CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

75852

BIOEQUIVALENCY REVIEW(S)

1.1

BIOEQUIVALENCY COMMENTS TO BE PROVIDED TO THE APPLICANT

ANDA: 75-852 APPLICANT: Baxter

DRUG PRODUCT: Milrinone Lactate Injection, 1 mg/mL
10 mL, 20 mL, and 50 mL vials

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

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,

/S/

Dale P. Conner, Pharm. D.
Director
Division of Bioequivalence
Office of Generic Drugs
Center for Drug Evaluation and Research

CC: ANDA 75-852
ANDA DUPLICATE
DIVISION FILE
HFD-651/ Bio Drug File
HFD-655/ Dhariwal

Printed in final on 06/07/2000

Endorsements: (Final with Dates)
HFD-655/ Dhariwal 6/7/00
HFD-655/ Nerurkar
HFD-650/ D. Conner 6/26/00

6/7/00

BIOEQUIVALENCY - ACCEPTABLE

Submission date: April 28, 2000

1. **WAIVER** (WAI)

Strengths: 1 mg/mL
10 mL vial
20 mL vial
50 mL vial

Outcome: **AC**

Outcome Decisions: **AC** - Acceptable

WinBio Comments:

Milrinone Lactate Injection
1 mg base/mL
10 mL, 20 mL, & 50 mL vials
ANDA # 75-852
Reviewer: Kuldeep R. Dhariwal
File name: 75852W.400

Baxter PPI
95 Spring St.
New Providence
NJ 07974
Submission Date:
April 28, 2000

Review of a Waiver Request

The firm has requested a waiver of *in vivo* bioequivalence study requirements for its product Milrinone Lactate injection, 1 mg/mL. The reference listed drug is Primacor® (1 mg base/mL) by Sanofi.

Milrinone Lactate injection is indicated for the short-term intravenous treatment of patients with acute decompensated heart failure.

Formulation:

Ingredient	Test	Reference
Milrinone	1 mg/mL	1 mg/mL
Dextrose Anhydrous	47 mg/mL	47 mg/mL
Lactic acid*	adjust pH	adjust pH
Sodium hydroxide	adjust pH	adjust pH
Water for injection	q.s.	q.s.

* The total concentration of lactic acid can vary between (0.95) mg/mL and ( ) mg/mL. The target amount for the test product is (, mg/mL.

Physicochemical Data:

	Test	Reference
Lot #	99H217	B835TB
pH		
Assay	%	%

** The pH is adjusted to between ( ) with

Comments:

1. The test product is a solution intended solely for intravenous administration.
2. The inactive ingredients are qualitatively and quantitatively the same in test and reference products.
3. The waiver may be granted.

Recommendation:

The Division of Bioequivalence agrees that the information submitted by Baxter Pharmaceutical Products demonstrate that Milrinone Lactate injection 1 mg/mL (10 mL, 20 mL, and 50 mL vials) falls under 21 CFR 320.22 (b)(1) of the Bioavailability/Bioequivalence Regulations. The waiver of *in vivo* bioequivalence study requirements for Milrinone Lactate injection 1 mg/mL is granted. From the bioequivalence point of view the Division of Bioequivalence deems the test product to be bioequivalent to Primacor® 1 mg/mL by Sanofi.

/S/

Kuldeep R. Dhariwal, Ph.D.
Review Branch II
Division of Bioequivalence

FD INITIALED S.NERURKAR
FT INITIALED S.NERURKAR /S/ Date 6/7/2000

Concur: /S/ Date 6/26/00
Dale P. Conner, Pharm.D.
Director
Division of Bioequivalence

OFFICE OF GENERIC DRUGS
DIVISION OF BIOEQUIVALENCE

ANDA # : 75-852 SPONSOR : Baxter Pharmaceutical Products

DRUG AND DOSAGE FORM : Milrinone Lactate Injection

STRENGTH(S) : 1 mg/mL

TYPES OF STUDIES : N/A

CLINICAL STUDY SITE(S) : N/A

ANALYTICAL SITE(S) : N/A

STUDY SUMMARY : The test and reference products are qualitatively and quantitatively the same. The waiver is granted.

DISSOLUTION : N/A

DSI INSPECTION STATUS

Inspection needed: YES / (NO)	Inspection status:	Inspection results:
First Generic _No__ New facility _____ For cause _____ Other _____	Inspection requested: (date) Inspection completed: (date)	

PRIMARY REVIEWER : Kuldeep R. Dhariwal BRANCH : II

INITIAL : _____ DATE : 6/7/00

TEAM LEADER : S. Nerurkar BRANCH : II

INITIAL : /S/ DATE : 6/7/2000

DIRECTOR, DIVISION OF BIOEQUIVALENCE : DALE P. CONNER, Pharm. D.

INITIAL : _____ DATE : 6/26/00