

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
40262

MICROBIOLOGY REVIEW

OFFICE OF GENERIC DRUGS, HFD-620
Microbiologist's Review #1
May 27, 1998

- A. 1. ANDA 40-262
- APPLICANT Pharmachemie BV
2. PRODUCT NAMES: Leucovorin Calcium for Injection
3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 350 mg/vial,
Lyophilized, Intravenous
4. METHOD(S) OF STERILIZATION:
5. PHARMACOLOGICAL CATEGORY: Folic Acid Antagonist
Antidote
- B. 1. DATE OF INITIAL SUBMISSION: July 28, 1997
Subject of this Review (Received, July 29, 1997)
2. DATE OF AMENDMENT: None
3. RELATED DOCUMENTS: None
4. ASSIGNED FOR REVIEW: 5/20/98
- C. REMARKS: The subject drug product is in
Room 1.3.12K and lyophilized in Room 1.3.13A at
the Haarlem, The Netherlands pharmaceutical
facility.
- D. CONCLUSIONS: The submission is not recommended for
approval on the basis of sterility assurance.
Specific comments regarding the
process are provided

JS/
Andréa S. High, Ph. D. 5/27/98

cc: Original ANDA
Duplicate ANDA
Division Copy
Field Copy
Drafted by A. High, HFD 620 x:wp\microrev\40-262
Initialed by R. Patel *re/ited 5/28/98*

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microbiologist review #1

OFFICE OF GENERIC DRUGS, HFD-620
Microbiologist's Review #2
April 20, 1999

A. 1. ANDA 40-262

APPLICANT Pharmachemie BV

2. PRODUCT NAMES: Leucovorin Calcium for Injection

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: 350 mg/vial,
Lyophilized, Intravenous

4. METHOD(S) OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: Folic Acid Antagonist
Antidote

B. 1. DATE OF INITIAL SUBMISSION: July 28, 1997
(Received, July 29, 1997)

2. DATE OF FAX AMENDMENT: **Subject of this Review:**
March 12, 1999
New Correspondence, March 18, 1999,
(Hard Copy Received, March 19, 1999)

3. RELATED DOCUMENTS: None

4. ASSIGNED FOR REVIEW: 4/19/99

C. REMARKS: The FAX amendment provides for the response to the
February 11, 1999 microbiology deficiency letter.

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

AS 4/20/99
Andrea S. High, Ph. D.

cc: Original **ANDA**
Duplicate ANDA
Division Copy
Field Copy

Drafted by A. High, HFD 620 x:wp\microrev\40-262a
Initialed by M. Fanning *MZ* 4/22/99

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microbiologist's review #3