

**CURRENT
AWARENESS
ISSUE**

Journal of Pharmaceutical Sciences

Volume 96 Number 2 February 2007

Univ. of Minn.
Bio-Medical
Library
02 07 07



American Pharmacists Association™
Improving medication use. Advancing patient care.

Articles Published Online in Wiley InterScience, 18 October 2006 - 1 November 2006

**DOCKET
ALARM**

Find authenticated court documents without watermarks at docketalarm.com.

JOURNAL OF Pharmaceutical Sciences



A Publication of the American Pharmacists Association



A Publication of the Board of Pharmaceutical
Sciences of the International Pharmaceutical
Federation



American Association of
Pharmaceutical Scientists

Published in Cooperation with the American
Association of Pharmaceutical Scientists

The *Journal of Pharmaceutical Sciences* (Print ISSN 0022-3549; Online ISSN 1520-6017 at Wiley Interscience, www.interscience.wiley.com) is published monthly (one volume per year), by Wiley-Liss, Inc., through Wiley Subscription Services, Inc., a Wiley Company, 111 River Street, Hoboken, NJ 07030, and the American Pharmacists Association, 2215 Constitution Avenue NW, Washington, DC 20037.

Copyright © 2006 Wiley-Liss, Inc., a Wiley Company, and the American Pharmacists Association. All rights reserved. No part of this publication may be reproduced in any form or by any means, except as permitted under section 107 or 108 of the 1976 United States Copyright Act, without either the prior written permission of the publisher, or authorization through the Copyright Clearance Center, 222 Rosewood Drive, Danvers, MA 01923, Tel.: (978) 750-8400, Fax: (978) 750-4470. Periodicals postage paid at Hoboken, NJ and at additional mailing offices.

The copyright notice appearing at the bottom of the first page of an article in this journal indicates the copyright holder's consent that 2 copies may be made for personal or internal use, or for personal or internal use of specific clients, on the condition that the copier pay for copying beyond that permitted by law. This consent does not extend to other kinds of copying such as copying for general distribution, for advertising or promotional purposes, for creating new collective works, or for resale. Such permission requests and other permission inquiries should be addressed to the Permissions Department, c/o John Wiley & Sons, Inc., 111 River Street, Hoboken, NJ 07030; Tel.: (201) 748-6011; Fax: (201) 748-6008; or visit <http://www.wiley.com/go/permissions>.

Subscription Price (Volume 96, 2007): Print only: \$1,295.00 in U.S., Canada, and Mexico, \$1,352.00 outside North America. For all other prices please consult the journal's website at www.interscience.wiley.com/jpharmsci. Subscriptions at the personal rate are available to individuals. All subscriptions containing a print element, shipped outside U.S., will be sent by air. Payment must be made in U.S. dollars drawn on U.S. bank. Claims for undelivered copies will be accepted only after the following issue has been delivered. Please enclose a copy of the mailing label. Missing copies will be supplied when losses have been sustained in transit and where reserve stock permits. Please allow four weeks for processing a change of address. For subscription inquiries, please call (201) 748-6645; E-mail: SUBINFO@wiley.com.

Postmaster: Send address changes to *Journal of Pharmaceutical Sciences*, Subscription Distribution, c/o John Wiley & Sons, Inc., 111 River Street, Hoboken, NJ 07030. For subscription inquiries, please call customer service at (201) 748-6645 or write to the above address.

Advertising Sales: Inquiries concerning advertising should be forwarded to Advertising Sales, c/o John Wiley & Sons, Inc., 111 River Street, Hoboken, NJ 07030, (201) 748-8832.

Manuscript Submission: Five copies of the manuscript must be submitted together with a transmittal letter and a signed Copyright Transfer Agreement to the Editor: Dr. Ronald T. Borcharadt, Department of Pharmaceutical Chemistry, The University of Kansas, 2095 Constant Ave., Room 121A, Lawrence, KS 66047. [Tel: (785) 864-5919; Fax: (785) 864-5875; E-mail: rborcharadt@ku.edu or tdunning@ku.edu]

Reprints: Reprint sales and inquiries should be directed to the Customer Service Department, c/o John Wiley & Sons, Inc., 111 River Street, Hoboken, NJ 07030, Tel.: (201) 748-8789.

Other Correspondence: Address all other correspondence to *Journal of Pharmaceutical Sciences*, Publisher, STM, c/o John Wiley & Sons, Inc., 111 River Street, Hoboken, NJ 07030 or jpsprod@wiley.com.

The contents of this journal are indexed in the following: *Analytical Abstracts (RSC)*, *CAB Abstracts*[®] (*CABI*), *Cambridge Scientific Abstracts (CIG)*, *CCR Database (Thomson ISI)*, *Chemical Abstracts Service/SciFinder (ACS)*, *Chemistry Server Compound Center (Thomson ISI)*, *Chemistry Server Reaction Center (Thomson ISI)*, *ChemPrep*[™] (*Thomson ISI*), *Chimica Database (Elsevier)*, *Chromatography Abstracts (RSC)*, *Current Chemical Reactions*[®] (*Thomson ISI*), *Current Contents*[®] (*Life Sciences (Thomson ISI)*), *EMBASE/Excerpta Medica (Elsevier)*, *Index Chemicus*[®] (*Thomson ISI*), *Index Medicus/MEDLINE/PubMed (NLM)*, *International Pharmaceutical Abstracts (Thomson ISI)*, *MDL Beilstein (Elsevier)*, *Reaction Citation Index*[™] (*Thomson ISI*), *Reference Update (Thomson ISI)*, *Science Citation Index*[®] (*Thomson ISI*), *Science Citation Index Expanded*[™] (*Thomson ISI*), *SCOPUS (Elsevier)*, and *SIC Databases (Sociedad Iberoamericana de Informacion Cientifica)*.

This paper meets the requirements of ANSI/NISO
Z39.48-1992 (Permanence of Paper).

JOURNAL OF
Pharmaceutical
Sciences

VOLUME 96, NUMBER 2
FEBRUARY 2007

REVIEW

- Lipid Formulation Strategies for Enhancing Intestinal Transport and Absorption of P-Glycoprotein (P-gp) Substrate Drugs: *In vitro/In vivo* Case Studies**
Panayiotis P. Constantinides* and Kishor M. Wasan 235
Published online 18 October 2006

COMMENTARY

- On the Calculation of the Concentration Dependence of Drug Binding to Plasma Proteins with Multiple Binding Sites of Different Affinities: Determination of the Possible Variation of the Unbound Drug Fraction and Calculation of the Number of Binding Sites of the Protein**
Leonid M. Berezhkovskiy 249
Published online 18 October 2006

COMMUNICATIONS

- Diffusion of Nutrients Molecules and Model Drug Carriers Through Mucin Layer Investigated by Magnetic Resonance Imaging with Chemical Shift Resolution**
Géraldine Lafitte,* Krister Thuresson, and Olle Söderman 258
Published online 12 October 2006
- Quantitation of Crystalline Material within a Liquid Vehicle using $^1\text{H}/^{19}\text{F}$ CP/MAS NMR**
Brian T. Farrer,* Andrey Peresyphkin, and Robert M. Wenslow 264
Published online 18 October 2006

RESEARCH ARTICLES

BIOTECHNOLOGY

- Quantitation of Aggregate Levels in a Recombinant Humanized Monoclonal Antibody Formulation by Size-Exclusion Chromatography, Asymmetrical Flow Field Flow Fractionation, and Sedimentation Velocity**
John P. Gabrielson, Mark L. Brader, Allen H. Pekar, Kathrin B. Mathis, Gerhard Winter, John F. Carpenter, and Theodore W. Randolph* 268
Published online 1 November 2006

(continued)

Journal of Pharmaceutical Sciences
VOL. 96, NO. 2, FEBRUARY 2007

WILEY This journal is online
InterScience®
www.interscience.wiley.com

Volume 96, Number 2 was mailed the week of January 25, 2007.

**DOCKET
ALARM**

Find authenticated court documents without watermarks at docketalarm.com.

DRUG DISCOVERY INTERFACE

- Impact of Cremophor-EL and Polysorbate-80 on Digoxin Permeability across Rat Jejunum: Delineation of Thermodynamic and Transporter Related Events Using the Reciprocal Permeability Approach**
Kasiram Katneni, Susan A. Charman, and Christopher J.H. Porter* 280
Published online 18 October 2006

PHARMACEUTICS PREFORMULATION AND DRUG DELIVERY

- Factors Affecting the Formation of Eutectic Solid Dispersions and Their Dissolution Behavior**
Sudha R. Vipparagunta,* Zeren Wang, Stefanie Hornung, and Steven L. Krill 294
Published online 18 October 2006

- Iontophoretic Drug Delivery across Human Nail**
S. Narasimha Murthy,* Dora E. Wiskirchen, and Christopher Paul Bowers 305
Published online 1 November 2006

- Precipitation Complexation Method Produces Cannabidiol/ β -Cyclodextrin Inclusion Complex Suitable for Sublingual Administration of Cannabidiol**
Janne Mannila,* Tomi Järvinen, Kristiina Järvinen, and Pekka Jarho 312
Published online 18 October 2006

- Selectivity of Similar Compounds Identification Using IR Spectroscopy: Steroids**
Nina Sadlej-Sosnowska* and Agnieszka Ocios 320
Published online 18 October 2006

- Analysis of Coating Structures and Interfaces in Solid Oral Dosage Forms by Three Dimensional Terahertz Pulsed Imaging**
J. Axel Zeitler, Yaochun Shen, Colin Baker, Philip F. Taday,* Michael Pepper, and Thomas Rades 330
Published online 30 October 2006

- Air-Liquid Interface (ALI) Culture of Human Bronchial Epithelial Cell Monolayers as an *In Vitro* Model for Airway Drug Transport Studies**
Hongxia Lin, Hong Li, Hyun-Jong Cho, Shengjie Bian, Hwan-Jung Roh, Min-Ki Lee, Jung Sun Kim, Suk-Jae Chung, Chang-Koo Shim, and Dae-Duk Kim* 341
Published online 1 November 2006

- Effect of Moisture and Pressure on Tablet Compaction Studied With FTIR Spectroscopic Imaging**
Noha Elkhider, K.L. Andrew Chan, and Sergei G. Kazarian* 351
Published online 1 November 2006

- Hot-Melt Extrusion for Enhanced Delivery of Drug Particles**
Dave A. Miller, Jason T. McConville, Wei Yang, Robert O. Williams III,* and James W. McGinity* 361
Published online 30 October 2006

- The Relationship Between Water Vapor Absorption and Desorption by Phospholipids and Bilayer Phase Transitions**
Heidi M. Mansour* and George Zografi 377
Published online 1 November 2006

PHARMACEUTICAL NANOTECHNOLOGY

- Biodistribution and Pharmacokinetic Analysis of Long-Circulating Thiolated Gelatin Nanoparticles Following Systemic Administration in Breast Cancer-Bearing Mice**
Sushma Kommareddy and Mansoor Amiji* 397
Published online 30 October 2006

PHARMACEUTICAL TECHNOLOGY

Modified Cellulose II Powder: Preparation, Characterization, and Tableting Properties

Maria de la Luz Reus Medina and Vijay Kumar* 408
Published online 30 October 2006

Preparation of Insulin Loaded PLGA-Hp55 Nanoparticles for Oral Delivery

Fu-de Cui,* An-jin Tao, Dong-mei Cun, Li-qiang Zhang, and Kai Shi 421
Published online 18 October 2006

In Vivo Drug Metabolism Model for Human Cytochrome P450 Enzyme Using Chimeric Mice with Humanized Liver

Miki Katoh, Toshiro Sawada, Yoshinori Soeno, Miki Nakajima, Chise Tateno, Katsutoshi Yoshizato, and Tsuyoshi Yokoi* 428
Published online 18 October 2006

Modifying Drug Release and Tablet Properties of Starch Acetate Tablets by Dry Powder Agglomeration

Riikka Mäki,* Eero Suihko, Susanne Rost, Minna Heiskanen, Matti Murtomaa, Vesa-Pekka Lehto, and Jarkko Ketolainen 438
Published online 30 October 2006

Determination of the Hydrolysis Kinetics of α -Naphthyl Acetate in Micellar Systems and the Effect of HPMC (Catalyst Present)

Pornpen Werawatganone and Dale Eric Wurster* 448
Published online 30 October 2006

PHARMACOKINETICS, PHARMACODYNAMICS AND DRUG METABOLISM

Development and Validation of a Preclinical Food Effect Model

Kimberley A. Lentz,* Megan Quitko, Daniel G. Morgan, James E. Grace Jr., Carol Gleason, and Punit H. Marathe 459
Published online 30 October 2006

In papers with more than one author, an asterisk (*) in the byline indicates the author to whom inquiries should be directed.

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.