

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*  
**74945**

**BIOEQUIVALENCY REVIEW(S)**

DEC 16 1996

Atracurium Besylate Injection                      Marsam Pharmaceuticals, Inc.  
10 mg/mL, 10 mL Multiple Dose Vial              Cherry Hill, NJ  
ANDA #74-945    Submission Date:  
Reviewer: Moheb H. Makary                              August 21, 1996  
WP 74945W.896

Review of a Waiver Request

I. Objective:

The firm requested a waiver of bioequivalence study requirements for its product Atracurium Besylate Injection, 10 mg/mL, 10 mL Multiple-Dose Vial. Innovator product is Tracrium® Injection 10 mg/mL, 5 mL (single-dose vials) and 10 mL (multiple-dose vials) manufactured by Glaxo Wellcome.

Atracurium Besylate is indicated, as an adjunct to general anesthesia, to facilitate endotracheal intubation and to provide skeletal muscle relaxation during surgery or mechanical ventilation. It should be administered intravenously.

II. Formulations:

The formulations of the proposed test product and reference product are shown below:

	Reference Product	Proposed Test Products
	Tracrium® Injection 10 mg/mL 10 mL Vial	Atracurium Besylate Injection 10 mg/mL 10 mg Vial
Atracurium Besylate	10 mg/mL	10 mg/mL
Benzenesulfonic Acid	To adjust pH	qs To adjust pH
Water for Injection	qs	qs
Benzyl Alcohol	0.9% ↓	0.9%

III. Comments:

1. As shown above, the proposed test product, Atracurium Besylate Injection, 10 mg/mL, 10 mL multiple-dose vial contains the same active and inactive ingredients in the same quantities per mL as the reference product, Tracrium® Injection, 10 mg/mL, 10 mL Vial.
2. The test product is a solution intended for intravenous administration.
3. Waiver of in vivo bioequivalence study requirements may be granted based on 21 CFR 320.22 (b) (1).

IV. Recommendation:

The Division of Bioequivalence agrees that the information submitted by Marsam Pharmaceuticals Inc., demonstrates that Atracurium Besylate Injection 10 mg/mL, 10 mL Multiple-Dose Vial, falls under Section 320.22 (b) (1) of Bioavailability/Bioequivalence Regulations. Waiver of in vivo bioequivalence study for the test product is granted. From the bioequivalence point of view, the Division of Bioequivalence deems the test injectable formulation, Atracurium Besylate Injection 10 mg/mL, 10 mL Multiple-Dose Vial, manufactured by Marsam Pharmaceuticals Inc., to be bioequivalent to Tracrium® Injection 10 mg/mL, 10 mL Vial manufactured by Glaxo Wellcome.

The firm should be informed of the above recommendation.

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Moneb H. Makary, Ph.D.  
Division of Bioequivalence  
Review Branch III

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Date: 12/4/96

Concur:

**/S/**

Date: 12/16/96

Rabindra Patnaik, Ph.D.  
Acting Director  
Division of Bioequivalence