INDIRAN PATHER, D. PHARM.

11991 Mandolin Way Rancho Cordova, CA 95742 email: <u>i.pather@yahoo.com</u> Phone: (H) 916-534-7409 (C) 916-865-6996

EXECUTIVE SUMMARY

Career Goals

- To disseminate knowledge by promoting innovative teaching, publications, presentations and consulting
- 2) To make a meaningful contribution to the improvement of human health through fostering research collaborations and excellence in the training of pharmacists

Present Position

Director of Research and Professor of Pharmaceutics, serving on numerous committees, including Research Committee (Chair), Strategic Planning Committee, Scholarship and Awards Committee (Chair) and IRB (Vice Chair). Previously served as Department Chair and also Chair of Curriculum Committee. Consultant to the pharmaceutical industry with regard to novel dosage form development and patents. Serve as reviewer for international pharmacy journals.

Previous Positions

Over a period of approximately 10 years in industry, held positions of increasing responsibility ranging from Senior Scientist to Director of Pharmaceutical Sciences at pharmaceutical companies. Responsibilities included in-house formulation development, scale up, technology transfer, establishing new labs and production suites (with engineers), patent writing and liaison with patent lawyers, analytical chemistry, and oversight of contract manufacturers. Approximately 15 years teaching experience prior to this: lab capabilities were greatly expanded, contract service to industry initiated, and helped plan major extensions to pharmacy building.

Achievements

One of initial faculty at new college: played a role in attaining accreditation, initiating teaching of first classes (served as Department Chair and Chair of Curriculum Committee). Major role in developing the first approved formulation for middle-of-thenight insomnia (Intermezzo®) and the lead role for a novel product for breakthrough cancer pain (Fentora®). Formulated and helped commercialize several vitamin, health supplement and OTC Dermatological products. Thirteen US patents with additional applications pending. Several papers and 4 book chapters; numerous presentations at international conferences. Invited speaker on drug delivery and patents.

Experience/ Skill Set

Experienced with accreditation (writing sections of documents and fielding questions from visiting teams). Skilled at teaching using Team-based learning. Set up and developed several labs (including GMP suites). Conducted University-based laboratory research that helped the school get funding & companies develop commercial products. Skilled in conceptualizing and developing innovative technologies, and in patent development. Some human Pharmacokinetic study experience (with CROs). Played a lead role in obtaining donor funding for major extensions to a Pharmacy School building.

Contents

Key Strengths and Accomplishments	3
Positions Held	3
Academic	8
Honorary Appointments	8
Professional Associations	9
Professional Advancement Courses	9
External Reviewer: Promotion and Tenure	9
Grant Reviewer	9
Journal Reviewer	9
Abstract Reviewer	10
South African Grants	10
U S Grant	10
Patents	10
Book Reviews	13
Books in Preparation	13
Publications	13
Abstracts	15
Presentations	16

KEY STRENGTHS AND ACCOMPLISHMENTS

ADMINISTRATION AND TEACHING

- Writing and editing accreditation documents
- Writing policies and contracts (latter reviewed by lawyer)
- Very good organizational and budgetary management skills
- Developing research collaborations and writing MOUs
- Excellent presentation skills investors and external relations
- Excellent teacher who is able to present complex ideas in a simple manner
- Experienced with Team Based Learning and introduced innovations
- Trained several students in research as part of their APPEs
- Have served as external examiner to other universities, central examiner for a national exam, grant and manuscript reviewer, external P&T reviewer

FORMULATION

- Aptitude for the development of novel dosage forms.
- Skilled formulator of pharmaceutical products
- Developed tablet formulations for the vitamin/ health supplement market
- Developed topical creams, and a gel for use during dental treatment
- Developed several marketed cosmetic products

CLINICAL TRIALS

- Assisted with planning, training and Compounding Record Writing for 3 clinical trials that used a compounding pharmacy for provision of clinical supplies
- Planning of clinical trials and writing of Protocol, Informed Consent and IRB submissions (with CRO)
- Clinical site visiting and serving as principal monitor
- Evaluation of results in collaboration with pharmacokineticists and medical consultants
- Presentation of data at meetings and in scientific literature

QUALITY CONTROL/ CHEMICAL ANALYSIS

 Experienced in many commonly-used techniques such as dissolution testing, spectrophotometry and HPLC. Some familiarity with flame photometry and FTIR.

POSITIONS HELD

2007 - California Northstate University College of Pharmacy, Sacramento, California.

Director of Research (from Oct 2010)

- Developing infrastructure and promoting research
- Developing policy documents
- Vice Chair of IRB
- Developing research collaborations

Chair: Pharmaceutical and Biomedical Sciences (Jan 2008 - Oct 2010)

- Assisted with preparation of syllabi & teaching materials for a new curriculum
- · Guided initial teaching

Professor of Pharmaceutics (from Oct 2007)

- Developed and implemented the Biopharmaceutics/ Pharmaceutics course using innovative teaching methods
- Oversaw initial development and implementation of curriculum as Chair of Curriculum Committee (2008 – July 2009)
- Other committees: Dean's executive, Bylaws and Policy Development Committee, Promotion and Tenure, Strategic Planning, ACPE self-study Steering Committee, Student Affairs, International travel, Scholarship and Awards, Physical Space Committee, and Educational Resources Subcommittee (Self Study Committee LCME application of proposed Medical College).

2004 - 2007 Transcept Pharmaceuticals, Inc.

Director of Pharmaceutical Sciences

- Directed all aspects of dosage form development
 - Tissue permeation studies
 - o Preformulation
 - o Formulation and small scale manufacturing
 - Analytical development
- Developed an innovative new dosage form Intermezzo[®]
- Directed plan to overcome scale up issues and modified formula to produce scalable product
- Directed the work of contract manufacturers to produce clinical supplies
- Compiled the CMC section of an IND and wrote portions of annual report and End of Phase 2 Meeting Briefing Document
- Prepared Clinical Trial Applications (CTA) for Canada
- Established a small scale manufacturing and testing facility from scratch
 - o Instructed architects on design of manufacturing suites
 - Selected equipment for facility
 - o Oversaw installation and qualification of equipment

- Hired staff to produce a functional facility
- Directed the efforts of a Packaging Engineer to find a packaging solution for a very unstable product
- Developed four patent applications as co-inventor (novel dosage form with new route of administration)

2002 - 2004 EURAND America, Inc., Dayton, OH.

Manager of New Technologies

- Responsible for New Technology development, and modifications of existing and acquired technologies
- Led successful technology transfer of Advatab technology acquired from Japan: visited Japan twice, hosted visits from Japanese colleagues, chaired joint meetings of technology groups and played leading role in improving the acquired technology
- Achieved fully functional new processing suites by deadline, working with Engineering group: process room design, equipment acquisition, modification and validation
- Working with lawyers, amended and enhanced licensed patent applications of innovator company; amended patents subsequently issued
- Successfully taste masked active of existing +\$1 Billion product for proposed life cycle management; served as Project leader liaising with big Pharma company
- Provided problem solving and development input for improving FDA approved and marketed products

1998 - 2002 Cima Labs, Inc., Minneapolis

Senior Associate Scientist – New Technologies (NT)

Served as head of the New and Innovative Technologies function. This involved:

- Working with Business Development to identify needs
- Conceptualization of innovative delivery platforms
- Literature and patent searches
- Basic research
- Negotiating contract research with universities
- Writing patents and working with patent lawyers
- Preformulation and formulation
- Communication with partners as products were being developed
- Production of clinical trial material
- Arranging clinical trials with CRO's

- Strategic Planning for NT and presentation to the Board of Directors
- Presentations on CIMA technologies to potential partners
- Evaluation of the technologies of other companies; devising and arranging collaborative projects with companies, including international arrangements
- Served as scientific advisor to the President regarding merger and acquisition activities
- Served on CIMA Management Committee for 1 year
- Coordination and liaison for all patent activities within CIMA
- Developed OraVescent Fentanyl from concept to successful PK studies and championed its commercialization to skeptical senior management; this product led to the company being acquired
- Input into the development of marketed products based on OraSolv and DuraSolv technologies; co-inventor of a patent extending their utility and intimately involved with discussions with patent lawyers aimed at expanding the patent family

1996 –1998 University of Missouri–Kansas City

Research Assistant Professor

- Industrial Pharmacy projects generic tablet developed; pharmaceutical development report (FDA-ready) provided to sponsor company
- Developed a project utilizing the gum from Hakea gibbosa in sustained release and mucoahesive buccal tablets and guided formulation work of Ph.D. student, Hemant Alur – 5 publications resulted
- Assisted M.Pharm. student, Ramola Desai mechanistic study on reducing capping tendency in direct compression tableting
- Taught portions of undergraduate, and graduate, courses in Pharmaceutics
- Served as School of Pharmacy representative on the University library committee

1981 – 1996 University of the Western Cape, South Africa

Pharmaceutics Lecturer (Professor)

- Served as Acting Chair of Pharmaceutics Department (Jan to June 1996)
- Chair of Organizing Committee for a national symposium on the future role of the Pharmacist
- Played a leading role (with Head of the School of Pharmacy, Prof. Peter Eagles, and External Relations Department) to develop a strategic plan for expansion and to secure donor

- funding for major extensions to the School of Pharmacy building
- Served as Advisor to M. Pharm. student, Johan van Niekerk novel formulations of indomethacin using solid solutions
- External Examiner to Natal University (Pharmaceutics) and University of Cape Town (Forensic Pharmacy)
- Central Examiner of the South African Pharmacy Council for Pharmacy Technician's Pharmaceutics national examination (1996)
- Taught several courses in Pharmaceutics covering Physical Pharmacy and Compounding; Industrial Pharmacy; Biopharmaceutics and Drug Delivery
- Consultant to pharmaceutical companies (1986 1996)
- University-based contract research involved:
 - o Formulation and development work
 - Scientific advice, for example, on excipient selection and production trouble shooting
 - Stability trials
 - Development of assay methods and performance of batch release testing of commercial batches
 - Formulation and test method development for natural/ herbal tablet formulations and cosmetics

The following are examples of products developed during this period:

Vigor 8 Tablets

Edelweiss Pharmaceuticals

Unique combination of herbal ingredients used as a dietary supplement.

Co-Trimoxazole Tablets

Elttab Pharmaceuticals

Assisted with formulation and developed assay method; performed batch release tests, such as assay and dissolution, on production batches

Trader Flu tablets

G.R. Pharmaceuticals

Assay method developed and stability trial performed - tablet containing 4 actives

Slim Tablets

Edelweiss Pharmaceuticals

Formulation, scale-up, assay method development for chromium polynicotinate tablets.

Jade Etching Gel

Dentapharm Manufacturers

Dental gel for etching teeth prior to filling cavities; clinical results (etching pattern) presented at an international dental conference

Kleerzit

3D Dermatologicals

Stabilized salicylic acid-containing face wash for acne

Developed diaper cream, soapless cleanser, shampoo, talc and Nursing Balm (nipple application for mothers)

1993 –1994 University of Missouri – Kansas City

Research Associate

(During sabbatical leave from University of the Western Cape)

- performed research on sustained release beads (partly at Marion-Merrill Dow)
- Developed a novel peptide drug in a tableted dosage form
- Novel method to study emulsion stability invited publication
- Consultant on extrusion and spheronization to a multi-national company

1990 Selected as an **international exchange visitor** (May to July)

- University of Missouri-Kansas City (May and June)
- Worked on instrumented tablet press at Marion-Merrill Dow
- Visited several multinational companies (July)

1978 – 1981 *Pather's Pharmacy*

Retail Pharmacy manager/owner

ACADEMIC

1975

1996 D. Pharm., University of the Western Cape, South Africa.
 Dissertation title: An Investigation of the Production of Non-Coated Sustained Release Beads by Extrusion and Spheronization

1993-1994 Doctoral research at the University of Missouri-Kansas City

M. Pharm., University of the Western Cape, South Africa.
 Dissertation title: Formulation and evaluation of a slow release theophylline tablet prepared by direct compression

B. Pharm., University of Durban-Westville, South Africa.

HONORARY APPOINTMENTS

2008 - Editorial Advisory Board: CRS Books

2006 - Adjunct Professor: Thomas J. Long School of Pharmacy and

Health Sciences, University of the Pacific, Stockton, CA.

2000 - 2002 Industrial Advisory Board of the Drug Delivery Center, University

of Minnesota.

PROFESSIONAL ASSOCIATIONS

1993 -	Member of the American Association of Pharmaceutical
	Scientists.
2000 -	Member of Controlled Release Society
1978 – 1992	Registered as a pharmacist with the South African Pharmacy
	Council
1978 – 1992	Member of the Pharmaceutical Society of South Africa.
1984 – 1992	Member of the Academy of Pharmaceutical Sciences.
1991 – 1995	Member of the Botanical Society of South Africa.

PROFESSIONAL ADVANCEMENT COURSES

2000	The Mechanics of Preparing INDs and NDAs and FDA Regulations. Short Course presented by The Center for Professional Advancement – Bocca
	Raton, Florida.
1998	AAPS/FDA Workshop on Permeability Definitions – Arlington, Virginia.
1998	AAPS Short Course on Therapeutic Proteins and Peptides - Chicago.
1990	Bioavailability and Bioequivalence of Medicines – University of
	Potchefstroom, South Africa.
1987	Waters Liquid Chromatography School – Cape Town, South Africa.
1986	Therapeutic Drug Monitoring – University of Durban-Westville, South
	Africa.

EXTERNAL REVIEWER: PROMOTION AND TENURE

2011 Jordan University of Science and Technology

GRANT REVIEWER

1995 - 1996	Academy of Pharmaceutical Sciences (South Africa)
1997 – 1998	University of Missouri Research Board – applications from multiple
	universities of the University of Missouri system
2000	Ad hoc reviewer – State of Pennsylvania Greenhouse Fund

JOURNAL REVIEWER

Served as ad hoc reviewer for the following journals:

Drug Development and Industrial Pharmacy International Journal of Pharmaceutics Journal of Pharmaceutical Sciences European Journal of Pharmaceutics and Biopharmaceutics MededPORTAL

ABSTRACT REVIEWER

Served as Abstract Reviewer for the following meetings which attract International participation:

Annual Meeting of the American Association of Pharmaceutical Scientists Annual Meeting of the Controlled Release Society

SOUTH AFRICAN GRANTS

1986-1996 Numerous industry grants received and fee-for-service projects

undertaken. Major contributing companies: Edelweiss Pharmaceuticals,

Alphen Pharmaceuticals, G.R. Pharmaceuticals

1982-1996 Extremely successful in obtaining internal funding, competing with many

departments in a large University, to develop the industrial pharmacy laboratories from practically zero to very well equipped – highly

appreciated by visiting American academics

USGRANT

2011

Undisclosed pharmaceutical company grant of \$65 000 for non-GMP development of a novel injection formulation of a new drug. I.Pather (Principal Investigator) and C.S. Kolli (co-investigator).

PATENTS Issued

Methods of treating middle-of-the-night insomnia Singh, Nikhilesh & Pather, Sathasivan Indiran

U. S. Patent 8,242,131; issued August 14, 2012

Sequential drug delivery systems. S.I. Pather, J. Hontz, J.M. Siebert. U.S. patent 7,670,617; issued March 2, 2010.

Sublingual buccal effervescent. S.I. Pather, R.K. Khankari, J.D.

Eichman, J.R. Robinson, J. Hontz.

US patent 6,974,590; issued December 13, 2005.

Effervescent drug delivery system for oral administration. S.I. Pather, J.R. Robinson, J.D. Eichman, R.K. Khankari, J. Hontz, S.V. Gupte.

US patent 6,764,696; issued July 20, 2004.

Emulsions as solid dosage forms. S. I. Pather, J. Hontz, R. K. Khankari, S.V. Gupte, R. Kumbale.

US patent 6,692,771; issued February 17, 2004

Effervescent drug delivery system for oral administration. S.I. Pather, J.R.

Robinson, J.D. Eichman, R.K. Khankari, J. Hontz, S.V. Gupte. US patent 6,641,838; issued November 4, 2003.

Pharmaceutical Compositions for rectal and vaginal administration. S.I. Pather, J.R. Robinson, J.D. Eichman, R.K. Khankari, J. Hontz US patent 6,576,250; issued June 10, 2003.

Effervescent drug delivery system for oral administration. S.I. Pather, J.R. Robinson, J.D. Eichman, R.K. Khankari, J. Hontz, S.V. Gupte. US patent 6,509,036; issued January 21, 2003.

Effervescent drug delivery system for oral administration. S.I. Pather, J.R. Robinson, J.D. Eichman, R.K. Khankari, J. Hontz, S.V. Gupte. US patent 6,391,335; issued May 21, 2002.

Orally disintegrable tablet forming a viscous slurry. J.M. Siebert, R.K. Khankari, S.I. Pather, U. Kositprapa. US patent 6,368,625; issued April 9, 2002.

Effervescent Drug Delivery System for Oral Administration. S.I. Pather, J.R. Robinson, J.D. Eichman, R.K. Khankari, J. Hontz, S.V. Gupte. US Patent: 6,450,470; issued February 26, 2002.

Microemulsions as solid dosage forms for Oral Administration. S. I. Pather, S.V. Gupte, R.K. Khankari, J. Hontz, J.R. Robinson, J.D. Eichman, R. Kumbale.

US Patent: 6,280,770; issued August 28, 2001.

Sublingual buccal effervescent. S.I. Pather, J.R. Robinson, J.D. Eichman, R.K. Khankari, J. Hontz. US Patent: 6,200,604; issued March 13, 2001.

Published Applications

US Publication No. 20130122099; Published 16 May 2013. Polyethylene glycol-coated sodium carbonate as a pharmaceutical excipient and compositions produced from the same. Davar; Nipun; Kavalakatt; Pauly; Pather; Indiran; Ghosh; Sangita; filed 7 May 2012.

US Publication No. 20120034300; Published February 9, 2012. Stabilized Zolpidem Pharmaceutical Compositions. N.N. Singh, S.I. Pather, P. Kavalakatt, D.W. Adair. Application No 13/ 078731; filed April 1, 2011.

US Publication No. 20110223115; September 15, 2011. Sublingual Buccal Effervescent. S.I. Pather, R.K. Khankari, J.D. Eichman, J.R. Robinson, J. Hontz. Application No 13/ 099003; filed May 2, 2011.

US Publication 20110212034 September 1, 2011 Sublingual Buccal Effervescent. S.I. Pather, R.K. Khankari, J.D. Eichman, J.R. Robinson, J. Hontz. Application No 13/ 098986; filed May 2, 2011.

Polyethylene glycol-coated sodium carbonate as a pharmaceutical excipient and compositions produced from the same. N. Davar, P. Kavalakatt, I. Pather, S. Ghosh. US: Pub No 20100266682 Application No 12/764489; filed April 21, 2010.

Compositions and methods for treating middle-of-the night insomnia. N. Singh, S.I. Pather. US: Pub No 20100249178 Application No 12/797,117; filed June 9, 2010.

Stabilized Zolpidem Pharmaceutical Compositions. N.N. Singh, S.I. Pather, P. Kavalakatt, D.W. Adair. US: Pub No 20100240695 Application No 12/795107; filed June 7, 2010.

Sublingual buccal effervescent. S.I. Pather, R.K. Khankari, J.D. Eichman, J.R. Robinson, J. Hontz. US: Pub No 20090202632 Application No 12/429,475; filed August 13, 2009.

Stabilized Zolpidem Pharmaceutical Compositions. N.N. Singh, S.I. Pather, P. Kavalakatt, D.W. Adair. US: Pub No 20080132535 Application No 11/948,259; filed June 5, 2008.

Compositions and methods for treating middle-of-the night insomnia. N. Singh, S.I. Pather. US: Pub No 20070225322 Application No 11/565,486; filed November 30, 2006.

Sublingual buccal effervescent. S.I. Pather, R.K. Khankari, J.D. Eichman, J.R. Robinson, J. Hontz. US: Pub No 20060292219 Application No 11/511,098; filed August 28, 2006.

Compositions and methods for treating middle-of-the night insomnia. N.N. Singh, S. I. Pather. US: Pub No 20060281783 Application No 11/439,873; filed May 23, 2006.

Solid compositions for treating middle-of-the night insomnia. N.N. Singh, S. I. Pather. US: Pub No 20060276501 Application No 11/440,410; filed May 23, 2006.

Methods for treating middle-of-the night insomnia. N.N. Singh, S. I. Pather. Application No 11/439,874; filed May 23, 2006.

Compositions and methods for treating middle-of-the night insomnia. N.N. Singh, S. I. Pather. Application No 11/439,884; filed May 23, 2006.

Pharmaceutical Compositions for rectal and vaginal administration. S.I. Pather, J.R. Robinson, J.D. Eichman, R.K. Khankari, J. Hontz US: Pub No 20050037072 Application No 10/946 556; filed Sept 21, 2004.

Sequential Drug Delivery Systems. S. I. Pather, J. Hontz, J.M. Siebert. US: Pub No 20050031677 Application No 10/936 185; filed Sept 8, 2004.

Emulsions as solid dosage forms. S. I. Pather, J. Hontz, R. K. Khankari, S.V. Gupte, R. Kumbale. US: Pub No 20030077306 Application No 10/303,197; filed Nov 25, 2002.

BOOK REVIEWS

Preparing for FDA Pre-Approval Inspections. Edited by Martin D. Heynes III. Marcel Dekker, Inc: New York, 1998. Review published in J. Am. Chem. Soc. 122 (2000) 1562-1562.

Mechanisms of Transdermal Drug Delivery, Russell O. Potts and Richard H. Guy (eds.) Review published in Am. J. Pharm. Ed., <u>61</u> (1997) 464-465.

BOOKS IN PREPARATION

Oral Mucosal Drug Delivery and Therapy, Edited by Michael Rathbone, Sevda Senel and Indiran Pather. To be published by Springer in Fall, 2013.

Pharmaceutics Textbook (exact title under discussion) by Indiran Pather and Chandra Sekhar Kolli. To be published by McGraw Hill Professional Publishing in Winter, 2014.

PUBLICATIONS

In preparation

Novel Developments in Buccal Drug Delivery. Invited review to be published in Drug Delivery and Industrial Pharmacy.

Invited

Recent developments in buccal and sublingual delivery systems. Sevda Şenel, Michael J. Rathbone, Merve Cansız, and Indiran Pather. *Expert Opinion in Drug Delivery*. 9(6):615-628 (2012).

Current status and the future of buccal drug delivery systems. S.I.Pather, M.J. Rathbone, and S. Senel, *Expert Opin Drug Deliv*. 5(5):531-542 (2008).

A comparison of two quality assessment methods for emulsions. S.I. Pather, S.H. Neau and S. Pather. *J. Pharm. Biomed. Anal.* <u>13</u> (1995) 1283-1289.

General

Effect of Experimental Temperature on the Permeation of Model Diffusants Across Porcine Buccal Mucosa. Upendra Dilip Kulkarni, Ravichandran Mahalingam, Xiaoling Li, Indiran Pather, Bhaskar Jasti. AAPS PharmSciTech; Vol. 12 Number 2, Jun 2011.

Porcine buccal mucosa as in vitro model: effect of biological and experimental variables. Kulkarni U, Mahalingam R, Pather I, Li X, Jasti B. J Pharm Sci. 99(3):1265-77 (2010).

Porcine buccal mucosa as an in vitro model: Relative contribution of epithelium and connective tissue as permeability barriers. Kulkarni U, Mahalingam R, Pather SI, Li X, and Jasti B. *Journal of Pharmaceutical Sciences* 98(2):471-483 (2009).

Introduction to Oral Mucosal Drug Delivery. S.I.Pather, M.J. Rathbone, and S. Senel, (Also Section Editors). In: Modified-Release Drug Delivery Technology, 2nd Edition. Edited by M.J. Rathbone, J. Hadgraft and M. Roberts. Marcel Dekker, New York and Basel; 2008 (pp 53 – 73).

Quick Dissolving Intraoral Tablets. S.I. Pather, R.K. Khankari and J.M. Siebert. *In: Intraoral Drug Delivery: Molecules to Market. Edited by T. K. Ghosh and W.R. Pfister. Marcel Dekker,* New York and Basel; 2005 (pp 291 to 310).

OraSolv[®] and DuraSolvTM: Efficient technologies for the production of orally disintegrating tablets. S. Indiran Pather, John Hontz, Rajendra K. Khankari and John Siebert. In: Modified Release Drug Delivery Sytems. Edited by M.J. Rathbone, J. Hadgraft and M. Roberts. Marcel Dekker, New York and Basel; 2003 (pp 203-216).

OraVescent[™]: A novel technology for the transmucosal delivery of drugs. S. Indiran Pather, John Hontz, Rajendra K. Khankari and John Siebert. In: Modified Release Drug Delivery Sytems. Edited by Mike Rathbone, Jonathan Hadgraft and Mike Roberts. Marcel Dekker, New York and Basel; 2003 (pp 463-469).

Enhanced buccal delivery of fentanyl using the OraVescent drug delivery system. S. I. Pather, J. M. Siebert, J. Hontz, R. K. Khankari, S. V. Gupte, and R. Kumbale. *Drug Delivery Technology*. <u>1</u> (2001) 54-57.

Fine-particle ethylcellulose as a tablet binder in direct compression, immediate-release tablets. Ramola P. Desai, Steven H. Neau, S. Indiran Pather, and Thomas P. Johnston. *Drug Dev. and Ind. Pharm.* 27 (7), 633-641 (2001).

Evaluation of a novel, natural oligosaccharide gum as a sustainedrelease and mucoadhesive component of calcitonin buccal tablets. H.H.

Alur, J.D. Beal, S.I. Pather, A.K. Mitra and T.P. Johnston. *J. Pharm. Sci.* 88 (1999) 1313-1319.

Transbuccal sustained-delivery of chlorpheniramine maleate in rabbits using a novel, natural mucoadhesive gum as an excipient in buccal tablets. H.H. Alur, S.I. Pather, A.K. Mitra and T.P. Johnston. *Int. J. Pharm.* 188 (1999) 1-10.

Evaluation of the gum from *Hakea gibbosa* as a sustained-release and mucoadhesive component in buccal tablets. H.H. Alur, S.I. Pather, A.K. Mitra and T.P. Johnston. *Pharm. Devel. Technol. 4* (1999) 347-358.

Sustained release theophylline tablets by direct compression. Part 1: Formulation and *in vitro* testing. S.I. Pather, I. Russell, J.A. Syce, and S.H. Neau. *Int. J. Pharm.* 164 (1998) 1-10.

ABSTRACTS

Influence of the Thickness of Buccal Mucosa and Effect of Heat Separation on the *in vitro* Transbuccal Permeation of Antipyrine and Caffeine. Bhaskara Jasti, Ravichandran Mahalingam, Xiaoling Li, Upendra Kulkarni, Indiran Pather. AAPS Journal, Vol, 8, No. S2, Abstract T2133.

Influence of Biological and Experimental Variables on the *in vitro* Transbuccal Permeation of Antipyrine and Caffeine. Bhaskara Jasti, Ravichandran Mahalingam, Xiaoling Li, Upendra Kulkarni, Indiran Pather. AAPS Journal, Vol. 8, No. S2, Abstract T2134.

Enhanced buccal delivery of fentanyl using the OraVescent[™] drug delivery system. S. I. Pather, J.M. Siebert, J. Hontz, R.K. Khankari, S. Gupte and R. Kumbale. Proceed. Int'l. Symp. Control. Rel. Bioact. Mater., 28 (2001) 830-831.

Exploring the utility of hakea gibbosa as a sustained-release and mucoadhesive component of buccal tablets. H.H. Alur, S. I. Pather, A.K. Mitra and T.P. Johnston. *PharmSci*, 1 (4) (1999) S-136.

In vitro assessment of the bioadhesive properties of the natural gum from Hakea gibbosa used in the buccal tablets. H.H. Alur, S.I. Pather, A.K. Mitra and T.P. Johnston. *PharmSci*, 1 (1998) S-171.

Transbuccal administration of Chlorpheniramine maleate in rabbits using a mucoadhesive buccal tablet containing the natural gum from Hakea gibbosa. H.H. Alur, S.I. Pather, A.K. Mitra and T.P. Johnston. *PharmSci*, 1 (1998) S-170.

Fine particle ethylcellulose as a binder in direct compression immediate release tablets. R.P. Desai, S.H. Neau, S.I. Pather and T.P. Johnston. PharmSci, 1 (1998) S-323.

Evaluation of the gum from Hakea gibbosa as a sustained-release and mucoadhesive component in buccal tablets. H.H. Alur, S.I. Pather, T. P. Johnston, and A. K. Mitra. *Pharm. Res.* 14 (1997) S-3.

Sustained release matrix beads prepared by extrusion and spheronization. S.I. Pather, I. Russell and S.H. Neau. *Pharm. Res.* 14 (1997) S-3.

A comparison of Two Quality Assessment Methods for Emulsions S.I. Pather, S.H. Neau and S. Pather. *Pharm. Res.* 11 (1994) S-12.

The Pharmacokinetics of Theophylline (T) from an Experimental Sustained Release (SR) Tablet, Utilizing a Novel Pig Model. S.I. Pather, I. Russell, J. A. Syce, R. Hickman and S.H. Neau. *Pharm. Res.* 11 (1994) S-436.

The formulation and evaluation of theophylline tablets prepared by direct compression. S.I. Pather, I. Russell, J.A. Syce and S.H. Neau. *Pharm. Res.* 10 (1993) S-156.

PRESENTATIONS

2012	Some advances in Oral Transmucosal Delivery of Bioactives; presented to University of Southern Florida, School of Pharmacy.
2008	Development of a Fentanyl buccal tablet; presented to Orchid Pharmaceuticals, Chennai, India. (February).
2007	Oral Transmucosal Delivery, presented to Durect Corporation, Sunnyvale, CA. (September).
2006	Buccal Delivery: Its Role And Limitations. Presentation to the Southern California Pharmaceutical Discussion Group (AAPS Chapter). (19 October). See http://www.aapspharmaceutica.com/inside/discussion_groups/socal/index.asp#mtgs
2005	Some Patenting Experiences. Presentation at the Intellectual Property Open Forum at the University of Nebraska Medical School. (March 14).
2001	The Oral Cavity – simply a portal to the gastrointestinal tract or an important site for drug delivery? A keynote address to the Academy of Pharmaceutical Sciences, Sun City, Southern Africa. (September 18).
1990	A comparison of various methods of enhancing the apparent solubility of indomethacin. Poster presentation. J. van Niekerk, S.I. Pather and I. Russell - Academy of Pharmaceutical Sciences Congress, South Africa.

An in vivo investigation of the slow release properties of a Theophylline test formulation. Podium presentation S.I. Pather, I. Russell and J.A. Syce - Academy of Pharmaceutical Sciences Congress, South Africa.