

Universities attended

Massachusetts Institute of Technology, 1989
Boston, MA
Advances in Controlled Release Technology

Duquesne University, Pittsburgh, PA U.S.A. 1985
Doctor of Philosophy (Ph.D.)
Major - Pharmaceutical Technology
Minor - Pharmaceutical chemistry
Dissertation Title: Polyethylenes as Potential Prolonged Release Tablet Excipients

Bombay University, Bombay, India 1978
Bachelor of Pharmacy (B. Pharm.)

Professional Career

University of Campinas 2004 – 2009
Department of Medicine
Campinas, SP- BRASIL
Adjunct Professor

Banakar Consulting Services 2000 - Present
Carmel, IN 46032
President

Creighton University 2001 – 2007
School of Pharmacy & Allied Health
Omaha, NE 68178
Adjunct Professor

Butler University 1997 - 1999
College of Pharmacy and Health Sciences
Indianapolis, IN 46208-3485
Professor of Pharmaceutics
Chairman, Pharmaceutical Sciences and Graduate Program

St. Louis College of Pharmacy 1990 -1997
St. Louis, MO 63110
Professor of Pharmaceutics 1994 - 1997
Associate Professor (Pharmaceutics) 1990 - 1993
Director of Research 1990 - 1996
Section Head: Pharmaceutical Sciences 1990 - 1996

Creighton University 1985 - 1990
School of Pharmacy & Allied Health, Omaha, NE 68178
Department of Pharmaceutical Sciences
Associate Professor (Pharmaceutics) 1988 - 1990
Assistant Professor (Pharmaceutics) 1985 - 1987

Duquesne University 1981 - 1984
School of Pharmacy, Pittsburgh, PA U.S.A.
Instructor-In-Charge (Pharmaceutics)

J.N. Medical College 1980
School of Pharmacy, Belgaum, India
Lecturer Pharmaceutics

Intl. Scientific Advisor (Drug/Product Design, Development and Evaluation: *in vitro* and clinical)

Pharmaceutical corporations worldwide (**partial listing**)

Merck S/A, Jacarepagua, Rio de Janeiro, **BRAZIL** (2011 – present)
Althaia, Atibai, **BRAZIL** (2013 - present)
Cipla, Mumbai, **INDIA** (2013 - present)
Vista Pharmaceuticals Inc., West Orange, New Jersey, **USA** (2005 – present)
Investigacion Farmaceutica y Biopharmaceutica (IFaB), Mexico City, **MEXICO** (2005 – present)
Marjan Farma S.A., Sao Paulo, **BRAZIL** (2008 – 2013)
Torrent Pharmaceuticals Limited, Ahmedabad, **INDIA** (1993 – 2008)
EMS, S.A., Hortolandia, SP, **BRAZIL** (2001 – 2008)
Wockhardt Limited, Mumbai, **INDIA** (1995 – 2005)
Shasun Drugs & Pharmaceuticals Limited, Chennai, **INDIA** (2005 – 2008)
PLIVA, d.d., Zagreb, **CROATIA** (1995 – 2000)

Clinical/Contract Research Organizations (CRO) (partial listing)

Lotus Labs, Bangalore, **INDIA** (Founder, Director – Technical) – 2000 – 2005
Quest Life Sciences Pvt. Ltd., Chennai, **INDIA** (Founder, Chairman) - 2003 - 2008

Expertise (not exclusive listing)

Disciplines:

- Drug product development and evaluation, conventional and non-conventional
- Dissolution and bio-availability assessment
- Novel drug delivery systems
- Data characterization, evaluation, and model development
- Dosage form design for bio-availability /pharmacokinetic studies
- Clinical Research and Development - Phase I - IV clinical trials including BA/BE

Testifying/Non-Testifying Expert [patent litigations] – as of March 2014

Biovail vs Andrx	Glaxo vs Andrx
Astra vs Andrx (2 cases)	Shire vs Impax
FTC vs Schering-Plough/Upsher-Smith/AHP	Shire vs Barr
Tishcon vs Douglas	Shire vs Nostrum
Eli Lilly vs Apotex (Canada)	Alza vs Andrx/Watson – 2 cases
Shire vs Sandoz	Shire vs Colony/Actavis
Shire vs Corepharma	Sanofi vs Sandoz
Shire vs Apotex	Purdue vs Impax
Shire vs Teva	Endo vs Roxane/Ranbaxy/Impax/Teva
Shire vs Zydus/Cadila (2 cases)	Alza vs Kremers
Lupin vs Paddock	Malinckrodt vs Watson
Depomed/Valeant vs Sun	Warner-Chilcott vs Zydus
Purdue vs Actavis	Purdue vs Impax/Sandoz/Par
UCB vs Teva	Par vs Breckenridge
Endo vs Impax/Thorx	MSD vs Warner-Chilcott/Actavis
Aptalis vs Mylan/Sandoz	Takeda vs Sun
Pfizer vs Fresenius Kabi	Merck, Sharp & Dohme vs Fresenius Kabi
Forest vs Teva	Lab. HRA Pharma vs Teva

Organizations – Professional Associations

Member of several professional organizations worldwide

PROFESSIONAL/ACADEMIC DISTINCTIONS (*partial listing*)

Invited as member of the Distinguished Editorial Board of 6-Volume, 93 Chapters, Text Series: **Nanobiomedicine**, Studium Press, LLC, Houston, TX, USA (to be published _____ 2015).

- **Dissolution/Release Testing in Drug Development: Basics, Advances and Applications**
- **Biorelevant Dissolution Method Development for Pharmaceutical Dosage Forms: *Conventional and Specialized (Topicals, Dermals, Implants)***
- **Bioefficacy Centered Dissolution Testing in Drug Development: *Essentials of IVIVC***
- **Comprehensive "First Time" Development of Controlled Release Drug Delivery Systems**
- **Comprehensive Understanding of the *In Vitro* Dissolution/Release Performance: *Characterization and Applications in Drug Development***
- **Drug Development Program: *Techno-Legal Considerations for Pharmaceutical Scientists***
- **IVIVC, Biowaivers and Clinical Applications of IVIVC**
- **Understanding Phase I Clinical Trial: *New versus First Time Drug Development***

Invited as **Course Director** to develop and present Professional Development Certification Course Series entitled: **Pharmaceutical Drug Development Process: *Role of Dissolution Testing - 5-Course series***, Society for Pharmaceutical Dissolution Science (SPDS), Mumbai, INDIA (March 2015)

- **Pharmaceutical Dissolution testing : Fundamentals and Advanced Applications.**
- **BioEfficacy Centered Dissolution, Method Development : Applications and Analysis**
- **Dissolution and Bioavailability : Fundamentals and Applications of IVIVC**
- **IVIVC , Biowaivers & Clinical Application of IVIVC**
- **QbD in Dissolution Method Development, QTTP, Critical Method Attributes, Discriminatory Method, DOE's, Method Finalization.**

Recipient of the Recognition Award for **Outstanding Contributions to Pharmaceutical Dissolution Science** awarded by Society for Pharmaceutical Dissolution Science (SPDS), Mumbai, INDIA (May 2014)

Invited as **Chief Guest and Guest of Honor**, Goa College of Pharmacy, Golden Jubilee Conference and Celebration, Panjim, Goa, INDIA (March 2014)

Invited to present a Special Focus 3-Day Intensive Program: **Dissolution, Bioavailability and IVIVC: *Fundamentals and Mechanics***; CHEMO Research, Madrid, SPAIN (March 2014).

Invited to present a Special Focus 1-Day Intensive Program: **Understanding Patents for Pharmaceutical Formulation Scientists**; Cipla - R&D, Vikhroli, Mumbai INDIA (March 2014).

Invited to present a Special Lecture: **In Vitro Dissolution Test: *Surrogate to Predict Bioavailability***; Vidya Prathishthan School of Biotechnology [VSBT], Baramati, INDIA (February 2014).

Invited to present a Plenary Lecture at **NANO-SCITECH 2014** International Conference, Chandigarh, INDIA (Feb. 2014)

Invited to present a Special Focus 2-Day Intensive Program: **IVIVC, Biowaivers and Clinical Applications of IVIVC**; Althaia, Atibaia, SP; BRAZIL (October 2013 and January 2014).

Invited to present a Special Focus 1-Day Intensive Program: **Bioequivalence Testing: *Understanding Challenges***; Cipla, Mumbai INDIA (January 2014).

Invited to present a Special Lecture: **Bioavailability and Beyond**; Mumbai Educational Trust [MET], Institute of Pharmacy, Mumbai, INDIA (October 2013).

Invited to present a Special Lecture: **Bioavailability and Beyond**; Punjab Univ., Postgraduate Institute - Pharmaceutical Sciences, Chandigarh, INDIA (August 2013).

Invited to present a Special Focus 3-Day Intensive Program: **Bioefficacy Centered Pharmaceutical Product, Design, Development and Evaluation: *Role of Dissolution Testing***; Canitec, Guadlajara, MEXICO (July 2013).

Invited to present a Special Focus 2-Day Intensive Program: **IVIVC, Biowaivers and Clinical Applications of IVIVC**; Canitec, Guadlajara, MEXICO (July 2013).

Invited to present a Special Focus 1-Day Intensive Program: **Understanding Patents for Pharmaceutical Formulation Scientists**; Althaia, Atibaia, SP-BRAZIL (July 2013).

Invited to present a Special Focus 1-Day Intensive Program: **Biosimilars: *Regulatory Perspectives and Challenges***; Merck S.A., Jacarapagua, RJ; BRAZIL (March 2013).

Invited to present a Special Focus 3-Day Intensive Program: **Bioefficacy Centered Pharmaceutical Product Design**

Invited to present a Special Focus 2-Day Intensive Program: **Pharmaceutical Drug Product Development: Role of Dissolution**; Cipla Ltd. (India), Vikhroli, Mumbai, INDIA (March 2013).

Invited to present a Special Focus 3-Day Intensive Program: **Dissolution Test Method Development for Pharmaceutical Dosage Forms**; Althaiia, Atibaia, SP; BRAZIL (Mar. 11,12 and May 27, 2013).

Invited to present a Special Focus 2-Day Intensive Program: **Dissolution and Bioequivalence of Generic Pharmaceuticals**; Agilent Technologies (India) Ltd., Hyderabad, INDIA (January 2013).

Invited to present a Special Focus 2-Day Intensive Program: **Correlating Dissolution and Bioavailability: Understanding IVIVC**; Agilent Technologies (India) Ltd., Mumbai, INDIA (January 2013).

Invited as a Founding Member and Principal International Scientific Advisor of **Society for Pharmaceutical Dissolution Sciences [SPDS]**; Mumbai, INDIA (Jan. 2013)

Invited to present a Special Focus 2-Day Intensive Program: **Dissolution and Bioequivalence of Generic Pharmaceuticals**; Agilent Technologies (Brazil) Ltd., Sao Paulo, BRAZIL (November 2012).

Invited to lead and moderate the Annual National Dissolution Discussion Group [DDG] meeting/conference, Agilent-Technologies - Brazil, Sao Paulo, BRAZIL (November 2012)

Invited to present a Special Focus 3-Day Intensive Program: **Principles in the Design, Development and Evaluation of Generic Pharmaceuticals**; Novo-Lab Kft, Budapest, HUNGARY (November 2012).

Invited as Chairperson and Moderate International Conference: **IVIVC and Biowaivers**; UBM-INDIA 2012, Mumbai, INDIA (October 2012).

Invited to present Keynote Address at the International Conference: **IVIVC and Biowaivers**; UBM-INDIA 2012, Mumbai, INDIA (October 2012).

Invited to present a Focus Session: **Strategic Mapping of IVIVC in Drug Development Program**, (Day 2) at the International Conference: **IVIVC and Biowaivers**; UBM-INDIA 2012, Mumbai, INDIA (October 2012).

Invited to present a Keynote Address at 3rd Annual PharmaLytics INDIA 2012 Conference [Day 2], Mumbai, INDIA: **Development of Discriminatory Media to achieve improved IVIVC in Drug Development**; PharmaLytics INDIA 2012, Mumbai, INDIA (August 2012).

Invited to present a Keynote Address at 3rd Annual PharmaLytics INDIA 2012 Conference [Day 3], Mumbai, INDIA: **IVIVC Based Drug Release Quality Control Specifications - A Case Study**; PharmaLytics INDIA 2012, Mumbai, INDIA (August 2012).

Invited to present a Keynote/Lead Address to SINDUSFARMA [Brazilian Pharmaceutical Industry Assoc./Syndicate]: **US FD&C Act Section 505(b)(2): Time to Revisit RDC 136**; Sao Paulo, BRAZIL (July 2012)

Invited to present a Special Focus 4-Day Intensive Program: **Comprehensive Development of Controlled Release Drug Delivery Systems: Oral Solid Dosage Forms**; Canitec, Guadalajara, MEXICO (March 2012).

Invited to present a Special Focus 4-Day Intensive Program: **Comprehensive Development of Controlled Release Drug Delivery Systems: Oral Solid Dosage Forms**; Canitec, Mexico City, Mexico, D.F., MEXICO (February 2012).

Invited to present a Keynote Address at International Analytical Conference – ANACON 2011, Mumbai, INDIA: **Application of Quality by Design (QbD) to Dissolution Testing Across Various Phases of Drug Development**; ANACON-2011, Mumbai, INDIA (Oct. 2011).

Invited to present a Keynote Address at National Congress of Pharmaceutical Sciences, Ixtapa-Zihuatanejo, MEXICO: **Bioavailability/Bioequivalence Issues and Challenges**; Asociacion Farmaceutica Mexicana, Mexico City, Mexico, D.F., MEXICO (Oct. 2011).

Invited to present a Keynote Address at National Congress of Pharmaceutical Sciences, Ixtapa-Zihuatanejo, MEXICO: **Dissolution Testing: QbD (Quality by Design) Approach**; Asociacion Farmaceutica Mexicana, Mexico City, Mexico, D.F., MEXICO (Oct. 2011).

Dosage Forms; Canitec, Mexico City, Mexico, D.F., MEXICO (June 2011).

Invited to present a Special Focus 4-Day Intensive Program: **Dissolution and Bioequivalence of Generic Pharmaceuticals**; Asociacion Farmaceutica Mexicana, Mexico City, D.F., MEXICO (Feb. 2011).

Invited to present a Strategic Special Focus 1-Day Intensive Program: **Enantiomeric Pharmaceuticals: Drug Development Considerations**; Merck-Brazil, Rio de Janeiro, BRAZIL (Feb. 2011).

Invited to present a Special Focus 4-Day Intensive Program: **Principles in the Design, Development and Evaluation of Generic Pharmaceuticals**; Asociacion Farmaceutica Mexicana, Mexico City, D.F., MEXICO (June 2010).

Invited to serve as International Scientific Advisor for Marjan Farma Industria, Sao Paulo, BRAZIL (Oct. 2008)

Invited to present The Golden Jubilee Celebration Seminar: **Dissolution Testing: Basic Concepts, Regulatory Considerations and In Vivo – In Vitro Correlation (IVIVC)**, Dr. B.A. Marathwada University, Aurangabad, INDIA (Aurangabad, India Feb. 25. 2008)

Invited to present a keynote address: **In Vivo – In Vitro Correlation (IVIVC): Its Place and Significance in Drug Development**; Intl. Conf. Drug Discovery and Nanotechnology, Dept. Of Chemistry, Yashwant Mahavidyalaya, Nanded, INDIA (Nanded, India Jan. 2008)

Invited as one of the Keynote Speakers at the inauguration function, presided by His Excellency Dr. APJ Abdul Kalam, President of India, of TRICell Stemcell Research Center, Chennai, INDIA (Chennai INDIA, Nov. 2007)

Invited to present a Special 2-day Session: **Dissolution Testing in Pharmaceutical Drug Development**, Center for Pharmaceutical Technology, Chulalongkorn University, Bangkok, Thailand and MediTop Inc., Bangkok, THAILAND (Bangkok, Thailand, March 2007).

Invited to present a keynote address: **Clinical Drug Development in Humans**; Intl. Sym. Drug Discovery, Faculdade de Ciências Farmacêuticas – UNESP – Araraquara – SP- Brazil (Araraquara, Brazil, July 2006)

Invited to present Pre-conference Workshop: **Biorelevant Dissolution Testing: Concept or Fallacy**, at the Intl Conf.: Dissolution Testing: Beyond Quality Control; Institute for International Research, New York, NY (Philadelphia, Jan. 2006).

Invited to deliver keynote presentation: **Stem Cell Research in Clinical Therapeutics: Potential Regulatory Implications**. 1st Intl. Sym.: Stem Cell Research, Lifecell (India) Ltd., Chennai (Jan 06, 2006); Mumbai (Jan. 07, 2006) and New Delhi (Jan. 08, 2006)

Invited to join the Management Board (Board of Directors) as International Scientific Advisor and Member – Board of Directors of Investigacio Farmacologia y Biopharmaceutica, S.A. de C.V., Tepepan, Mexico D.F., MEXICO (2005)

Invited to serve as International Scientific Advisor to Shasun Chemicals & Pharmaceuticals Ltd., Chennai INDIA (2005).

Invited to present a 2-Day intensive Professional Advancement Training Program: **Dissolution and Bioequivalence of Generic Pharmaceutical Dosage Forms**; INFARMED (Central Drug Regulatory Agency of Portugal) and E.A. Campos, S.A., Lisbon, PORTUGAL (April 2005).

Invited to present a special focus session: **Biologically Relevant Dissolution Testing in Drug Development**; Government Pharmaceutical Organization, Bangkok, THAILAND (Feb. 2005).

Invited to present a special focus session: **Discriminatory Dissolution Testing in Drug Development**; Ministry of Public Health (MOPH), Bangkok, THAILAND (Feb. 2005).

Invited to serve on the Editorial Advisory Board, Pharmacokinetic/Pharmacodynamic and Biopharmaceutics Section for the Brazilian Journal of Biological and Medical Sciences, Brazil (2004).

Invited to develop and present a Graduate Course for Masters and Doctoral program at University of Campinas, Department of Medicine, Campinas, Brasil (Dec. 2003). Course Title: CLINICAL PHARMACY PRACTICE: Pharmacokinetics for the Practicing Healthcare Professional

Invited to present a keynote address at the International Symposium on Pharmaceutical Issues in NDA and ANDA; 55th Indian Pharmaceutical Congress, Chennai, INDIA (Dec. 2003); Title of presentation: **Techno-legal considerations in defending an**

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