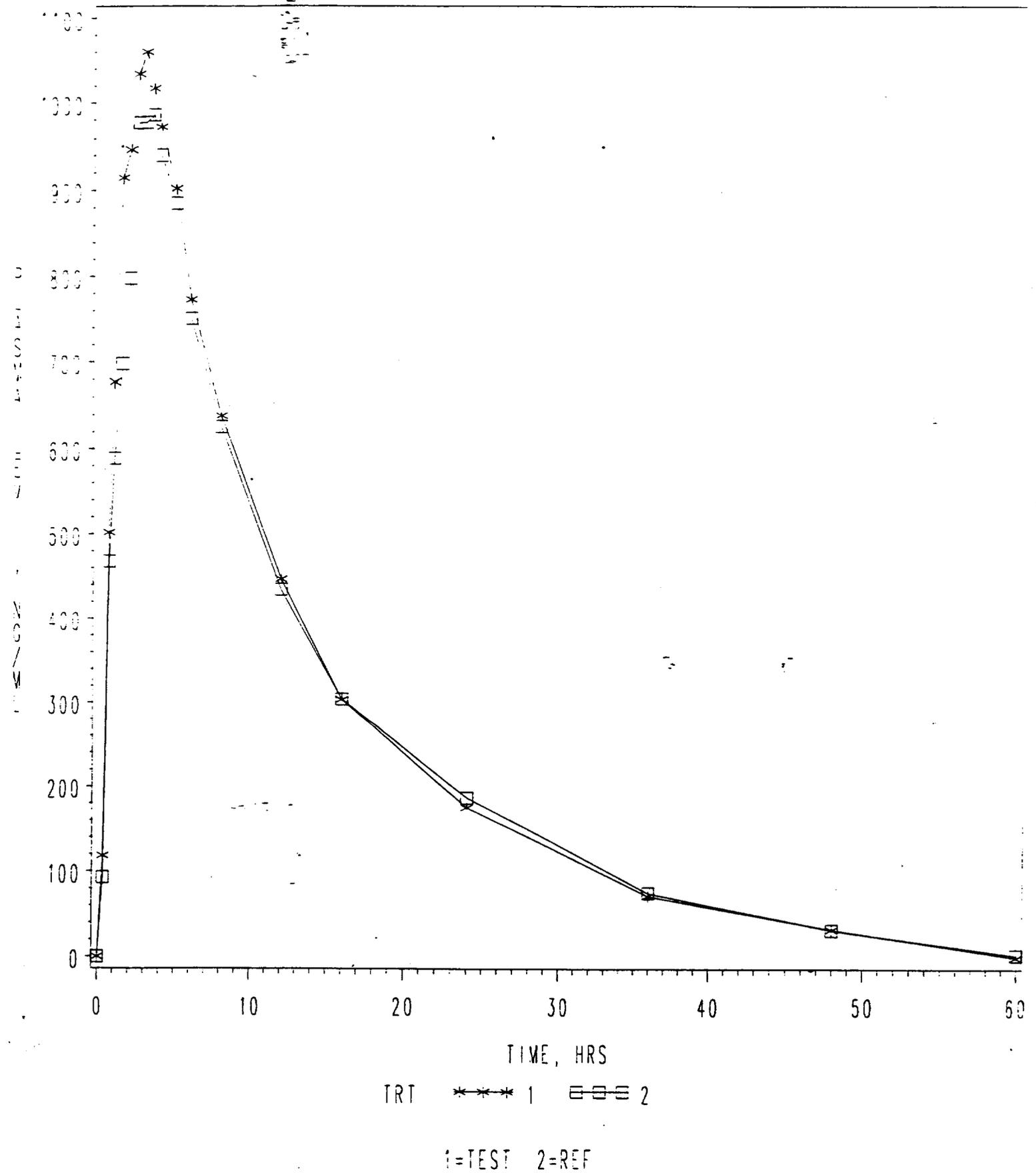
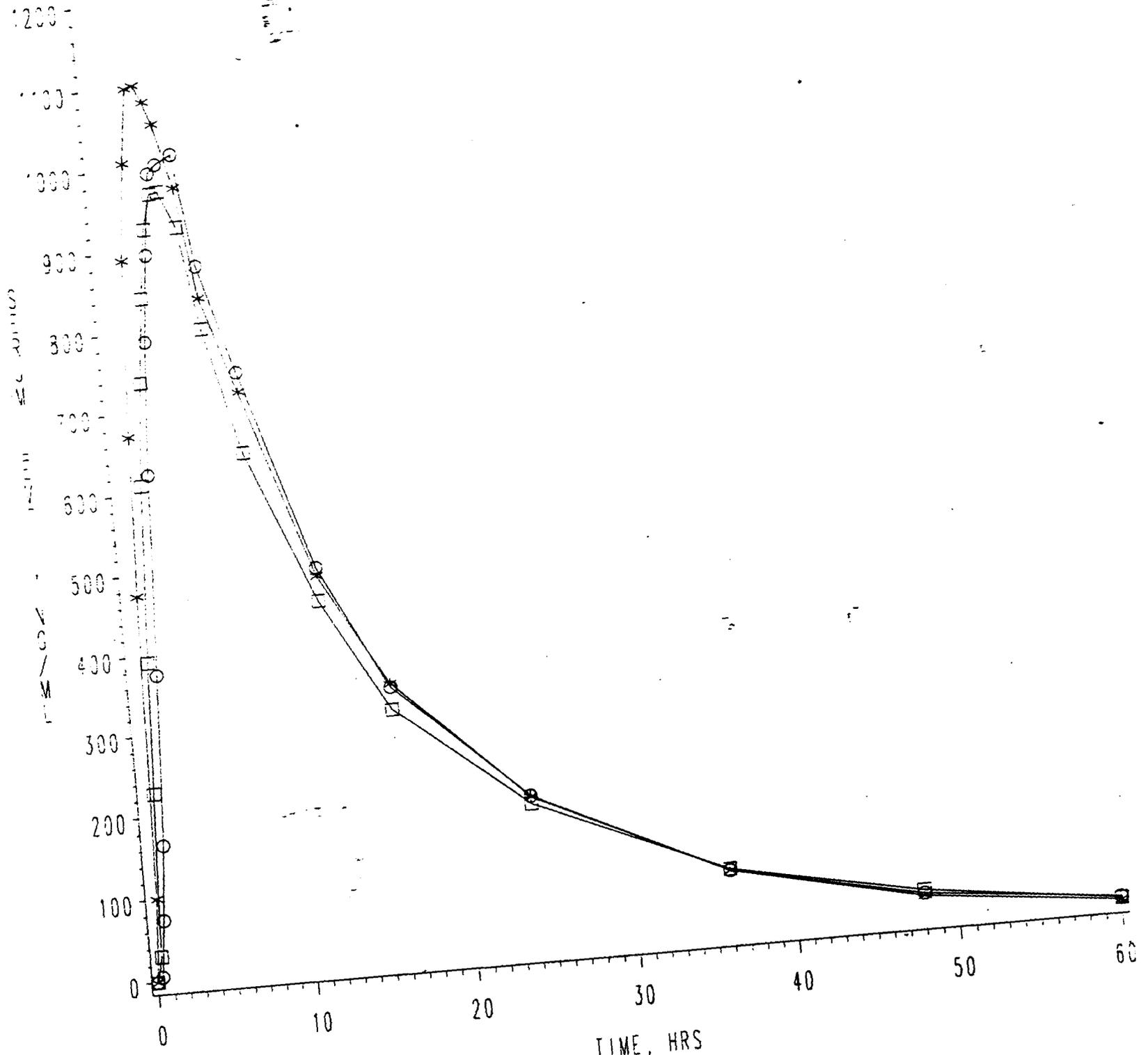


FIGURE 2. Plasma Sotalol LEVELS

SOLING TABLETS, 160 MG, ANDA #75-422
 UNDER FAS-ING/NON-FAS-ING COND. TIONS
 DOSE=1 X 160 MG



TRT *-*-* 1 □-□-□ 2 ○-○-○ 3

1=TEST(Fastina) 2=Test(FOOD) 3=Ref(EGIS-FAST)

ANDA 75-429

TEVA Pharmaceuticals USA
Attention: Deborah A. Jaskot
1510 Delp Drive
Kulpsville, PA 19443
|||||

AUG 31 1998

Dear Madam:

We acknowledge the receipt of your abbreviated new drug application submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act.

NAME OF DRUG: Sotalol Hydrochloride Tablets, 80 mg, 120 mg, 160 mg and 240 mg

DATE OF APPLICATION: July 31, 1998

DATE (RECEIVED) ACCEPTABLE FOR FILING: August 3, 1998

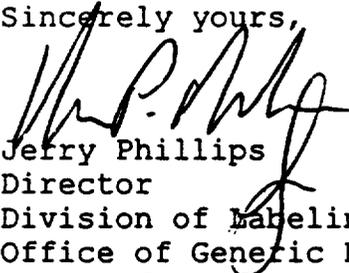
We will correspond with you further after we have had the opportunity to review the application.

Please identify any communications concerning this application with the ANDA number shown above.

Should you have questions concerning this application, contact:

Mark Anderson
Project Manager
(301) 827-5849

Sincerely yours,


Jerry Phillips
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research
8/25/98

Comments:

1. The dissolution data are acceptable. The dissolution results comply with the firm's specification of "not less than _____, dissolved in 30 minutes".
2. Based on the dissolution data submitted, the reviewer recommends higher specification i.e., "not less than _____, dissolved in 30 minutes".

Composition

(Not To Be Released Under FOI)

Ingredients	Amount (mg) /Tablet			
	80 mg	120 mg	160 mg	240 mg
Sotalol				
Lactose Monohydrate				
Starch NF				
FD&C Blue No.				
Povidone				
Magnesium Stearate				
Total				

Waiver Request

The firm requests waiver of requirements for in vivo bioequivalence testing on its 80 mg, 120 mg and 240 mg strengths per 21 CFR section 320.22 (d) (2).

Comments:

1. Assay method validation: Pre-study and within-study validations are acceptable.
2. Fasting and Non-fasting bioequivalence studies conducted with 160 mg strength are acceptable.
3. The dissolution data of all 4 strengths (240 mg, 160 mg, 120 mg, 80 mg) meet the specification of "not less than _____) dissolved in 30 minutes".
4. The formulations of 80 mg, 120 mg and 240 mg strengths are proportionally similar to the 160 mg strength in their active and inactive ingredients.

Recommendations:

1. The *in vivo* bioequivalence study conducted under fasting conditions by Teva Pharmaceuticals on its sotalol HCl tablets, 160 mg, lot # K-22947, comparing it to Berlex Laboratories' Betapace® tablets, 160 mg, lot # W70050, is acceptable.

2. The *in vivo* bioequivalence study conducted under non-fasting conditions by Teva Pharmaceuticals on its sotalol HCl tablets, 160 mg, lot # K-22947, comparing it to Berlex Laboratories' Betapace® tablets, 160 mg, lot # W70050, is acceptable.
3. The *in vitro* dissolution testing submitted by the firm on its sotalol HCl tablets (240 mg, 160 mg, 120 mg, 80 mg) is acceptable.
4. The waiver of requirements for *in vivo* bioequivalence testing on the 80 mg, 120 mg and 240 mg strengths can be granted per 21 CFR 320.22 (d) (2).
5. The dissolution testing should be incorporated into the firm's manufacturing controls and stability program. The dissolution should be conducted in 900 mL of water at 37° C using USP apparatus 2 (paddle) at 50 rpm. The test product should meet the following specifications:

Not less than _____ of the labeled amount of sotalol in the dosage form is dissolved in 30 minutes

Jahnavi S. Kharidia
 Jahnavi S. Kharidia, Ph.D.
 Review Branch III
 The Division of Bioequivalence

RD INITIALED BDAVIT BND 11/4/98
 FT INITIALED BDAVIT Barbara M Davis Date 11/5/98

Concur: Dale P. Conner Date 11/5/98
 Dale P. Conner, Pharm.D.
 Director
 Division of Bioequivalence

cc:

ANDA 75-429

TEVA Pharmaceuticals USA
Attention: Deborah A. Jaskot
1510 Delp Drive
Kulpsville, PA 19443

AUG 31 1998

|||||

Dear Madam:

We acknowledge the receipt of your abbreviated new drug application submitted pursuant to Section 505(j) of the Federal Food, Drug and Cosmetic Act.

NAME OF DRUG: Sotalol Hydrochloride Tablets, 80 mg, 120 mg,
160 mg and 240 mg

DATE OF APPLICATION: July 31, 1998

DATE (RECEIVED) ACCEPTABLE FOR FILING: August 3, 1998

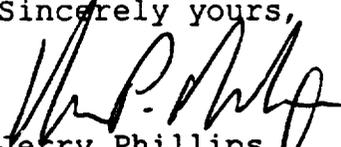
We will correspond with you further after we have had the opportunity to review the application.

Please identify any communications concerning this application with the ANDA number shown above.

Should you have questions concerning this application, contact:

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Project Manager
(301) 827-5849

Sincerely yours,


Jerry Phillips
Director
Division of Labeling and Program Support
Office of Generic Drugs
Center for Drug Evaluation and Research
8/25/98