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PHARMACEUTICAL EXCIPIENTS COME OF AGE

For a great variety of reasons, but all with the objective of serving the needs of its membership specifically and the needs of the profession of pharmacy and the health care community in general, APhA has embarked on a broad publication program which now includes a complete spectrum of journals, pamphlets, workbooks, textbooks, audio-visual aids, newsletters, and so on. If it is true that *"Heinz has pickles,"* then it can equally be said that *"APhA has publications!"*

Given the fact that the Association is knee-deep in the products of its publications program, something really special would need to come along for us to devote this column to a discussion of just one of these literary undertakings. Moreover, if the end-product of that undertaking is still a couple of years off, then it needs to be more than special but even extra-special. And, in our opinion, the prospective item we have in mind looks as if it will be just that.

For many years, pharmaceutical scientists have devoted considerable time, attention, and effort to devising definitions, tests, standards, assays, specifications, and the like for drug entities and drug dosage forms. Indeed, they did such a good job that Congress legally recognized two products of this activity—the *United States Pharmacopeia* and the *National Formulary*—as "official compendia," and mandated that bulk drug substances and marketed drug dosage forms comply with the standards or be subject to enforcement actions on legal grounds of misbranding or adulteration.

In formulating drug dosage forms, pharmaceutical research and development staff will generally utilize a variety of substances that are intended to transform the simple drug active ingredient into a pharmaceutically elegant dosage form. These substances are broadly referred to as pharmaceutical excipients, aids, or adjuncts, and while contributing to the overall quality of the product, they are not intended to have any physiological effect of their own. They impart improved properties such as appearance, flavor, stability, ease of administration, and convenience.

Although standards, specifications, and the like have also been devised for some of these excipients, neither the breadth nor the depth of these efforts has compared to that devoted to the drug entities and dosage forms. Moreover, no concerted effort has been made to pull all this information together in a single reference source where it would be conveniently available as well as presented in a uniform and consistent format. Finally, the *kinds* of information most useful to a pharmaceutical scientist involved in product formulation are often quite different from those that may be appropriate for an excipient which is recognized in a compendium of tests and standards.

Given this background, a pharmacist and pharmaceutical scientist with a long background in drug product formulation, research, development, analysis, and specifications concluded that the time was over-ripe for someone to respond to this need. The man of vision in this case is Jack Cooper, a person who has been long active in APhA, its old Scientific Section and Industrial Pharmacy Section, and then the initial Past President when the APhA Academy of Pharmaceutical Sciences was created in the mid-1960's.

Approximately three years ago, Mr. Cooper conceived of the idea of developing a *Handbook of Pharmaceutical Excipients*, and then went about the job, virtually single-handedly, of convincing others of the value and need for such a compilation. In this process, he took his proposal to the APhA Academy of Pharmaceutical Sciences, and he won their endorsement, support, and agreement to take on the task as an Academy-sponsored project. He also recruited some 120 pharmaceutical scientists for service as volunteer collaborators on the various committees to identify and select excipients for inclusion, to ascertain and compile information currently known about those excipients, to develop new information in order to fill gaps in what is known, to verify literature values and data, and to prepare the resultant information in an orderly, organized monograph format.

Presently, Mr. Cooper reports that the project is moving steadily along, but it is still too early to predict a completion date. We do, however, wish to take this opportunity to congratulate the APS for taking on the sponsorship of this important project, and to salute Jack Cooper for his vision, determination, and dedication in undertaking immediate responsibility for its development. At the same time, we would encourage any of our readers with an interest in this subject to volunteer their efforts. As Project Chairman, Mr. Cooper can use all the assistance he can get. In his own words, "*. . . it has become increasing clear that a direct relationship exists between the amount of technical data in the monographs and the potential value of the book to pharmaceutical scientists.*"