

Journal of pharmaceutical sciences.(IM)  
v. 96, no. 10 (Oct. 2007)  
General Collection  
W1 JO829  
2007-10-18 10:34:25

# Pharmaceutical Sciences

Volume 96 Number 10 October 2007



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

Articles Published Online in Wiley InterScience, 11 May 2007 - 14 August 2007

**DOCKET  
ALARM**

Page 1 of 17

Find authenticated court documents without watermarks at [docketalarm.com](http://www.docketalarm.com)

Kaken Exhibit 2048

Acruz v. Kaken

IPR2007-00190

# 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](http://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 © 2007 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](http://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](mailto: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. Borchardt, 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: [rborchardt@ku.edu](mailto:rborchardt@ku.edu) or [tdunning@ku.edu](mailto: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](mailto: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 *SIIC Databases (Sociedad Iberoamericana de Informacion Cientifica)*.

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

This material was copied

JOURNAL OF  
Pharmaceutical  
Sciences

VOLUME 96, NUMBER 10  
OCTOBER 2007

**Editorial**

Ronald T. Borhardt . . . . . 2507  
*Published online 13 August 2007*

**MINIREVIEWS**

**Enaminones: Exploring Additional Therapeutic Activities**

Ivan O. Edafiogho, Samuel B. Kombian, Kethireddy V. V. Ananthalakshmi, Noha N. Salama,  
Natalie D. Eddington, Tiffany L. Wilson, Mariano S. Alexander, Patrice L. Jackson, Clive D. Hanson,  
and K.R. Scott\* . . . . . 2509  
*Published online 9 July 2007*

**Effects of Cyclodextrins on Drug Delivery Through Biological Membranes**

Thorsteinn Loftsson\*, Stine Byskov Vogensen, Marcus E. Brewster, and Fífa Konráðsdóttir. . . . . 2532  
*Published online 13 July 2007*

**REVIEWS**

**Role of Nanotechnology in Pharmaceutical Product Development**

Harikrishna Devalapally, Ananthsrinivas Chakilam and Mansoor M. Amiji\* . . . . . 2547  
*Published online 9 August 2007*

**Evaluation of the Chemical Compatibility of Plastic Contact Materials and  
Pharmaceutical Products; Safety Considerations Related to Extractables and  
Leachables**

Dennis Jenke . . . . . 2566  
*Published online 13 August 2007*

**Effect of Placental Fatty Acid Metabolism and Regulation by Peroxisome Proliferator  
Activated Receptor on Pregnancy and Fetal Outcomes**

Yan Xu, Qing Wang, Thomas J. Cook, and Gregory T. Knipp\* . . . . . 2582  
*Published online 4 June 2007*

(continued)

Journal of Pharmaceutical Sciences  
VOL. 96, NO. 10, OCTOBER 2007

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

Volume 96, Number 10 was mailed the week of September 24, 2007.

## RESEARCH ARTICLES

### BIOTECHNOLOGY

#### **The LC/MS Analysis of Glycation of IgG Molecules in Sucrose Containing Formulations**

Himanshu S. Gadgil\*, Pavel V. Bondarenko, Gary Pipes, Doug Rehder, Arnold Mcauley, Natalie Perico, Tom Dillon, Margaret Ricci, and Michael Treuheit . . . . . 2607  
*Published online 9 July 2007*

### DRUG DISCOVERY INTERFACE

#### **In Vitro Penetration of A Novel Oxaborole Antifungal (AN2690) into the Human Nail Plate**

Xiaoying Hui\*, Stephen J. Baker, Ronald C. Wester, Sherry Barbadillo, Anne K. Cashmore, Virginia Sanders, Karin M. Hold, Tsutomu Akama, Yong-Kang Zhang, Jacob J. Plattner, and Howard I. Maibach . . . . . 2622  
*Published online 9 July 2007*

### PHARMACEUTICS, PREFORMULATION AND DRUG DELIVERY

#### **An Examination of the Rheological and Mucoadhesive Properties of Poly(Acrylic Acid) Organogels Designed as Platforms for Local Drug Delivery to the Oral Cavity**

David S. Jones\*, Brendan C.O. Muldoon, A. David Woolfson, and F. Dominic Sanderson . . . . . 2632  
*Published online 13 August 2007*

#### **Critical Assessment of Inverse Gas Chromatography as Means of Assessing Surface Free Energy and Acid-Base Interaction of Pharmaceutical Powders**

Martin J. Telko and Anthony J. Hickey\* . . . . . 2647  
*Published online 22 May 2007*

#### **Effect of Polymer Molecular Weight on The Production of Drug Nanoparticles**

S. Sepassi, D.J. Goodwin, A.F. Drake, S. Holland, G. Leonard, L. Martini, and M.J. Lawrence\* . . . . . 2655  
*Published online 14 August 2007*

#### **The Role of the Cyclic Imide in Alternate Degradation Pathways for Asparagine-containing Peptides and Proteins**

Michael P. Dehart and Bradley D. Anderson\* . . . . . 2667  
*Published online 22 May 2007*

#### **Combined Use of Crystalline Salt Forms and Precipitation Inhibitors to Improve Oral Absorption of Celecoxib from Solid Oral Formulations**

Héctor R. Guzmán\*, Mark Tawa, Zhong Zhang, Pasut Ratanabanangkoon, Paul Shaw, Colin R. Gardner, Hongming Chen, Jean-Pierre Moreau, Örn Almarsson, and Julius F. Remenar. . . . . 2686  
*Published online 22 May 2007*

#### **Relaxation and Crystallization of Amorphous Carbamazepine Studied by Terahertz Pulsed Spectroscopy**

J. Axel Zeitler\*, Philip F. Taday, Michael Pepper, and Thomas Rades . . . . . 2703  
*Published online 14 August 2007*

### PHARMACEUTICAL TECHNOLOGY

#### **Modulation of Ganciclovir Intestinal Absorption in Presence of Absorption Enhancers**

Pranav Shah, Viral Jogani, Pushpa Mishra, Anil Kumar Mishra, Tamishraha Bagchi, and Ambikanandan Misra\* . . . . . 2710  
*Published online 6 August 2007*

<b>Utilization of a Modified Special-Cubic Design and an Electronic Tongue for Bitterness Masking Formulation Optimization</b> Lianli Li*, Venkatesh Naini, and Salah U. Ahmed . . . . .	2723
<i>Published online 16 May 2007</i>	
<b>Application of Direct Crystallization for Racemic Compound Propranolol Hydrochloride</b> Xiujuan Wang*, Jie Lu and Chi Bun Ching . . . . .	2735
<i>Published online 4 June 2007</i>	
<b>Investigation of the Influence of Particle Size on the Excipient Percolation Thresholds of HPMC Hydrophilic Matrix Tablets</b> Antonia Miranda, Mónica Millán*, and Isidoro Caraballo. . . . .	2746
<i>Published online 16 May 2007</i>	
<b>Fluorescence Studies of the Dehydration of Cefadroxil Monohydrate</b> Harry G. Brittain. . . . .	2757
<i>Published online 9 July 2007</i>	
<b>Solid State Chemistry of Proteins: I. Glass Transition Behavior in Freeze Dried Disaccharide Formulations of Human Growth Hormone (hGH)</b> Michael J. Pikal*, D.R. Rigsbee, and M.I. Roy . . . . .	2765
<i>Published online 9 July 2007</i>	
<b>pH Indicator Titration: A Novel Fast pKa Determination Method</b> Xiaole Kong, Tao Zhou, Zudong Liu, and Robert C. Hider*. . . . .	2777
<i>Published online 9 July 2007</i>	
<b>PHARMACOKINETICS, PHARMACODYNAMICS AND DRUG METABOLISM</b>	
<b>High Pressure Differential Scanning Calorimetry Investigations on the Pressure Dependence of the Melting of Paracetamol Polymorphs I and II</b> J. Ledru*, C.T. Imrie, C.R. Pulham, R. Céolin, and J.M. Hutchinson . . . . .	2784
<i>Published online 31 May 2007</i>	
<b>Role of Nitric Oxide in Downregulation of Cytochrome P450 1a1 and NADPH: Quinone Oxidoreductase 1 by Tumor Necrosis Factor-<math>\alpha</math> and Lipopolysaccharide</b> Negar Gharavi and Ayman O.S. El-Kadi* . . . . .	2795
<i>Published online 22 June 2007</i>	
<b>Grapefruit Juice–Drug Interactions: Grapefruit Juice and Its Components Inhibit P-Glycoprotein (ABCB1) Mediated Transport of Talinolol in Caco-2 Cells</b> Whocely Victor De Castro, Susanne Mertens-Talcott, Hartmut Derendorf, and Veronika Butterweck* . . . . .	2808
<i>Published online 31 May 2007</i>	
<b>Relative <i>in vitro</i> Efficacy of the Phosphate Binders Lanthanum Carbonate and Sevelamer Hydrochloride</b> Valerie Autissier, Stephen J.P. Damment, and Richard A. Henderson* . . . . .	2818
<i>Published online 11 May 2007</i>	

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.