

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

MICROBIOLOGY REVIEW(S)

REVIEW FOR OFFICE OF GENERIC DRUGS
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #1 OF ANDA 75-241
2 June 1998

A. 1. ANDA 75-241

APPLICANT: Abbott Laboratories
200 Abbott Park Road, D-389, AP30
Abbott Park, IL 60064-3537

2. PRODUCT NAMES: Furosemide Injection, USP

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
The product is a sterile injectable preparation for intravenous infusion.

4. METHODS OF STERILIZATION:
The product is into 5 or 10 ml plastic syringes which
are subsequently sterilized. The product is to
parametrically released.

5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE
INDICATION:
The product is a diuretic.

B. 1. DATE OF INITIAL SUBMISSION: 31 October 1997

2. DATE OF AMENDMENT: (none)

3. INNOVATOR PRODUCT/MANUFACTURER:
Lasix R Injection / Hoechst Marion Roussel

4. ASSIGNED FOR REVIEW: 17 April 1998

C. REMARKS: The application provides for the manufacture of the
product at the applicant's facility located at

The product will be packaged in 5 and 10 mL plastic
syringes (4 mL fill in 5 mL syringe; L or 10 mL fills in

10 mL syringe). All products are identical in concentration of drug substance, 10 mg/mL.

This is the second syringe product applied for under parametric release specifications. A comparison with James McVey's review of ANDA was made to assure uniformity.

D. CONCLUSIONS: The application is recommended for approval on the basis of sterility assurance.

PSI
✓ Paul Stinavage, Ph.D. 2 June 1998
ATC 6/5/98

cc:

Page (s) 4

Contain Trade Secret,

Commercial/Confidential

Information and are not

releasable. 6/2/98

Micro Review 1