

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*  
**50-795**

**STATISTICAL REVIEW(S)**



U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Pharmacoepidemiology and Statistical Science  
Office of Biostatistics

# STATISTICAL REVIEW AND EVALUATION

## CLINICAL STUDIES

**NDA # :** 50-795

**Drug Name:** Doryx (doxycycline hyclate delayed release tablets) 75 and 100 mg

**Indication(s):** New dosage form

**Applicant:** Warner Chilcott on behalf of F H Faulding & Co Ltd (t/a Mayne Pharma International)

**Date(s):** CDER Stamp Date 07 Apr 2004

**Review Priority:** Standard

  

**Biometrics Division:** Division of Biometrics III (HFD-725)

**Documents Reviewed:** Volume 1 of NDA 50-795

  

**Statistical Reviewer:** B. Sue Bell, Ph.D.

**Concurring Reviewers:** Daphne Lin, Ph.D.

**Medical Division:** Division of Anti-Infective Drug Products (HFD-520)

**Clinical Reviewer:** Charles Cooper, M.D.

**Project Manager:** Judit Milstein

## **1. Executive Summary**

### **1.1 Conclusions and Recommendations**

No statistical comment is required. The application did not include any new clinical studies of efficacy or safety. The Biopharmaceutical Reviewer will review and comment on the studies on the bioequivalence of the Capsule versus the Tablet dosage forms.

### **1.2 Brief Overview of Clinical Studies**

The submission contains an application for a new Tablet dosage form of the existing marketed product, Doryx® 75 mg and 100 mg Capsules that are marketed under approved NDA 50-582. Two clinical pharmacokinetic studies were conducted to compare the bioavailability of the new Tablets with the current Capsules. Under fasting conditions, the sponsor found the dose regimens to be bioequivalent. With food, the rate but not the extent of the doxycycline absorption was decreased but the decrease was not clinically significant.

B. Sue Bell, Ph.D.  
Mathematical Statistician, DB III

Concur: Daphne Lin, Ph.D.  
Mathematical Statistician (Team Leader), DB III

CC:  
Archival: NDA #50-795  
HFD-520  
HFD-520/Ms. Milstein  
HFD-520/Dr. Cooper  
HFD-520/Dr. Alexander  
HFD-520/Dr. Tworzyanski  
HFD-725/Dr. Bell  
HFD-725/Dr. Lin  
HFD-725/Dr. Huque  
HFD-700/Dr. Anello

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/s/

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Sue Bell  
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