

AAPS ELECTRONIC SCIENTIST

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Science and Research
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**AAPS
PharmSciTech®**
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The Pramlintide Studies

Pramlintide is a 37-amino acid peptide under development for diabetes therapy. AAPS PharmSciTech has published a series of three articles concerning this peptide in the first two issues .

Orthogonal HPLC Methods For Quantitating Related Substances and Degradation Products of Pramlintide

By Richard A. Kenley, Wade Demond, James L. Italien, David Lokensgard, and G. Weilersbacher

This investigation describes analytical test methods for assuring the purity of the drug. These methods may have general application for analysis of complex peptides intended for therapeutic use.

Kinetics of Pramlintide Degradation in Aqueous Solution as a Function of Temperature and pH

By Richard A. Kenley, Scott Tracht, Anna Stepanenko, Michael Townsend, and James L'Italien .

The stability of pramlintide, in aqueous solution, was studied as a function of pH and temperature. Samples of pramlintide formulated as a parenteral product were exposed to elevated temperatures and to realistic storage conditions for as long as 30 months.

Pramlintide Injection Drug Product Robustness Studies

By Richard A. Kenley, Fred Bancroft, James L'Italien, Anna Stepanenko, Michael Townsend, and Trupti Dixit.

The article examines the effects of temperature excursions and actual dose withdrawal on the quality of pramlintide injection, a multidose liquid parenteral formulation. Studies were designed to demonstrate product robustness under conditions that may occur during patient use. Pramlintide injection drug product is extremely robust to challenging stress conditions that may occur during patient use of this multidose product for chronic administration.

Volume 1 Issue 2

Other articles in the second issue of AAPS PharmSciTech included:

Influence of Formulation and Process Parameters on Pellet Production by Powder Layering Technique

By: Claudio Nastruzzi, Rita Cortesi, Elisabetta Esposito, Alberto Genovesi, Alessandro Spadoni, Carlo Vecchio, Enea Menegatti

The goal of the present study was to evaluate the influence of the formulation and operating conditions on pellet preparation by pan technique. To this end, a new pelletization process, typified by the application of powdered drug on sugar-based cores using the GS coating system was studied.

AAPS PharmSciTech:
Volume 1 Issue 2 (cont.)

Next Generation Fluidized Bed Granulator Automation

By: Jukka Rantanen, Markku
Känsäkoski, Janne Suhonen, Jussi
Tenhunen, Seppo Lehtonen, Tarja
Rajalahti, Jukka-Pekka Mannermaa and
Jouko Yliruusi

In this study, Fluidized bed granulator (FBG) automation with in-line multi-channel NIR moisture measurement and a unique air flow rate measurement design was assembled, and the information gained was investigated. Development of process analytical methods together with new data visualization algorithms creates new tools for in-process control of the fluidized bed granulation.

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AAPS PharmSci – Theme Issues

AAPS PharmSci will continue to accept submissions for publication in Theme Issues. One very successful theme issue is continuing to accept submissions on the topic of:

Pharmacogenetics- Pharmacogenomics

Manuscripts are invited from the broad range of topics including:

- 1) Genetic basis of variability in drug response;
- 2) Polymorphisms of receptors, enzymes, and transporters;
- 3) Phenotyping tissues for drug effects;
- 4) Detection of polymorphisms;
- 5) Genome-wide mapping of single nucleotide polymorphisms in drug trials;
- 6) Genes conferring disease susceptibility and/or sensitivity to drug therapy;
- 7) DNA microarray technology;
- 8) Genomics, proteomics, cellomics;
- 9) Cloning genes relevant to drug effects;
- 10) Clinical drug studies involving pharmacogenetics - pharmacogenomics;
- 11) Pharmacokinetics/Pharmacodynamics and genetic variations;
- 12) Pharmacogenomics in drug discovery and development;
- 13) Genomics of microorganisms and viruses related to drug treatment;
- 14) Incidence of adverse drug effects in relation to genetic variations;
- 15) Pharmacoepidemiology;
- 16) Pharmacoeconomics.

NOTICE: There is still time to be a part of the historic first volume of the new online journal *AAPS PharmSciTech* !
Easy Submissions, super-fast expert review, and the full use of electronic publication technology all translates into the quickest publication time you've ever seen!