# INDIRAN PATHER, D. PHARM.

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# **EXECUTIVE SUMMARY**

## **Career Goals**

- 1) 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

## **Positions Held**

Presently serving as Chair of the Department of Pharmaceutical Sciences, Howard University. Previous positions in academia include Associate Dean of Academic Affairs and Assessment, Director of Research and Chair of Pharmaceutical and Biomedical Sciences. Have served on numerous committees including Research Committee (Chair), Curriculum and Assessment Committee (Chair), Scholarship and Awards Committee (Chair), IRB (Vice Chair) and Strategic Planning Committee. Consultant to the pharmaceutical industry with regard to novel dosage form development and patents. Serve as reviewer for international pharmacy journals. The highlights of approximately 15 years of prior pharmacy teaching in South Africa are: laboratory capabilities were greatly expanded, an active and profitable contract service to industry was initiated, major extensions to, and fund-raising for, a new building were initiated.

Over a period of approximately 10 years in the US pharmaceutical industry, held positions of increasing responsibility ranging from Senior Scientist to Director of Pharmaceutical Sciences. 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.

#### **Achievements**

As a founding faculty member 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-the-night 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. Eighteen US patents with additional applications pending. Several papers and 8 book chapters; co-edited a book on oral mucosal drug delivery; 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 laboratories (including GMP suites). Conducted University-based laboratory research that helped a school get funding & companies develop commercial products. Skilled in conceptualizing and developing innovative technologies and products, 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	8
Professional Advancement Courses	8
External Reviewer: Promotion and Tenure	9
Grant Reviewer	9
Journal Reviewer	9
Abstract Reviewer	9
South African Grants	9
J S Grant	9
Patents	10
Book Reviews	14
Books	14
Publications	15
Abstracts	16
Presentations	17

#### **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 to pedagogy
- 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
- Lead role in two US prescription 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 analytical techniques such as dissolution testing, spectrophotometry and HPLC. Some familiarity with flame photometry and FTIR. Well-versed in stability testing, product release testing and cleaning validation.

#### **POSITIONS HELD**

2018 – Howard University, College of Pharmacy, Washington, DC.

## **Chair and Professor: Department of Pharmaceutical Sciences**

- Major responsibility: development of the research enterprise and entrepreneurship
- Oversight of teaching and learning within the Department
- Faculty Development

# 2015 – 2017 Larkin Health Sciences Institute, College of Pharmacy, Miami, FL.

#### Associate Dean for Academic Affairs and Curricular Assessment

- Administrative Team member
- Contributed to preparation of application for accreditation
- Contributed to development of lab and other facilities
- Chair of Admissions Committee (Pro tem); ad hoc member of numerous committees
- Development of Academic Affairs Policies and Procedures
- 2007 2015 California Northstate University College of Pharmacy (CNUCOP), Sacramento, CA.

## **Director of Research** (Oct 2010 – Jan 2015)

- Developing infrastructure and promoting research
- Developing policy documents
- Developing research collaborations

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

- Assisted with preparation of syllabi & teaching materials for a new curriculum
- Guided initial teaching
- Oversaw initial development and implementation of curriculum as Chair of Curriculum Committee (2008 – 2009)

## **Professor of Pharmaceutics** (from Oct 2007)

- Developed and implemented the Biopharmaceutics / Pharmaceutics course using innovative teaching methods
- Introduced lab component of course
- Introduced compounding elective

#### **Committee Service at CNUCOP:**

- Dean's executive Committee
- Bylaws and Policy Development Committee
- Curriculum Committee (Chair)
- Promotion and Tenure Committee (Chair)\*
- Strategic Planning Committee (Director)\*, and Chair of Research Planning Subcommittee\*
- ACPE self-study Steering Committee
- Student Affairs Committee
- International Travel Committee
- Scholarship and Awards (Chair)\*
- Faculty Awards (Chair)\*
- Research Committee (Chair)\*
- IRB (vice chair)\*
- Enrollment Initiative Committee\*
- Physical Space Committee\*
- Educational Resources Subcommittee of Self Study Committee for LCME application proposed Medical College

<sup>\*</sup> Committee Involvement during final 12 months

# 2004 - 2007 Transcept Pharmaceuticals, Inc.

## **Director of Pharmaceutical Sciences**

- Directed all aspects of dosage form development
  - Tissue permeation studies
  - Preformulation
  - Formulation and small scale manufacturing
  - Analytical development
- Developed an innovative new dosage form Intermezzo<sup>®</sup>
- Directed plan to overcome scale up issues
- 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
  - Instructed architects on design of manufacturing suites
  - Selected equipment for facility
  - 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 presentations 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 onOraSolv 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 courses in Pharmaceutics
- Taught 50% of graduate course 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:
  - 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

# Bloom's Range of Baby Products Alphen Pharmaceuticals

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

# 1978 – 1981 *Pather's Pharmacy*

## Retail Pharmacy manager/owner

- Independent pharmacy started from scratch
- Served and intimately involved with local community
- Sold in 1984 continues as a successful pharmacy

## **ACADEMIC**

- 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
- 1989 M.Pharm. University of the Western Cape, South Africa.
   Dissertation title: Formulation and evaluation of a slow release theophylline tablet prepared by direct compression
- 1976 B.Pharm. University of Durban-Westville, South Africa.

## HONORARY APPOINTMENTS

2008	Books Advisory Committee: Controlled Release Society
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
1990	International exchange visitor: 2 months at University of Missouri-Kansas City, research on instrumented tablet press at Marion-Merrill Dow, and visited several multinational companies in the US and England

#### PROFESSIONAL ASSOCIATIONS

1993 -	Member of the American Association of Pharmaceutical Scientists
2000 -	Member of Controlled Release Society
1978 – 1992	Registered as a pharmacist - 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:

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

## **ABSTRACT REVIEWER**

For many years, served as Abstract Reviewer for the following annual 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**

(Only US patents mentioned unless an International patent is significantly different from US one)

#### Issued

Sunscreen comprising a curcuma extract. I.Pather, T.Z.Woldemariam. US Patent 8,815,220 issued August 26, 2014.

Sublingual buccal effervescent. S.I.Pather, R.K.Khankari, J.D.Eichman, J.R.Robinson, J.Hontz. US Patent 8,802,130 issued August 12, 2014.

Transmucosal effervescent. J.D.Eichman, J.Hontz, R.K.Khankari, S.I.Pather, J.R.Robinson. U.S. Patent 8,765,100; issued July 1, 2014.

Sublingual buccal effervescent. J.D.Eichman, J.Hontz, R.K.Khankari, S.I.Pather, J.R.Robinson. U.S. Patent 8,753,611; issued June 17, 2014.

Sublingual buccal effervescent. J.D.Eichman, J.Hontz, R.K.Khankari, S.I.Pather, J.R.Robinson. U. S. Patent 8,728,441; issued May 20, 2014.

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**

(Only US applications mentioned)

US Publication No. 20140056830 Published: 27 February 2014.

Method of producing a safe, whole-extract of curcuma for oral and topical use.

Pather, Indiran; Woldemariam, Tibebe, Zewdie.

Application No.13/717677 filed: December 17, 2012.

US Publication No. 20140056829 Published: 27 February 2014.

Sunscreen comprising a curcuma extract. Pather, Indiran; Woldemariam, Tibebe,

Zewdie.

Application No. 13/717670 filed: December 17, 2012.

US Publication No. 20140056828 Published: February 27, 2014.

Novel formulations and uses for curcuma extracts. Pather, Indiran;

Woldemariam, Tibebe Zewdie.

Appl. No. 13/590188 filed: August 21, 2012.

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.

Application No. 13/465953 filed: 7 May 2012.

US Publication No. 20120034300 Published: 9 February 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 Published: 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 No. 20110212034 Published: 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.

US Publication No. 20100266682 Published: October 21, 2010.

Polyethylene glycol-coated sodium carbonate as a pharmaceutical

excipient and compositions produced from the same. N.Davar, P.Kavalakatt, I.Pather,

S.Ghosh.

Application No. 12/764489 filed: April 21, 2010.

US Pub No. 20100249178 Published: September 30, 2010.

Compositions and methods for treating middle-of-the night insomnia. N.Singh, S.I. Pather.

Application No. 12/797117 filed: June 9, 2010.

US Pub No. 20100240695 Published: September 23, 2010.

Stabilized Zolpidem Pharmaceutical Compositions. N.N.Singh, S.I.Pather, P.Kavalakatt,

D.W.Adair.

Application No.12/ 795107 filed: June 7, 2010.

US Pub No 20090202632 Published: August 13, 2009

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

Hontz.

Application No. 12/429475 filed: August 13, 2009.

US: Pub No. 20080132535 Published: June 5, 2008

Stabilized Zolpidem Pharmaceutical Compositions. N.N. Singh, S.I. Pather, P. Kavalakatt, D.W.

Adair.

Application No. 11/948259 filed: June 5, 2008.

US: Pub No. 20070225322 Published: September 27, 2007

Compositions and methods for treating middle-of-the night insomnia. N.Singh and S.I. Pather.

Application No. 11/565486 filed: November 30, 2006.

US Publication No. 20070123562 Published: May 31, 2007

Compositions and methods for treating middle-of-the-night insomnia. Singh, Nikhilesh; Pather;

Sathasivan Indiran.

Application No.11/439884 filed: May 23, 2006.

US Publication No. 20070066643 Published: March 22, 2007.

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

Application No. 11/439874 filed: May 23, 2006.

US: Publication No 20060292219 Published: December 28, 2006.

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

J.Hontz.

Application No. 11/511,098 filed: August 28, 2006.

US Publication No 20060281783 Published: December 14, 2006.

Compositions and methods for treating middle-of-the night insomnia. N.N. Singh, S. I. Pather.

Application No. 11/439873 filed: May 23, 2006.

US Publication No 20060276501 Published: December 7, 2006.

Solid compositions for treating middle-of-the night insomnia. N.N.Singh, S.I.Pather.

Application No. 11/440410 filed: May 23, 2006.

US Publication No 20050064030 Published: March 24, 2005.

Sublingual buccal effervescent. Pather, Sathasivan Indiran; Khankari, Rajendra K; Eichman,

Jonathan D; Robinson, Joseph R; Hontz, John.

Application No. 10/977029 filed: October 29, 2004.

US: Publication No 20050037072 Published: February 17, 2005.

Pharmaceutical Compositions for rectal and vaginal administration. S.I. Pather, J.R. Robinson,

J.D. Eichman, R.K. Khankari, J. Hontz

Application No. 10/946556 filed: Sept 21, 2004.

US: Publication No 20050031677 Published: February 10, 2005. Sequential Drug Delivery Systems. S.I. Pather, J. Hontz, J.M. Siebert.

Application No. 10/936185 filed: Sept 8, 2004.

US: Publication No. 20030232080 Published: December 18, 2003.

Sequential Drug Delivery Systems. Pather, S.Indiran; Hontz, John; Siebert, John M.

Application No. 10/623069 filed: July 18, 2003.

US: Publication No. 20030133976 Published: July 17, 2003.

Effervescent Drug Delivery System for Oral Administration. Pather, S.Indiran; Robinson, Joseph R.; Eichman, Jonathan D.; Khankari, Rajendra K.; Hontz, John; Gupte, Sangeeta V.

Application No. 10/346829 filed: March 18, 2003.

US: Publication No. 20030118645 Published: June 26, 2003.

Pharmaceutical Compositions for rectal and vaginal administration.

Pather, S. Indiran; Robinson, Joseph R.; Eichman, Jonathan D.; Khankari,

Raiendra K.: Hontz. John:

Application No. 10/360050 filed: February 4, 2003.

US: Publication No. 20030091629 Published: May 15, 2003.

Sublingual Buccal Effervescent. Pather, S.Indiran; Khankari, Rajendra K.; Eichman, Jonathan

D.; Robinson, Joseph R.; Hontz, John.

Application No. 10/269669 filed: October 11, 2002.

US: Publication No. 20030077306 Published: April 24, 2003.

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

Kumbale.

Application No. 10/303197 filed: Nov 25, 2002. US: Publication No. 20030068356 Published: April 10, 2003.

Sequential Drug Delivery Systems. Pather, S. Indiran; Hontz, John; Siebert, John, M.

Application No. 09/901983 filed: July 10, 2001.

US: Publication No. 20020160049 Published: October 31, 2002.

Emulsions as Solid Dosage forms for Oral Administration. Pather, S. Indiran; Gupte, Sangeeta

V; Khankari, Rajendra K.; Hontz, John; Kumbale, Ramya.

Application No. 09/792659 filed: February 23, 2001.

US: Publication No. 20020110578 Published: August 15, 2002.

Sublingual Buccal Effervescent. Pather, S. Indiran; Khankari, Rajendra K.; Eichman, Jonathan

D.; Robinson, Joseph R.; Hontz, John.

Application No. 10/080016 filed: February 20, 2002.

US: Publication No. 20020076439 Published: June 20, 2002.

Effervescent Drug Delivery System for Oral Administration. Pather, S. Indiran; Robinson,

Joseph R.; Eichman, Jonathan D.; Khankari, Rajendra K.; Hontz, John; Gupte, Sangeeta V.

Application No. 10/021109 filed: October29, 2001.

US: Publication No. 20020071809 Published: June 13, 2002.

Effervescent Drug Delivery System for Oral Administration. Pather, S. Indiran; Robinson, Joseph

R.; Eichman, Jonathan D.; Khankari, Rajendra K.; Hontz, John; Gupte, Sangeeta V.

Application No. 10/021486 filed: October 29, 2001.

#### **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., 61 (1997) 464-465.

Oral Mucosal Drug Delivery and Therapy, Edited by Michael Rathbone, Sevda Senel and Indiran Pather. To be published by Springer in Fall, 2014.

#### **BOOKS**

Oral Mucosal Drug Delivery and Therapy. Michael Rathbone, Sevda Senel, Indiran Pather (Eds.) Springer (for Controlled Release Society), 2015.

Pharmaceutics Textbook (exact title under discussion). To be published by McGraw Hill Professional Publishing in spring, 2017.

#### **PUBLICATIONS**

#### Invited

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

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#### ABSTRACTS

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#### **PRESENTATIONS**

- 2014 Development of 505(b)2 Complex Drug Formulations: Opportunities, Challenges and Solutions. Presented at Absorption Systems Seminar, NJ (September)
- 2014 Insights into Sublingual Drug Delivery, a 1 hour telephone interview by a panel from Arthur D. Little, a business strategic development consulting company (May)

- 2012 Some advances in Oral Transmucosal Delivery of Bioactives; presented to University of Southern Florida, School of Pharmacy. (January)
- 2008 Development of a Fentanyl buccal tablet; presented to Orchid Pharmaceuticals, Chennai, India. (February).
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