

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
75-036

BIOEQUIVALENCE

100-100000

MAY 16 1997

Cisplatin Injection
1 mg/mL- 50 mL and 100 mL
ANDA # 75-036
Reviewer: Jahnvi S. Kharidia
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Bedford Laboratories
Bedford, Ohio
Submission Date:
December 23, 1996

Review of a Waiver Request

Introduction:

Cisplatin is indicated for metastatic advanced bladder, ovarian and testicular cancers. The firm has requested a waiver of *in vivo* bioavailability requirements for its Cisplatin injection, 1 mg/mL, 50 mL and 100 mL vials based upon 21 CFR 320.22(b)(1).

Comparative Formulation (Not to be released through FOI):

Ingredients	Bedford Laboratories (mg/mL)	Bristol (mg/mL)
Cisplatin,	1.0	1.0
Sodium Chloride,	9.0	9.0
Hydrochloric acid	for pH adjustment	for pH adjustment
Sodium hydroxide,	for pH adjustment	for pH adjustment
Water for injection,	qs to 1.0 mL	qs to 1.0 mL

Comments

1. The formulations for the test product Cisplatin 1 mg/mL injection and the innovator product, Platinol-AQ 1 mg/mL injection (Bristol) are qualitatively and quantitatively identical.
2. The dosage form, route of administration (intravenous), strength (1 mg/mL) and labeling of the test drug product are identical to those of the innovator product, Platinol-AQ.
3. From the bioequivalence point of view, the waiver of *in vivo* bioequivalence study requirement should be granted based on 21 CFR 320.22(b)(1).

Recommendation

The Division of Bioequivalence agrees that the information submitted by Bedford Laboratories on its Cisplatin 1 mg/mL injection, 50 mL and 100 mL vials, falls under 21 CFR 320.22 (b)(1) of the Bioavailability/Bioequivalence Regulations. The waiver of *in vivo* bioequivalence study for 1 mg/mL injection, 50 mL and 100 mL vials of the test product is granted.

From the bioequivalence point of view, the Division of Bioequivalence deems the test injection of Cisplatin 1 mg/mL, 50 mL and 100 mL vials to be bioequivalent to Platinol-AQ 1 mg/mL, 50, and 100 mL vials, respectively, manufactured by Bristol Labs.

The firm should be informed of the recommendation.

J-S. Kharidia
Jahnvi S. Kharidia, Ph.D.
Review Branch III
The Division of Bioequivalence

RD INITIALED RMHATRE
FT INITIALED RMHATRE Ramakant M. Mhatre Date 5/13/97
Ramakant M. Mhatre, Ph.D.
Chief, Branch III
Division of Bioequivalence

Concur: N. Baluach Date 5/16/97
for Nicholas Fleischer, Ph.D.
Director
Division of Bioequivalence

cc:

Drug File, Division File