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RESEARCH**

*APPLICATION NUMBER:*

**65-027**

**BIOEQUIVALENCE**

Clindamycin Phosphate Injection  
In 5% Dextrose, USP 6, 12, 18 mg/mL  
ANDA 65-027  
Reviewer: Surendra P. Shrivastava  
WP 65027w.998

1-1  
Abbott Laboratories, Inc.  
Abbott Park, Ill  
Submission Date:  
September 9, 1998

**REVIEW OF WAIVER REQUESTS FOR  
THREE INJECTABLE FORMULATIONS**

The firm has requested a waivers for *in vivo* bioequivalence studies for its Clindamycin Phosphate in 5% dextrose injectable formulations, 6, 12 and 18 mg/mL USP, under 21 CFR 320.22(b)(1). The firm had made similar request under another ANDA #63-344, which was withdrawn on September 3, 1993, due to Chemistry deficiencies (see Attachments 1, 2).

The firm has submitted the comparative amounts for ingredients in Cleocin<sup>R</sup> Phosphate (Reference) and the test product formulations. The test products are injectable i.v. solutions.

**COMMENTS**

1. The composition of the innovator and Abbott Laboratories, Inc. formulations are identical (see Table 1).

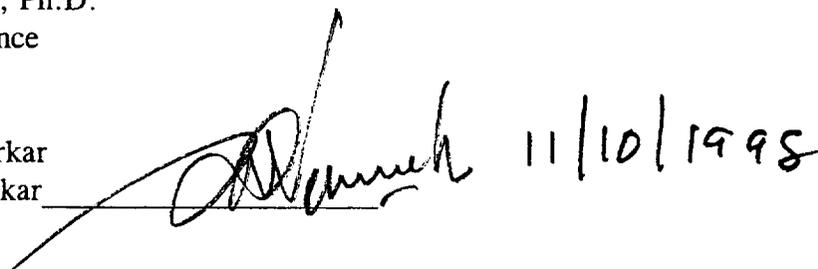
**RECOMMENDATION**

The Division of Bioequivalence agrees that the information submitted by Abbott Laboratories, demonstrates that clindamycin phosphate in 5% dextrose injectable, 6, 12 and 18 mg/mL, falls under 21 CFR Section 320.22(b)(1) of the Bioavailability Regulations. The waivers of *in vivo* bioequivalence study for 6, 12 and 18 mg/mL of the test products are granted. From the bioequivalence point of view, the Division of Bioequivalence deems the test injectable formulations to be bioequivalent to Cleocin<sup>R</sup> Phosphate in dextrose, 6, 12 and 18 mg/mL, manufactured by Pharmacia Upjohn Company.



Surendra P. Shrivastava, Ph.D.  
Division of Bioequivalence  
Review Branch II

RD INITIALED SNerurkar  
FT INITIALED SNerurkar



Concur: Dale P. Conner Date 11/12/98  
Dale Conner, Pharm.D.  
Director  
Division of Bioequivalence

Attachments-2  
SPS/sps/11-9-98/65027w.998

cc: