

**CENTER FOR DRUG  
EVALUATION AND  
RESEARCH**

**APPLICATION NUMBER:**

**65-156**

**ADMINISTRATIVE  
DOCUMENT(S)**



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Establishment :      CFN : 2248121                      FEI : 1000222352

OHM LABORATORIES INC

1385 LIVINGSTON AVE

NORTH BRUNSWICK, NJ 08902

DMF No:

AADA:

Responsibilities:      FINISHED DOSAGE MANUFACTURER

Profile                :      TCM                                      OAI Status:      NONE

Last Milestone:      OC RECOMMENDATION

Milestone Date:      02-APR-03

Decision             :      ACCEPTABLE

Reason                :      DISTRICT RECOMMENDATION

-----

**APPEARS THIS WAY  
ON ORIGINAL**

**CENTER FOR DRUG  
EVALUATION AND  
RESEARCH**

**APPLICATION NUMBER:**

**65-156**

**CORRESPONDENCE**

**RANBAXY**  
PHARMACEUTICALS INC.

February 10, 2003

Office of Generic Drugs  
Center for Drug Evaluation and Research  
Food and Drug Administration  
Metro Park North II  
7500 Standish Place, Room 150  
Rockville, MD 20855-2773

UPS

**Reference: Minocycline Hydrochloride Tablets USP, 50mg, 75mg and 100mg  
Abbreviated New Drug Application**

Dear Sir/Madam:

Ranbaxy Laboratories Limited (RLL) herewith submits an abbreviated new drug application (ANDA) for Minocycline Hydrochloride Tablets, USP, 50mg, 75mg and 100mg pursuant to Section 505 (j) of the Federal Food, Drug, and Cosmetic Act.

This ANDA refers to the listed drug, Minocin® Capsules, 50mg, 75mg and 100mg which are manufactured by Lederle, the holder of the approved application and which are listed in the 2002 "Approved Drug Products with Therapeutic Equivalence Evaluations", 22<sup>nd</sup> Edition.

In the applicant's opinion and to the best of its knowledge, no patent claims have been submitted to the FDA. In addition, the applicant is not aware of any marketing exclusivity.

The \_\_\_\_\_ of Minocycline hydrochloride, USP ( \_\_\_\_\_ ) used to produce the ANDA batch of the drug product is ( \_\_\_\_\_ ) The DMF \_\_\_\_\_ is filed. A sample of the \_\_\_\_\_ is available and will be provided to the Agency upon request.

The drug product manufacturer is Ohm Laboratories, Inc., North Brunswick, New Jersey. This application provides for the manufacture, processing and packaging at Ohm Laboratories, Inc. The release and stability studies on the finished drug product are also carried out at the same location. Ohm Laboratories, Inc. is 100% owned by Ranbaxy Pharmaceuticals Inc. (RPI). RPI is a 100% wholly owned subsidiary of

APPEARS THIS WAY  
ON ORIGINAL

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FEB 12 2003  
OGD / CDER

Food and Drug Administration  
Minocycline Hydrochloride Tablets USP, 50mg, 75mg and 100mg  
Abbreviated New Drug Application  
Page 2

Ranbaxy Laboratories Limited (RLL), the Parent Company and sponsor of this ANDA. Abha Pant is RLL's U.S. Agent and RPI's Director of Regulatory Affairs. This application submitted by RLL will therefore contain information with either RLL, RPI or OHM's name on the document. An authorization letter from RLL appointing Abha Pant as the official U.S. Agent and representative for Ranbaxy Laboratories Limited is attached.

The required bioavailability/ bioequivalence studies were conducted on Minocycline Hydrochloride Tablets, USP, 100mg and Lederle's Minocin® Capsules, 100 mg at .The studies indicate Minocycline Hydrochloride Tablets, USP, 100mg are equivalent to Minocin® Capsules 100mg. The *in-vitro* dissolution for Minocycline Hydrochloride Tablets, USP, 50mg, 75mg and 100mg are comparable to those of Minocin®, 50mg and 100mg and Danbury's Dynacin Capsules 75mg. Therefore a waiver of *in vivo* bioavailability /bioequivalence study requirements for Minocycline Hydrochloride Tablets, USP, 50mg and 75mg is requested.

Minocycline Hydrochloride Tablets, USP, is stable and a two year expiration dating is requested. The two year expiration dating of these products is supported by one, two, and three months accelerated stability data ( $40^{\circ}\text{C} \pm 2^{\circ}\text{C}/75\% \pm 5\%$  relative humidity).

The route of administration, indications and usage, active ingredient, potency and labeling (except **DESCRIPTION**, and **HOW SUPPLIED** sections) for Minocycline Hydrochloride Tablets, USP are the same as those for Minocin® Capsules.

This ANDA is submitted in 10 volumes:

Volume I: Section 1 through Section 5

Volume II:  
through Section 6  
Volume VII:

Volume VIII: Section 7 through Section 11  
Volume IX: Section 12 through Section 14  
Volume X: Section 15 through Section 22

Ranbaxy Laboratories Limited commits to resolve any issues identified in the methods validation process after approval.

Food and Drug Administration  
Minocycline Hydrochloride Tablets USP, 50mg, 75mg and 100mg  
Abbreviated New Drug Application  
Page 3

Please contact the undersigned at 609-720-5666 if you have any questions regarding this submission.

**FIELD COPY:** We certify that a true copy of the technical section described in 21 CFR 314.94 (d)(5) of this submission has been provided to the FDA New Jersey District Office, North Brunswick NJ since the manufacturing is done at Ranbaxy's facility, Ohm Laboratories, Inc. in North Brunswick, NJ.

Sincerely,



Abha Pant  
US Agent for Ranbaxy Laboratories Ltd.

**APPEARS THIS WAY  
ON ORIGINAL**

**RANBAXY**  
PHARMACEUTICALS INC.

March 19, 2003

Office of Generic Drugs  
Center for Drug Evaluation and Research  
Food and Drug Administration

Metro Park North II  
7500 Standish Place, Room 150  
Rockville, MD 20855

UPS and Fax

ADDITIONAL  
INFORMATION

NEW CORRESP

*Ne*

**Reference: Minocycline Hydrochloride Tablets**  
**50 mg, 75 mg & 100 mg**  
**ANDA - 65-156**

Dear Mr. Patel,

Reference is made to our pending ANDA 65-156 for Minocycline Hydrochloride Tablets 50 mg, 75 mg, & 100 mg submitted to the Agency on February 10, 2003.

Reference is also made to the Telephone comments received March 17, 2003.

We have addressed all of the agency's concerns and the revised Section 2 (Basis for ANDA submission) with the supporting data is enclosed.

**Field Copy:** We certify that a true copy of the technical section described in 21 CFR 314.94 (d)(5) of this response has been provided to the FDA New Jersey District Office, North Brunswick, NJ since the manufacturing is done at Ohm Laboratories in North Brunswick, NJ.

Please contact me at 609-720-5328, or Abha Pant at 609-720-5666 if you have any questions regarding this amendment. Thank you.

Sincerely,

  
Mini S Nair

Sr. Manager, Regulatory Affairs (for)  
Abha Pant  
US Agent for Ranbaxy Laboratories Limited

RECEIVED  
MAR 20 2003  
OGD / CDER

**RANBAXY**  
PHARMACEUTICALS INC.

March 20, 2003

Office of Generic Drugs  
Center for Drug Evaluation and Research  
Food and Drug Administration  
Metro Park North II  
7500 Standish Place, Room 150  
Rockville, MD 20855

UPS

ADDITIONAL INFORMATION

NEW CORRESP

NC

**Reference: Minocycline Hydrochloride Tablets**  
**50 mg, 75 mg & 100 mg**  
**ANDA – 65-156**

Dear Mr. Patel,

Reference is made to our pending ANDA 65-156 for Minocycline Hydrochloride Tablets 50 mg, 75 mg, & 100 mg submitted to the Agency on February 10, 2003.

Reference is also made to the Telephone comments received March 17, 2003 and our response of March 19, 2003. Please disregard the response sent on March 19, 2003 as by error the suitability petition enclosed was of the capsules. Please find enclosed the revised information.

We have addressed all of the agency's concerns and the revised Section 2 (Basis for ANDA submission) with the supporting data is enclosed.

**Field Copy:** We certify that a true copy of the technical section described in 21 CFR 314.94 (d)(5) of this response has been provided to the FDA New Jersey District Office, North Brunswick, NJ since the manufacturing is done at Ohm Laboratories in North Brunswick, NJ.

Please contact me at 609-720-5328, or Abha Pant at 609-720-5666 if you have any questions regarding this amendment. Thank you.

Sincerely,

  
Mini S Nair

Sr. Manager, Regulatory Affairs (for)  
Abha Pant  
US Agent for Ranbaxy Laboratories Limited

RECEIVED

MAR 21 2003

OGD / CDER

**RANBAXY**  
PHARMACEUTICALS INC.

**ORIGINAL**

March 25, 2003

Office of Generic Drugs  
Center for Drug Evaluation and Research  
Food and Drug Administration  
Metro Park North II  
7500 Standish Place, Room 150  
Rockville, MD 20855

UPS

ADDITIONAL INFORMATION  
NEW CORRESP

NC

**Reference: Minocycline Hydrochloride Tablets**  
**50 mg, 75 mg & 100 mg**  
**ANDA – 65-156**

Dear Mr. Patel,

Reference is made to our pending ANDA 65-156 for Minocycline Hydrochloride Tablets 50 mg, 75 mg, & 100 mg submitted to the Agency on February 10, 2003.

Reference is also made to the Telephone comments received March 17, 2003 and our responses of March 19, 2003 and March 20, 2003. Reference is also made to the telephone contact made on March 24, 2003.

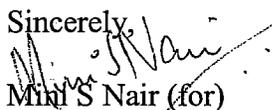
We have addressed all of the agency's concerns and are providing the following:

- Revised 356h indicating Minocin<sup>®</sup> Tablets as the Reference Listed Drug
- Comparison Between Generic Drug and Reference Listed Drug(Section 4) to indicate Minocin<sup>®</sup> Tablets as the Reference Listed Drug.
- As already communicated in our response dated March 20, 2003, we have provided the correct suitability petition 98P-0213/CP1 together with the FDA approval for the 75 mg strength of Minocycline Hydrochloride Tablets.

**Field Copy:** We certify that a true copy of the technical section described in 21 CFR 314.94 (d)(5) of this response has been provided to the FDA New Jersey District Office, North Brunswick, NJ since the manufacturing is done at Ohm Laboratories in North Brunswick, NJ.

Please contact me at 609-720-5328, or Abha Pant at 609-720-5666 if you have any questions regarding this amendment. Thank you.

Sincerely,

  
Mini S Nair (for)  
Abha Pant

US Agent for Ranbaxy Laboratories Limited

**RECEIVED**

**MAR 26 2003**

**OGD / CDER**

ANDA 65-156

Ranbaxy Pharmaceuticals, Inc.  
U.S. Agent for: Ranbaxy Laboratories Limited  
Attention: Abha Pant  
600 College Road East  
Princeton, NJ 08540

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.

Reference is made to the telephone conversations dated March 17, 2003 and March 24, 2003 and to your correspondence dated March 19, 2003, March 20, 2003 and March 25, 2003.

NAME OF DRUG: Minocycline Hydrochloride Tablets USP, 50 mg, 75 mg and 100 mg

DATE OF APPLICATION: February 10, 2003

DATE (RECEIVED) ACCEPTABLE FOR FILING: February 12, 2003

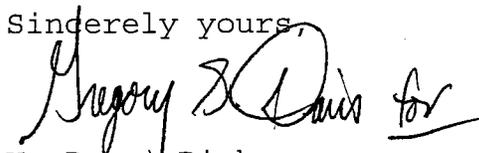
We will correspond with you further after we have had the opportunity to review the application.

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

Should you have questions concerning this application, contact:

Wanda Pamphile  
Project Manager  
(301) 827-5848

Sincerely yours,



Wm Peter Rickman  
Director  
Division of Labeling and Program Support  
Office of Generic Drugs  
Center for Drug Evaluation and Research

**RANBAXY**  
PHARMACEUTICALS INC.

June 26, 2003

Office of Generic Drugs  
Center for Drug Evaluation and Research  
Food and Drug Administration  
Metro Park North II  
7500 Standish Place, Room 150  
Rockville, MD 20855

UPS

MINOR  
AMENDMENT (CMC)

Reference: **Minocycline Hydrochloride Tablets, USP**  
**50 mg, 75 mg, & 100 mg**  
**ANDA - 65-156**

ORIG AMENDMENT,  
N/A

Dear Mr. Anderson,

Reference is made to our pending ANDA 65-156 for Minocycline Hydrochloride Tablets, 50 mg, 75 mg & 100 mg submitted to the Agency on February 10, 2003.

Reference is also made to the Minor Amendment, CMC comments, received June 25, 2003.

The deficiency questions and responses are addressed and detailed on the following page.

**Field Copy:** We certify that a true copy of the technical section described in 21 CFR 314.94 (d)(5) of this response has been provided to the FDA New Jersey District Office, North Brunswick, NJ since the manufacturing is done at Ohm Laboratories in North Brunswick, NJ.

Please contact me at 609-720-5328, or Abha Pant at 609-720-5666 if you have any questions regarding this amendment. Thank you.

Sincerely,

*Mini S Nair*  
Mini S Nair

Manager, Regulatory Affairs (for)  
Abha Pant  
US Agent for Ranbaxy Laboratories Limited

RECEIVED

JUN 27 2002<sup>3</sup>

OGD/CDEH

*AC*  
*7/8/03*

**RANBAXY**  
PHARMACEUTICALS INC.

July 25, 2003

Office of Generic Drugs  
Center for Drug Evaluation and Research  
Food and Drug Administration  
Metro Park North II  
7500 Standish Place, Room 150  
Rockville, MD 20855

FAX & UPS

TELEPHONE  
AMENDMENT (CMC)

Reference: **Minocycline Hydrochloride Tablets, USP**  
**50 mg, 75 mg, & 100 mg**  
**ANDA - 65-156**

ORIG AMENDMENT  
N/AM

Dear Mr. Furness,

Reference is made to our pending ANDA 65-156 for Minocycline Hydrochloride Tablets, 50 mg, 75 mg & 100 mg submitted to the Agency on February 10, 2003 and to the Minor Amendment, CMC comments, received June 25, 2003 and the response submitted to the Agency, dated June 26, 2003.

Reference is also made to the Telephone Amendment of July 17, 2003. The deficiency questions and responses raised in the Telephone Contact are addressed and detailed on the following page.

**Field Copy:** We certify that a true copy of the technical section described in 21 CFR 314.94 (d)(5) of this response has been provided to the FDA New Jersey District Office, North Brunswick, NJ since the manufacturing is done at Ohm Laboratories in North Brunswick, NJ.

Please contact me at 609-720-5328, or Abha Pant at 609-720-5666 if you have any questions regarding this amendment. Thank you.

Sincerely,

*Mimi S Nair*  
Mimi S Nair  
Manager, Regulatory Affairs (for)  
Abha Pant  
US Agent for Ranbaxy Laboratories Limited

RECEIVED

JUL 28 2003

UGD/CDER

**RANBAXY**  
PHARMACEUTICALS INC.

July 28, 2003

Office of Generic Drugs  
Center for Drug Evaluation and Research  
Food and Drug Administration  
Metro Park North II  
7500 Standish Place, Room 150  
Rockville, MD 20855

**FAX & UPS**

**TELEPHONE  
AMENDMENT (CMC)**

**ORIG AMENDMENT**

**Reference: Minocycline Hydrochloride Tablets, USP  
50 mg, 75 mg, & 100 mg  
ANDA - 65-156**

*N/AM*

Dear Mr. Furness,

Reference is made to our pending ANDA 65-156 for Minocycline Hydrochloride Tablets, 50 mg, 75 mg & 100 mg submitted to the Agency on February 10, 2003. Reference is also made to the Telephone Amendment of July 17, 2003 and response dated July 25, 2003. Reference is also made to the Telephone Amendment of July 28, 2003.

The deficiency questions and responses raised in the Telephone Contact are addressed and detailed on the following page.

**Field Copy:** We certify that a true copy of the technical section described in 21 CFR 314.94 (d)(5) of this response has been provided to the FDA New Jersey District Office, North Brunswick, NJ since the manufacturing is done at Ohm Laboratories in North Brunswick, NJ.

Please contact me at 609-720-5328, or Abha Pant at 609-720-5666 if you have any questions regarding this amendment. Thank you.

Sincerely,

*Mimi S Nair*  
Mimi S Nair

Manager, Regulatory Affairs (for)  
Abha Pant  
US Agent for Ranbaxy Laboratories Limited

**RECEIVED**

**JUL 28 2003**

**OGD/CDER**

**RANBAXY**  
PHARMACEUTICALS INC.

August 12, 2003

Office of Generic Drugs  
Center for Drug Evaluation and Research  
Food and Drug Administration  
Metro Park North II  
7500 Standish Place, Room 150  
Rockville, MD 20855

**UPS & FAX**

**TELEPHONE  
AMENDMENT**

**Reference: Minocycline Hydrochloride Tablets, USP  
50 mg, 75 mg, & 100 mg  
ANDA - 65-156**

**ORIG AMENDMENT**

*N/A*

Dear Sir/Madam,

Reference is made to our pending ANDA 65-156 for Minocycline Hydrochloride Tablets, 50 mg, 75 mg & 100 mg submitted to the Agency on February 10, 2003.

Reference is also made to the Telephone Contact from Aaron Sigler, Project Manager, Division of Bioequivalence on August 11, 2003, requesting the long term stability data of plasma samples upto 27 days.

The deficiency question and response with the data are addressed and detailed on the following page.

**Field Copy:** We certify that a true copy of the technical section described in 21 CFR 314.94 (d)(5) of this response has been provided to the FDA New Jersey District Office, North Brunswick, NJ since the manufacturing is done at Ohm Laboratories in North Brunswick, NJ.

Please contact me at 609-720-5328, or Abha Pant at 609-720-5666 if you have any questions regarding this amendment. Thank you.

Sincerely,

*Mini S Nair*  
Mini S Nair

Manager, Regulatory Affairs (for)  
Abha Pant  
US Agent for Ranbaxy Laboratories Limited

**RECEIVED**

**AUG 14 2003**

**OGD/CDEH**

**RANBAXY**  
PHARMACEUTICALS INC.

*Labeling review  
drafted 11/3/03  
A. Nair*

October 10, 2003

Office of Generic Drugs  
Center for Drug Evaluation and Research  
Food and Drug Administration  
Metro Park North II  
7500 Standish Place, Room 150  
Rockville, MD 20855

UPS FAXED  
**LABELING AMENDMENT**

**ORIG AMENDMENT**

**Reference: Minocycline Hydrochloride Tablets**  
**50 mg, 75 mg & 100 mg**  
**ANDA - 65-156**

*N/AF*

Dear Sir/Madam,

Reference is made to our pending ANDA 65-156 for Minocycline Hydrochloride Tablets 50 mg, 75 mg, & 100 mg and to a labeling deficiency of September 24, 2003 in which Ranbaxy was asked to further revise the labels and package insert for the above referenced product.

Provided on the following pages are the agency's deficiencies followed by Ranbaxy's responses. The labeling has been revised as requested. Twelve sets of the final printed labeling are included in the "**original**" copy and an additional 6 sets of the labeling are in the duplicate copy in **Attachment 1**. To facilitate review we have provided a side-by-side comparison with Ranbaxy's revised labeling and previously submitted, with all differences shown with the use of color, in **Attachment 2**.

**Please Note:** In addition to the changes recommended by the Agency, we have updated the package insert to include the statements required for systemic antibacterial drug products as per the final rule Docket 00N-1463, "Labeling Requirements for Systemic Antibacterial Drug Products Intended for Human Use", Federal Register /Vol 68, No 25/Thursday-February 6, 2003/ Rules and Regulations.

Please contact the undersigned at 609-720-5328, or Abha Pant at 609-720-5666, if you have any questions regarding this labeling amendment.

Sincerely,  
*Mimi S Nair*  
Mimi S Nair  
Manager, Regulatory Affairs (for)  
Abha Pant  
US Agent for Ranbaxy Laboratories Limited

**RECEIVED**  
OCT 14 2003  
OGD/CDEH

**RANBAXY**  
PHARMACEUTICALS INC.

November 3, 2003

Office of Generic Drugs  
Center for Drug Evaluation and Research  
Food and Drug Administration  
Metro Park North II  
7500 Standish Place, Room 150  
Rockville, MD 20855

UPS

ORIG AMENDMENT

N/AB

BIOEQUIVALENCE  
DEFICIENCIES

**Reference: Minocycline Hydrochloride Tablets, USP**  
**50 mg, 75 mg, & 100 mg**  
**ANDA – 65-156**

Dear Sir/Madam,

Reference is made to our pending ANDA 65-156 for Minocycline Hydrochloride Tablets, 50 mg, 75 mg & 100 mg submitted to the Agency on February 10, 2003. Reference is also made to the Bioequivalency Deficiency of October 21, 2003.

The deficiency questions and responses raised in the Telephone Contact are addressed and detailed on the following page.

**Field Copy:** We certify that a true copy of the technical section described in 21 CFR 314.94 (d)(5) of this response has been provided to the FDA New Jersey District Office, North Brunswick, NJ since the manufacturing is done at Ohm Laboratories in North Brunswick, NJ.

Please contact me at 609-720-5328, or Abha Pant at 609-720-5666 if you have any questions regarding this amendment. Thank you.

Sincerely,



Mini S Nair

Manager, Regulatory Affairs (for)  
Abha Pant  
US Agent for Ranbaxy Laboratories Limited

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NOV 04 2003

OGD/CDE:R

**RANBAXY**  
PHARMACEUTICALS INC.

**ORIG AMENDMENT**

*N/A/M*

December 16, 2003

Office of Generic Drugs  
Center for Drug Evaluation and Research  
Food and Drug Administration  
Metro Park North II  
7500 Standish Place, Room 150  
Rockville, MD 20855

UPS /FAX

**ADDITIONAL INFORMATION**

**Reference: Minocycline Hydrochloride Tablets**  
**50 mg, 75 mg & 100 mg, ANDA - 65-156**

Dear Mr. Shimer,

Reference is made to our pending ANDA 65-156 for Minocycline Hydrochloride Tablets 50 mg, 75 mg, & 100 mg submitted to the Agency on February 10, 2003.

Reference is also made to the Telephone contact of December 16, 2003. Please find enclosed the following information requested:

-Amended 356h, showing Minocycline Hydrochloride Tablets of Medicis as the Reference Listed Drug.

-Amended Section 2, Basis of Submission, showing the RLD as Minocycline Hydrochloride Tablets of Medicis (ANDA 65-131).

-Revised Patent and Exclusivity Certification.

Please contact me at 609-720-5328, or Abha Pant at 609-720-5666 if you have any questions regarding this amendment. Thank you.

**Field Copy:** We certify that a true copy of the technical section described in 21 CFR 314.94 (d)(5) of this response has been provided to the FDA New Jersey District Office, North Brunswick, NJ since the manufacturing is done at Ohm Laboratories in North Brunswick, NJ.

Sincerely,

*Mini S Nair*

Mini S Nair

Manager, Regulatory Affairs (for)

Abha Pant

US Agent for Ranbaxy Laboratories Limited

RECEIVED

DEC 17 2003

ODD/CDEn