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EDITORIAL

The subject of the 4th International Pharmaceutical Technology Symposium (IPTS-88) which was held during September 12-14,1988 at Hacettepe University,Ankara,Turkey,was stated as "New Approaches to the Formulation Studies in Pharmaceutical Solid Dosage Forms".

In IPTS-88 experts from universities,pharmaceutical industry and regulatory authorities were invited as speakers and Solid Dosage Forms were discussed in great detail by these invited speakers and the participants.

IPTS-88 has started with the opening speechs of the President of the Hacettepe University,Prof.Dr.A.Yüksel Bozer and the Dean and Chairman of the IPTS Organizing Committee,Prof.Dr.A.Atilla Hıncal. The opening ceremony has proceeded by the concert of the Anatolia Chamber Orchestra conducted by the State Artist Prof.Hikmet Şimşek.

21 plenary lectures were presented by the invited lecturers during the scientific session in the Meeting Halls of the Hacettepe University. 62 accepted scientific posters in pharmaceutical technology,drug analysis and quality control,biopharmaceutics and pharmacokinetics,and other pharmaceutical sciences were presented and one of the posters were given the "Best Scientific Poster Award" by a committee composed of the three invited lecturers. 150 participants and 21 invited lecturer from 19 different countries participated in IPTS-88.

The oral and the poster presentations have shown that there was a very balanced group between university,industry and regulatory authorities in discussing the new approaches in Solid Dosage Forms. We were very glad to present you in this special issue most of the papers of the invited lecturers.

The scientific sessions has started on September 12,1988 with the opening lecture of A.Le Hir (Universite Rene Descartes,Paris V, France) on "Good Manufacturing Practice in Pharmaceutical Production". In his talk,A.Le Hir has emphasized the importance of the implementation of the international system for the certification of the quality of pharmaceuticals,and also assurance. He also talked about the fundamentals of the recent French GMP.

S.A.Hanna (Bristol-Myers Co Labs.Syracuse,N.Y.,USA) has evaluated the importance of quality assurance in solid dosage forms and talked in detail about "Quality Assurance System".M.Traisnel (l'Universite du Droit et de la Sante, Faculte de Pharmacie,Lille,France) has talked about the quality assurance and staff training. He also stated

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that this training is carried out within the framework of the directives and recommendations of WHO and UNIDO.

The importance of standardization and physical performance of powders used in producing tablets and capsules were shown by P.J.Lockwood who talked in place of J.N.Staniforth (School of Pharmacy, University of Bath, Bath, U.K.) He also pointed out that the variations due to test methods and the apparatus could be the results of the variations among personnel and manipulations and he concluded that these factors are important in quality assurance. Y.Çapan (Faculty of Pharmacy, Hacettepe University, Ankara, Turkey) talked about the influence of technological factors on formulation of sustained release tablets. He also suggested the application of mathematical models to evaluate the release profiles. H.Nyqvist (ACO Lakemedel AB,Solna,Sweden) in his talk on "Influence of Substance Properties on Scaling up Tablet Formulations", showed the technological problems caused by the absorbed water during the formulation stage of furosemid tablets. M.J.Gamlen (Wellcome Foundation Ltd.,Kent, U.K.) demonstrated the importance of factorial design and statistical design by giving examples and also showed the advantages and limitations of accelerated stability tests and Arrhenius equation. A.Stamm (Faculte de Pharmacie l'Universite de Strasbourg,Strasbourg,France) showed the importance of formulation factors in solid dosage forms, whereas J.E.Hogan (Colorcon,S.R.L.,Milan,Italy) talked about the usage of hydroxypropylmethylcellulose in sustained release technology and has given examples of the application of HPMC as a hydrophilic matrix in oral controlled drug delivery. A.Cuine (Ardix,Orleans,France) compared the drug release from a hydrophilic,lyphophilic matrix system and an undissolved polymer and stated that the hydrophilic matrix is best for release kinetics. P.Guitard who talked in place of H.Sucker (Sandoz Ltd.,Basel,Switzerland), demonstrated the use of optimization techniques in pharmaceutical development. He pointed out the importance of factorial design, Stange-Pool equation,computerized grid search and the pharmacokinetical optimization.

J.Lignau (Bayer AG, Leverkusen, West Germany) emphasized the optimization and validation of manufacturing processes and also stated that according to the new draft FDA guidelines, drug products for clinical use have to comply with the GMP regulations. P. Colombo (Institute of Pharmaceutical Technology, Parma, Italy) demonstrated that the meaning and role of the word process validation is not well defined in pharmaceutical production. He emphasized the importance of obtaining the quality of each tablet in a lot. H.E.Junginger (Department of Pharmaceutical Technology, Leiden, The Netherlands) has given information in tablet formulation from microporous polypropylene and has demonstrated bioavailability results of oxprenolol tablets coated by microporous propylene. F. Hıncal (Faculty of Pharmacy, Hacettepe University, Ankara, Turkey) has giving the paper of W.A.Ritschel (University of Cincinnati, College of Pharmacy, Cincinnati, Ohio, USA; couldn't attend due to unexpected reasons) on biopharmaceutic and pharmacokinetic aspects in the design of controlled peroral drug delivery system. D. Trottman (Lab. Roussel-Uclaf, Paris, France) has given an interesting talk on applying GMP to computerization in the production of solid oral dosage forms.

During the symposium, besides the talks on design, formulation, bioavailability and pharmacokinetic evaluation of solid dosage forms by industrial and academic researchers, L.T. Grady (USP Convention, Rockville, Maryland, USA) and C.M.Edwards (FDA, Philedilphia, USA), has brought the regulations for solid dosage forms. L.T.Grady emphasized the compendial standards like identity, strength, quality, purity, packaging, storage and labeling. He also stated that dosage forms packaging are inseparable in discussing drug product quality and compendial standards for packaging materials.

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C.M.Edwards has stated that final version of a guideline for process validation for pharmaceutical manufacturing has been published in May 1987. He also talked about the definitions of process validation, worse case , installation, qualification, the number of runs required, acceptance criteria, batch record instructions, establishement of acceptable range limits, revalidation and retrospective validation. J.Lanet (UNIDO, Vienna, Austria; present address: Techniques d'Aide aux Affaires, Paris, France) in his talk emphasized the importance of self-inspection and audit. T.Geçgil (Roche İlaç Sanayi Ltd. Şti., İstanbul, Turkey) showed the role of quality assurance in preventing the error as opposed to detection and correction in all solid dosage production phases.

The scientific content of the symposium was complemented by a number of social events. Especially the performance of the Turkish State Folk Dance Group, the closing dinner at State Guest House and the post-symposium tour to Hierapolis/Aphrodisias/Ephesus/Kuşadası/İzmir formed the social side of the symposium.

We would like to thank Hacettepe University, International Scientific Committee, all the firms of the Turkish pharmaceutical industry and all the invited speakers and participants for their cooperation and support at different stages.

This special issue on 4th International Pharmaceutical Technology Symposium which is published in Drug Development and Industrial Pharmacy is composed of the lectures of the invited speakers which are approved by the reviewers. The acceptance of the papers by a popular journal like DDIP once again emphasized the scientific level of the Pharmaceutical Technology Symposiums held in Hacettepe University, Ankara, Turkey. We would like to express our sincere thanks to Prof.C.T.Rhodes for giving us the opportunity to publish the IPTS-88 proceedings in Drug Development and Industrial Pharmacy.

A. Atilla Hıncal, Ph.D.
H. Süheyla Kaş, Ph.D.
Murat Şumnu, Ph.D.

Hacettepe University
Faculty of Pharmacy
06100 - Ankara, Turkey
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