

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
74944

MICROBIOLOGY REVIEW

OFFICE OF GENERIC DRUGS, HFD-640
Microbiologists Review #1
October 15, 1996

A. 1. ANDA 74-944

APPLICANT Marsam Pharmaceuticals, Inc

2. PRODUCT NAMES: Atracurium Besylate Injection

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:

10 mg/mL, 5 mL Single Dose glass vial, Intravenous

4. METHOD(S) OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: Skeletal muscle relaxant
(neuromuscular block)

B. 1. DATE OF INITIAL SUBMISSION: August 21, 1996

(Received August 22, 1996)

2. DATE OF AMENDMENT: None

3. RELATED DOCUMENTS: DMF

DMF

DMF

4. ASSIGNED FOR REVIEW: 10/8/96

C. REMARKS The subject drug is into 5 mL
vials on the filling line 303, Room 15 of the
Cherry Hill NJ pharmaceutical manufacturing
facility.

D. CONCLUSIONS: The submission is not recommended for
approval on the basis of sterility assurance.
The specific comments regarding the
process are provided in

IS/
Andrea S. High, Ph. D. 10/15/96

cc: Original ANDA
Duplicate ANDA
Division Copy
Field Copy

Drafted by A. High, HFD 640 x:wp\microrev\74-944

Initialed by F. Fang or F. Holcombe, Jr. 10/17/96

OFFICE OF GENERIC DRUGS, HFD-640
Microbiologists Review #3
June 9, 1997

- A. 1. ANDA 74-944
- APPLICANT Marsam Pharmaceuticals, Inc
2. PRODUCT NAMES: Atracurium Besylate Injection
3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
10 mg/mL, 5 mL Single Dose glass vial, Intravenous
4. METHOD(S) OF STERILIZATION:
5. PHARMACOLOGICAL CATEGORY: Skeletal muscle relaxant
(neuromuscular block)
- B. 1. DATE OF INITIAL SUBMISSION: August 21, 1996
(Received August 22, 1996)
2. DATE OF AMENDMENT: May 21, 1997
Subject of This Review (Received May 22, 1997)
3. RELATED DOCUMENTS: None
4. ASSIGNED FOR REVIEW: 6/9/97
- C. REMARKS The subject amendment provides for the response to the microbiology deficiencies in the letter dated May 8, 1997. The amendment also provides for a change in the closure sterilization cycles.
- D. CONCLUSIONS: The submission is recommended for approval on the basis of sterility assurance. The specific comments regarding the process are provided

JSI 6/10/97
Andrea S. High, Ph. D.

cc: Original ANDA
Duplicate ANDA
Division Copy
Field Copy

Drafted by A. High, HFD 640 x:wp\microrev\74-944a.2
Initialed by F. Fang or F. Holcombe, Jr.

6/17/97