

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

65-027

CHEMISTRY REVIEW(S)

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Generic Drugs
Abbreviated New Drug Application Review

1. CHEMISTRY REVIEW NO. 3
2. ANDA #65-027
3. NAME AND ADDRESS OF APPLICANT
Abbott Laboratories
Attention: Mr. Chris Markos
200 Abbott Park Road D-389 AP30
Abbott Park, IL 60064-3537
4. BASIS OF SUBMISSION
The RLD is Cleocin® Phosphate (clindamycin phosphate injection) in 5% dextrose, 6, 12 and 18 mg/mL manufactured by Pharmacia Upjohn Co., marketed in plastic containers. The patent has expired and it is not entitled to a period of marketing exclusivity. NDA 50-639 was approved on 8/30/89.
5. SUPPLEMENT (s)
N/A
6. Proprietary Name
N/A
7. NONPROPRIETARY NAME
Clindamycin Phosphate Injection in 5% Dextrose, 300 mg/50 mL
Clindamycin Phosphate Injection in 5% Dextrose, 600 mg/50 mL
Clindamycin Phosphate Injection in 5% Dextrose, 900 mg/50 mL

All in 50 mL plastic container
8. SUPPLEMENT (s) PROVIDE (s) FOR
N/A
9. AMENDMENTS AND OTHER DATES:
August 31, 1998-- Original Submission
September 9, 1998-- Acceptable for filing
October 1, 1998-- Telecom
October 13, 1998-- New correspondence
November 10, 1998-- Bio waiver acceptable
November 25, 1998-- Labeling review

April 22, 1999-----Chemistry Deficiency letter
 October 29, 1999----Major Amendment
 May 24, 2000-----Minor Amendment
 June 16, 2000 ----Microbiology Amendment
 May 11, 2001-----Chemistry/Microbiology Amendment

10. **PHARMACOLOGICAL CATEGORY**

Antibacterial

11. **Rx or OTC**

Rx

12. **RELATED DMF's**

ner

USP

13. **DOSAGE FORM**

Injection

14. **POTENCY**

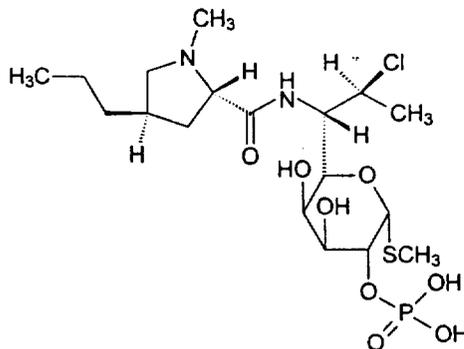
6 mg (base)/mL (300 mg)

12 mg (base)/mL (600 mg)

18 mg (base)/mL (900 mg)

15. **CHEMICAL NAME AND STRUCTURE**

Clindamycin Phosphate. *L-threo- α -galacto-Octopyranoside, methyl 7-chloro-6,7,8-trideoxy-6-[[(1-methyl-4-propyl-2-pyrrolidiny) carbonyl]-amino]-1-thio-, 2-(dihydrogen phosphate), (2*S-trans*)-*. C₁₈H₃₄ClN₂O₈PS. 504.97.
 CAS # 24729-96-2.



16. **RECORDS AND REPORTS**

None

17. COMMENTS:

- A methods validation package was sent to the district laboratory. The laboratory found the methods to be satisfactory. The following finished dosage methods were tested:
 - Potency Assay of Clindamycin Phosphate
 - Related Substances of Clindamycin Phosphate
 - Dextrose Assay
 - Low level Hydrogen Peroxide determination
 - EDTA Assay
- Although the DMF for the FFS container has been found to be adequate within the past year, another look has been taken at the extraction data provided. DMF was again found to be adequate. The DMF for the drug substance is also adequate.
- EER inspection found the plant to be acceptable.
- Micro review has been completed and is satisfactory as of 5/22/01.
- Labeling has issued an approval summary to be attached to the chemistry review.

18. CONCLUSIONS AND RECOMMENDATIONS:- Recommend approval

19. <u>REVIEWER</u>	<u>DATE COMPLETED</u>
Susan Zuk	5/30/01

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Contain Trade Secret,
Commercial/Confidential
Information and are not
releasable.

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5/30/01