

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**65-027**

**MICROBIOLOGY REVIEW**

OFFICE OF GENERIC DRUGS, HFD-640  
Microbiology Review #3  
May 22, 2001

A. 1. ANDA 65-027

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

2. PRODUCT NAME: Clindamycin Phosphate Injection in 5% Dextrose  
3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Solution for I.V. injection (6mg/mL, 12mg/mL and 18mg/mL) in single dose 50 mL plastic containers (Form Fill Seal)  
4. METHOD(S) OF STERILIZATION:  
5. PHARMACOLOGICAL CATEGORY: Antibiotic

- B. 1. DATE OF INITIAL SUBMISSION: August 31, 1998  
2. DATE OF AMENDMENT: May 11, 2001  
Subject of this review (Received May 14, 2001)  
4. RELATED DOCUMENTS: None  
5. ASSIGNED FOR REVIEW: May 21, 2001

C. REMARKS: The subject drug product was filled into flexible plastic containers made using \_\_\_\_\_ process at the Rocky Mount, NC facility of Abbott Laboratories. The subject amendment provides for the response to microbiology deficiencies in the facsimile letter, dated July 25, 2000.

D. CONCLUSIONS: The submission is **recommended** for approval on the basis of sterility assurance. Specific comments are provided in "E. Review Notes".

Nrapendra Nath, Ph.D. 5/22/01

Nrapendra Nath, Ph.D.

② 5/22/01

cc: Original ANDA

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Micro Rev. 3

5/22/01

OFFICE OF GENERIC DRUGS, HFD-640  
Microbiology Review #2  
July 12, 2000

A. 1. ANDA 65-027

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

2. PRODUCT NAME: Clindamycin Phosphate Injection in 5% Dextrose
3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Solution for I.V. injection (6mg/mL, 12mg/mL and 18mg/mL) in single dose 50 mL plastic containers (Form Fill Seal)
4. METHOD(S) OF STERILIZATION:
5. PHARMACOLOGICAL CATEGORY: Antibiotic

B. 1. DATE OF INITIAL SUBMISSION: August 31, 1998

2. DATE OF AMENDMENT: June 16, 2000  
Subject of this review (Received June 19, 2000)

4. RELATED DOCUMENTS: None

5. ASSIGNED FOR REVIEW: June 23, 2000

C. REMARKS: The subject drug product was filled into flexible plastic containers made using \_\_\_\_\_ process at the Rocky Mount, NC facility of Abbott Laboratories. The subject amendment provides for the response to microbiology deficiencies in the facsimile letter, dated April 27, 2000.

D. CONCLUSIONS: The submission is **not recommended** for approval on the basis of sterility assurance. Specific comments are provided in "E. Review Notes" and "Microbiology Comments To Be Provided To The Applicant" found at the end of this review. The above deficiencies represent a minor amendment.

*Nrapendra Nath* 7/12/2000  
Nrapendra Nath, Ph.D.

cc:

*(CSA)* 7/12/00

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micro Rev 2

2/12/00

OFFICE OF GENERIC DRUGS, HFD-640  
Microbiology Review #1  
April 19, 2000

A. 1. ANDA 65-027

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

2. PRODUCT NAME: Clindamycin Phosphate Injection in 5%  
Dextrose

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Solution for  
I.V. injection (6mg/mL, 12mg/mL and 18mg/mL) in single  
dose 50 mL plastic containers (Form Fill Seal)

4. METHOD(S) OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: Antibiotic

B. 1. DATE OF INITIAL SUBMISSION: August 31, 1998

Subject of this Review (Received Sep.9, 1998)

2. DATE OF AMENDMENT: October 29, 1999

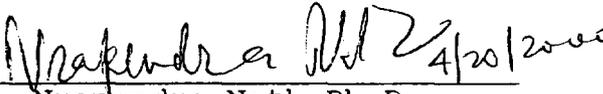
~~Subject of this review~~ (Received November 2, 1998)

4. RELATED DOCUMENTS: None

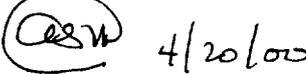
5. ASSIGNED FOR REVIEW: November 16, 1999

C. REMARKS: The subject drug product was filled into flexible  
plastic containers made from \_\_\_\_\_ process  
at the Abbott Laboratories manufacturing facilities in Rocky  
Mount, NC. The subject drug product solution was sterile  
filtered. The amendment dated October 29, 1999 was reviewed  
for its microbiology content.

D. CONCLUSIONS: The submission is **not recommended** for  
approval on the basis of sterility assurance.  
Specific comments are provided in "E. Review  
Notes" and "Microbiology Comments To Be  
Provided To The Applicant" found at the end  
of this review. The above deficiencies  
represent a **major** amendment.

  
\_\_\_\_\_  
Nrapendra Nath, Ph.D.

cc:

  
4/20/00

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