

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 75-086

BIOEQUIVALENCE REVIEW(S)

OFFICE OF GENERIC DRUGS
DIVISION OF BIOEQUIVALENCE

ANDA/AADA # 75-086 SPONSOR: Taylor Pharmaceuticals

DRUG: Diltiazem HCl

DOSAGE FORM: Injection

STRENGTHS/(S): 5mg/ml

TYPE OF STUDY: Single_ Multiple_ Fasting_ Fed_ N/A

STUDY SITE:

N/A

STUDY SUMMARY: Waiver granted per 21 CFR 320.22 (4)(1)
Products are Q and Q

DISCUSSION:

N/A

PRIMARY REVIEWER: Jenny Lee BRANCH: II

INITIAL: _____ DATE 6/12/97

TEAM LEADER: S. Nerurkar, Ph.D BRANCH: II

INITIAL: _____ DATE 6/13/1997

DIRECTOR, DIVISION OF BIOEQUIVALENCE: Nicholas Fleischer, Ph.D

INITIAL: _____ DATE 8/13/97

DIRECTOR, OFFICE OF GENERIC DRUGS:

INITIAL: _____ DATE _____

JUN 13 1997

Diltiazem HCl Injection
5 mg/ml in 5 ml and 10 ml vials
NDA #75-086
Reviewer: J. Lee
75086W.297

Taylor Pharmaceuticals
(an Akorn Co.)
Decatur, Illinois
Submission date:
February 28, 1997

Review of a Request for Waiver

The sponsor has submitted an application for diltiazem HCl injection 5 mg/ml and is requesting a waiver of in-vivo bioequivalence requirements under 21 CFR 320.22 (b)(1).

In support of the waiver request the sponsor has submitted a formulation comparison as well as a side-by-side comparison of the proposed product vs Cardizem Injection (Marion Merrell Dow) with respect to conditions of use, active and inactive ingredients, dosage form, route of administration and strength (appended).

The drug product is intended for direct IV bolus injection and continuous IV infusion; it is AP listed.

	<u>Taylor</u> per ml	<u>Cardizem</u> per ml
Diltiazem HCl	5 mg	5 mg

see package insert

Recommendation:

1. The Division of Bioequivalence agrees that the information submitted by Taylor Pharmaceuticals demonstrates that diltiazem HCl injection 5 mg/ml falls under 21 CFR 320.22 (b)(1) of Bioavailability/Bioequivalence Regulations. The Division of Bioequivalence recommends that the waiver of an in-vivo bioavailability study be granted. Taylor's diltiazem HCl injection 5 mg/ml is deemed bioequivalent to Cardizem[®] Injectable 5 mg/ml manufactured by Marion Merrell Dow.

E. Lee 6/12/97

J. Lee
Division of Bioequivalence

Review Branch II

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6/13/1997

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JLee/jl/06-12-97