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PREFACE

The theme for the 1983 Industrial Pharmaceutical R & D Symposium at Rutgers University, College of Pharmacy was devoted to Oral Controlled Drug Administrations: Impact of Science, Technology, and Regulation. This symposium was organized with objective of providing scientific and regulatory information to those interested in the fundamentals of oral controlled drug administrations and in the development of novel oral drug delivery systems for long-term, continuous medication. It took place on January 19 & 20, 1983 at the newly completed Hyatt Regency Hotel in New Brunswick. Like the first symposium we had organized in 1982 on Transdermal Controlled Release Medication, this conference again provided a forum for multidisciplinary interactions and scientific exchange among academia, industry, regulatory agencies and financial circles.

This 2-day symposium was organized in a logical format to consist of 4 sessions:

A) Fundamentals of Oral Drug Administrations
   1) Physiological considerations
   2) Physico-chemical considerations
   3) Pharmacokinetic considerations

B) Development and Assessment of Oral Sustained-release Drug Delivery Systems
   1) Developmental concepts
   2) Spansule sustained-release formulations
   3) Theodur-pediatric sustained-release formulations

C) Exploration in Oral Controlled-release Drug Delivery Systems
   1) Potential developments and new approaches
   2) Hydrodynamically-balanced system
   3) Oros osmotic-controlled formulations - new developments
   4) Susadrin transmucosal tablets

D) Regulatory and General Review of Oral-controlled Drug Administration
   1) Review of manufacturing and controls requirements
   2) Review of biopharmaceutics requirements
   3) Review of medical requirements
   4) Design of oral drug delivery systems - past, present and future

The 14 lectures were delivered, in the logical sequence outlined above, by six academic researchers, five industrial scientists, and three regulatory officers. These lectures were well received and highly commented by the more than 150 participants.

Professor A. F. Hofmann of The University of California at San Diego, Professor N. F. H. Ho of The University of Michigan, and Professor P. G. Welling of the University of Wisconsin were invited to analyze the fundamentals of oral drug administrations from physiological, physicochemical and pharmacokinetic points of view. Professor J. R. Robinson of The University of Wisconsin outlined the concepts behind the development of various sustained-release drug delivery systems. Professor Y. W. Chien of Rutgers University reviewed various potential developments and new approaches in oral controlled-release drug delivery systems. Professor W. I. Higuchi of The University of Utah highlighted the past, present and future of the design of oral drug delivery systems to conclude the 2-day conference.

We at Rutgers University, College of Pharmacy were very pleased to have 5 industrial scientists discussing their innovative development of various oral sustained- and controlled-release drug delivery systems: Dr. L. Ravin of Smith, Kline & Beckman Corporation gave a historical overview of the development of Spansule formulations; Dr. M. A. Gonzales of Key Pharmaceuticals, Inc. discussed their new development of Theo-Dur Sprinkle formulation for pediatric patients; Dr. A. H. Goldberg of Roche Laboratories reported their patented development of hydrodynamically-balanced system to prolong the gastric residence time of drug delivery systems; Dr. F. Theeuwes of Alza Corporation outlined the successful application of elementary osmotic pump principles in the development of an oral controlled-release tablet for indomethacin; Dr. J. M. Schor of Forest Laboratories, Inc. highlighted the development of saliva-activated adhesive tablets for prolonged buccal administration of highly hepatic clearance drugs to bypass the hepatic first-pass elimination.

We were also very fortunate to have Dr. C. Kumkumian, Dr. H. Malinowski, and Dr. V. Karusaitis of Food and Drug Administration participating our conference to outline various regulatory submissions and review processes of oral controlled-release drug products. They reviewed various requirements of manufacturing and controls, biopharmaceutics, and medical in the submissions.

As the organizer, I wish to express my sincere thanks for the encouragement, inputs and support from Dean J. L. Colaizzi, Professor W. I. Higuchi, Dr. L. Lachman, Professor N. G. Lordi, and Professor B. J. Sciarrone. The assistance of Ms. J. A. Kulesza and Mr. J. Hegelmann from Rutgers College of Pharmacy's extension office was greatly appreciated. Without their invaluable inputs and supports, a successful symposium like the one we had would not have been possible.

In response to the overwhelming request from the symposium participants and others interested in the research and development of oral controlled-release drug delivery systems, we have again collaborated with the Marcel Dekker, Inc. to publish the lectures as a special symposium issue in Drug Development and Industrial Pharmacy. As the first symposium issue on Transdermal Controlled Release Medication [DD & IP, 9 (4) 497-744 (1983)], each of the 12 articles published in this special symposium issue has been subjected to peer review process and accepted for publication on its own scientific merit based on the publication guidelines and standards established for this journal. So it may have taken a slightly longer time from the conference to the publication than other symposium proceedings do. We are very pleased with this peer review process, which assures the readership the quality of the scientific information in this publication that he or she has received.

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