

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 4429

NATIONAL ACADEMY OF SCIENCES—NATIONAL RESEARCH COUNCIL
Division of Medical Sciences

DRUG EFFICACY STUDY

Form A

(To be submitted in duplicate by applicant)

1. NDA Number 60306¹ (90136) 2. Date Originally Approved October 5, 1951 3. Rx ☒ OTC ☐
4. Brand Name Chloromycetin Palmitate Oral Suspension
5. Applicant's Name Parke, Davis & Company
6. and Address Joseph Campau at the River; Detroit, Michigan

6. Quantitative Formula

Published (Non-Proprietary) Name of Active Ingredients (in order shown on label)	Amount (per tablet, per ml., etc.)
Chloramphenicol Palmitate	125 mg./4 cc.

Dosage Form (tablets, etc.) suspension

Route of Adm. (Oral, etc. Where a new drug application covers different routes of administration, separate forms should be used.) oral

Therapeutic Claims—Attach 10 labels and 10 package inserts (if used) to original Form A (blue) and 1 copy to duplicate Form A (white).

List of literature references most pertinent to an evaluation of the effectiveness of the drug for the purposes for which it is offered in the label, the package insert, or brochure. Approximately 5 to 10 key references are requested, if available. (Attach 10 copies to original Form A (blue) and 1 copy to duplicate Form A (white).)

The applicant is invited, if he so desires, to submit any unpublished material that is pertinent to the evaluation of the drug by the Academy—Research Council. This supplementary material should be packaged with Form A (white). A single copy of this material is requested.

In this space, please list and describe briefly the supplementary material that is submitted with Form A (white).