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Sarfaraz K Niazi, Ph.D.

Executive Summary

- Dr. Sarfaraz K. Niazi has over 35 years of worldwide experience in managing multidisciplinary research; he has been teaching and conducting research in the field of pharmaceutical and biotechnology sciences and has published over 100 research articles, dozens of books, both technical and literary including several textbooks. He is a recipient of several research recognition awards. He is a licensed practitioner of patent law before the US Patent and Trademark Office and serves the global pharmaceutical and biotechnology industry in the transition of research ideas into useful technology. Dr. Niazi holds several major US and worldwide patents for his inventions and writes in the fields of philosophy, sociology, rhetoric and poetry; he is the author of the first book on clinical pharmacokinetics and the largest work on pharmaceutical manufacturing formulations and also on the manufacturing of therapeutic proteins. He has extensive experience in global management of research in healthcare systems.

Summary of Qualifications/ Achievements

- 1971 – Present
  - Doctoral degree in pharmaceutical sciences.
  - Global management of pharmaceutical research (drug delivery systems, pharmacokinetics, biopharmaceutics, biotechnology, recombinant manufacturing, drugs, vaccines) licensing, intellectual property creation and acquisition; business planning, projections and execution; regulatory filings and clinical study protocols; top-level corporate work force training and development; web-based education and information systems. ISO system certification.
  - Licensed by Patent Bar; practitioners (agent) for US Patent and Trademark Office, Washington, DC.
  - Over 100 refereed research articles.
  - Fellowships in learned societies: Pakistan Academy of Medical Sciences, National Academy of Clinical Biochemistry, Institute of Biology; honors, awards.
  - Textbooks, consumer health books, philosophy and literature treatise, hundreds of consumer health articles, syndicated newspaper column, web-presence, invited talks around the world (drug discovery, formulation, TQM, regulatory affairs, international code of harmonization, American art, professional time management, classical poetry).
  - Competitive research grants, research and teaching awards, fellowships of scholarly societies, academic teaching and extensive networking; training of US FDA inspectors; several high-profile patents. Over 30 graduate students now holding highly visible positions worldwide.
  - Consultant to WHO (TOKTEN Fellow), foreign government agencies.

Education

1971 - 1974 **University of Illinois** **Chicago, IL**
Ph.D. Pharmaceutical Sciences

- Pharmacokinetics, drug delivery systems.

1970 - 1971 **Wash. State University** **Pullman, WA**

M.S. Pharmaceutical Sciences

- Biopharmaceutics, bioavailability, drug delivery systems, crystalline and amorphous drug form development.

Professional Experience

2004–present **International Center for Chemical Sciences, Karachi University/HEC**

Foreign Professor

- Pharmacokinetics and bioequivalence testing, intellectual property creation and establishment of Bioequivalence Testing Laboratory in Pakistan.

2005–present **Higher Education Commission, ISB**

Coordinator

- Establish a patenting system for Pakistani scientists through the website of HEC; organize lectures countrywide to promote entrepreneurship, intellectual property creation and securing outsourcing of contracts to academia; academia-private sector partnerships.

2005-present **Ministry of Health Government of Pakistan**

Consultant

- Pharmacokinetics and bioequivalence testing, intellectual property creation and establishment of an office of technology transfer for the Government of Pakistan; consultant to Ministry of Health.

2003–present **Nextar Pharma (Pvt) Ltd, Karachi**

Chairman and Chief Scientific officer

- Management of the first biotechnology company in Pakistan; licensee of International Center for Biotechnology and Genetic Engineering, Triest, Italy. Recombinant production of interferon, filgrastim and erythropoietin; sterile filling of vials, mostly for export to US and UK. A $10 Million investment.

2004–present **University of Houston, Texas**

Adjunct Professor, College of Pharmacy

- Visiting Professor in Pharmaceutical Sciences.

2003–present **Therapeutic Proteins Ltd, London, UK**

Chairman and Chief Scientific Officer

- Technology and regulatory development of biogeneric (biosimilar) recombinant therapeutic proteins; optimization and certification, technology transfer. Global management of technologic research.

1998–present **Pharmaceutical Scientist, Inc., Chicago, IL**

Chief Executive Officer

- Consultant to the pharmaceutical industry worldwide; biotechnology, genetic engineering, intellectual property, BA/BE; project management; regulatory approvals. Clients worldwide.

1999 – 2002 **Julphar Pharma Inc** **Deerfield, IL**

Chief Executive Officer

- Business development for Gulf Pharmaceutical Industries; complete assistance in design, regulatory, formulation and FDA filings; full FDA

approval achieved.

1996 – 1999 **Gulf Pharmaceutical Industries** **UAE**

Director Quality Affairs

QA, QC, Regulatory, Product Development; design and implementation of new manufacturing facilities.

1991 **Abbott International** **Abbott Park, IL**

Volwiler Fellow

- Highest research achievement recognition by Abbott Laboratories. Volwiler fellowship is a position awarded.

1988 -1996 **Abbott Laboratories** **Karachi, Pakistan**

Director, Technical Affairs

- Regulatory and technical affairs. Research and development; drug delivery systems, bioequivalence studies, formulation changes for cost-optimization.

1988 - 1996 **Aga Khan University** **Pakistan**

Professor of Pharmacology

- Teaching of pharmacology (pharmacokinetics); drug delivery systems.

1972 - 1988 **University of Illinois** **Chicago, IL**

Instructor to Associate Professor

- Research, teaching, scholarly activity. Tenured professorship. Senior Graduate School Faculty appointment, research grants, teaching awards, patents; the first textbook in Biopharmaceutics and Clinical Pharmacokinetics (John-Wiley & Sons). Trained 30 Ph.D. and M.S. students; trained FDA inspectors.

Patents and publications

Patents

Thirteen key patents issued as of 2002. Seven patent applications are pending issuance. Several patent applications in final stages of approval: Novel drug delivery systems, technique to prevent post-surgical adhesions and female infertility, a unique formulation for lower back-ache pain that delivers a muscle relaxant and an NSAID, a dual-action product for weight loss curbing carbohydrate craving (a side effect of lipase inhibitors) and reducing absorption of fat through use of lipase inhibitors, a combination therapy on preventing rectal leakage of oil in the use of lipase inhibitors used for weight loss. Several other patents are in various stages of concept testing and writing planning.

6,555,118	Pharmaceutical preparation for the treatment of topical wounds and ulcers
6, 495, 174	Herbal composition for the treatment of alopecia
6, 462, 083	Suppository base
6, 447, 820	Pharmaceutical composition for the prevention and treatment of scar tissue
6, 419, 963	Composition and method for the treatment of diaper rash using natural products
6, 365, 198	Pharmaceutical preparation for the treatment of gastrointestinal ulcers and hemorrhoids
6, 338, 862	Composition and method of use in treating sexual dysfunction using cGMP-specific phosphodiesterase type 5 inhibitors
6, 312, 735	Method for instantaneous removal of warts and moles

6, 251, 421	Pharmaceutical composition containing psyllium fiber and a lipase inhibitor
6, 235, 796	Use of fluorocarbons for the prevention of surgical adhesions
6, 235, 314	Analgesic, anti-inflammatory and skeletal muscle relaxant compositions
4, 639, 368	Chewing gum containing a medicament and taste maskers
4, 530, 936	Composition and method for inhibiting the absorption of nutritional elements from the upper intestinal tract

Publications, partial listing; over 100 contributions (partial listing)

- Iqbal MP, Baig JA, Ali AA, Niazi SK, Mehboobali N, Hussain MA. The effects of non-steroidal anti-inflammatory drugs on the disposition of methotrexate in patients with rheumatoid arthritis. Biopharm Drug Dispos. 1998 Apr; 19(3):163-7.
- Niazi SK, Alam SM, Ahmad SI. Partial-area method in bioequivalence assessment: naproxen. Biopharm Drug Dispos. 1997 Mar; 18(2):103-16.
- Niazi SK, Alam SM, Ahmad SI. Dose dependent pharmacokinetics of naproxen in man. Biopharm Drug Dispos. 1996 May; 17(4):355-61.
- Iqbal MP, Niazi SK, Mehboobali N, Zaidi AA. Disposition kinetics of aditoprim in two monkeys in comparison to other mammalian species. Biopharm Drug Dispos. 1995 Nov; 16(8):713-8.
- Iqbal N, Ahmad B, Janbaz KH, Gilani AU, Niazi SK. The effect of caffeine on the pharmacokinetics of acetaminophen in man. Biopharm Drug Dispos. 1995 Aug; 16(6):481-7.
- Iqbal MP, Niazi SK, Ashfaq MK, Mahboobali N. Pharmacokinetics of aditoprim in normal and febrile sheep. Biopharm Drug Dispos. 1995 May; 16(4):343-9. No abstract available.
- Iqbal MP, Ashfaq MK, Niazi SK, Mahboobali M, Khawaja KN. Pharmacokinetics of aditoprim and trimethoprim in buffalo calves. Biopharm Drug Dispos. 1994 Mar; 15(2):173-7.
- Niazi SK, Hussain M. Disposition kinetics of 7, 12-dimethylbenz(a)anthracene in rats. Biopharm Drug Dispos. 1992 Nov; 13(8):591-6.
- Ahmad M, Niazi SK, Ahmad T, Muzaffar NA, Nawaz M. Effect of dehydration on the disposition kinetics of erythromycin in rabbits. Biopharm Drug Dispos. 1992 Mar; 13(2):77-82.
- Bhutta ZA, Niazi SK, Suria A. Chloramphenicol clearance in typhoid fever: implications for therapy. Indian J Pediatr. 1992 Mar-Apr; 59(2):213-9.
- Iqbal MP, Mahboobali N, Niazi SK, Mahmood MA. Pharmacokinetics of aditoprim in goats using a radioassay. Biopharm Drug Dispos. 1990 Aug-Sep; 11(6):533-41.
- Prasad P, Niazi S, Jung D. Effect of acute water deprivation on renal function in rats. Biopharm Drug Dispos. 1988 May-Jun; 9(3):259-65.
- Zafar NU, Niazi S, Jung D. Influence of water deprivation on the disposition of paracetamol. J Pharm Pharmacol. 1987 Feb; 39(2):144-7.
- Prasad P, Jung D, Niazi S. Influence of short-term water deprivation on antipyrine disposition. J Pharm Sci. 1985 Mar; 74(3):338-9.
- Prasad PP, Niazi S. Effect of water deprivation on antipyrine disposition kinetics in rats. Biopharm Drug Dispos. 1984 Apr-

Jun; 5(2):195-8. No abstract available.

- Gurwich EL, Raees SM, Skosey J, Niazi S. Unbound plasma salicylate concentration in rheumatoid arthritis patients. Br J Rheumatol. 1984 Feb; 23(1):66-73.
- El-Rashidy R, Niazi S. A new metabolite of butylated hydroxyanisole in man. Biopharm Drug Dispos. 1983 Oct-Dec; 4(4):389-96.
- Bakar SK, Niazi S. Effect of water deprivation on aspirin disposition kinetics. J Pharm Sci. 1983 Sep; 72(9):1030-4.
- Bakar SK, Niazi S. Simple reliable method for chronic cannulation of the jugular vein for pharmacokinetic studies in rats. J Pharm Sci. 1983 Sep; 72(9):1027-9.
- Bakar SK, Niazi S. Stability of aspirin in different media. J Pharm Sci. 1983 Sep; 72(9):1024-6.
- Bakar SK, Niazi S. High-performance liquid chromatographic determination of aspirin and its metabolites in plasma and urine. J Pharm Sci. 1983 Sep; 72(9):1020-3.
- Niazi S, Vishnupad KS, Veng-Pedersen P. Absorption and disposition characteristics of nitrofurantoin in dogs. Biopharm Drug Dispos. 1983 Jul-Sep; 4(3):213-23.
- Ahmad T, Parveen G, Niazi S. Effect of water deprivation on chloramphenicol disposition kinetics in humans. J Pharm Sci. 1982 Nov; 71(11):1309-10.
- Niazi S, Lim J, Bederka JP. Effect of ascorbic acid on renal excretion of lead in the rat. J Pharm Sci. 1982 Oct; 71(10):1189-90. No abstract available.
- El-Rashidy R, Niazi S. Comparative pharmacokinetics of butylated hydroxyanisole and butylated hydroxytoluene in rabbits. J Pharm Sci. 1980 Dec; 69(12):1455-7.
- Niazi S. Multicompartment pharmacokinetic analysis and simulations using a programmable calculator. Int J Biomed Comput. 1979 May; 10(3):245-55.
- El-Rashidy R, Niazi S. GLC determination of butylated hydroxyanisole in human plasma and urine. J Pharm Sci. 1979 Jan; 68(1):103-4.
- El-Rashidy R, Niazi S. Binding of butylated hydroxyanisole to human albumin using a Novel dynamic method. J Pharm Sci. 1978 Jul; 67(7):967-70.
- Niazi S. Thermodynamics of mercaptopurine dehydration. J Pharm Sci. 1978 Apr; 67(4):488-91.
- Bakar S, Niazi S. Simplified method to study stability of pharmaceutical systems. J Pharm Sci. 1978 Jan; 67(1):141.
- Hussain M, Niazi S, Arambulo A, Long DM. Perfluorooctyl bromide: a potential antiobesity compound. J Pharm Sci. 1977 Jun; 66(6):907-8.
- Huang ML, Niazi S. Polymorphic and dissolution properties of mercaptopurine. J Pharm Sci. 1977 Apr; 66(4):608-9.
- Niazi S. Application of a programmable calculator in data fitting according to one and two compartment open models in clinical pharmacokinetics. Comput Programs Biomed. 1977 Mar; 7(1):41-4.
- Niazi S, Chiou WL. Fluorocarbon aerosol propellants XI: Pharmacokinetics of dichlorodifluoromethane in dogs following single and multiple dosing. J Pharm Sci. 1977 Jan; 66(1):49-53.
- Niazi S. Volume of distribution and tissue level errors in instantaneous intravenous input assumptions. J Pharm Sci. 1976 OCT; 65(10):1539-40.

- Niazi S. Comparison of observed and predicted first-pass metabolism of nortriptyline in humans. J Pharm Sci. 1976 OCT; 65(10):1535-6.
- Chiou WL, Niazi S. Pharmaceutical applications of solid dispersion systems: dissolution of griseofulvin-succinic acid eutectic mixture. J Pharm Sci. 1976 Aug; 65(8):1212-4.
- Niazi S. Comparison of observed and predicted first-pass metabolism of imipramine in humans. J Pharm Sci. 1976 Jul; 65(7):1063-4.
- Niazi S. Errors involved in instantaneous intravascular input assumptions. J Pharm Sci. 1976 May; 65(5):750-2.
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- Niazi S. Effect of polyethylene glycol 4000 on dissolution properties of sulfathiazole polymorphs. J Pharm Sci. 1976 Feb; 65(2):302-4.
- Niazi S, Chiou WL. Fluorocarbon aerosol propellants X: pharmacokinetics of dichlorotetrafluoroethane in dogs. J Pharm Sci. 1976 Jan; 65(1):60-4.
- Niazi S, Chiou WL. Fluorocarbon aerosol propellants. VI: Interspecies differences in solubilities in blood and plasma and their possible implications in toxicity studies. J Pharm Sci. 1975 Sep; 64(9):1538-41.
- Niazi S, Chiou WL. Fluorocarbon aerosol propellants IV: pharmacokinetics of trichloromonofluoromethane following single and multiple dosing in dogs. J Pharm Sci. 1975 May; 64(5):763-9.
- Niazi S, Chiou WL. Partition coefficients of fluorocarbon aerosol propellants in water, normal saline, cyclohexane, chloroform, human plasma, and human blood. J Pharm Sci. 1974 Apr; 63(4):532-5.
- Chiou WL, Niazi S. A simple and ultra-sensitive head-space gas chromatographic method for the assay of fluorocarbon propellants in blood. Res Commun Chem Pathol Pharmacol. 1973 Sep; 6(2):481-98.
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Books

- **Textbook of Clinical Pharmacokinetics and Biopharmaceutics.** John-Wiley & Sons. NY. 1979. **New edition under preparation. 2007]**
- **The Omega Connection.** Esquire Press. 1986**.** [Suggested trans-fat labeling recently accepted by the FDA.]
- **Wellness Guide**. Ferozsons Publishers. Pakistan 2002**.** [Health tips on over 600 topics; compilations of a worldwide syndicated newspaper column.]
- **Love Sonnets of Ghalib.** Rupa & Co., India and Ferozsons Pakistan 2002. [First complete English translation and explication of the works of the most famous Urdu poet. (http://www.ghalib.org]
- **Filing Patents Online: A Professional Guide**. CRC Press. 2003. [An IT/Law book; first book on the subject, over 500 pages.]

- **Handbook of Pharmaceutical Manufacturing Formulations** Volumes 1-6; CRC Press, 2004
- **Pharmacokinetic and Pharmacodynamic Modeling in Early Drug Development,** Chapter in The PROCESS of NEW DRUG DISCOVERY and DEVELOPMENT (SECOND EDITION), Charles G. Smith Ph. D. and James T. O'Donnell Pharm. D., Editors. CRC Press 2006.
- **Handbook of Therapeutic Protein Manufacturing: Manufacturing, Regulatory, Testing and Intellectual Property Issues.** CRC Press. 2005.
- **Handbook of Preformulation:** Drugs, Botanicals and Biological Pharmaceutical Products. CRC Press 2006.
- **Handbook of Bioequivalence Testing:** CRC Press, 2007

Current Research Interests:

- Therapeutic protein manufacturing—yield improvement.
- Pegylation systems for therapeutic proteins and as means of drug delivery systems.
- Novel oral viral vaccine development.
- Basal stem cell stimulation using β-sitosterol and other naturally occurring compounds.
- Modulation of absorption profile of nutrients using soluble fiber in the treatment of diabetes.
- Combination of botanical drugs with ethical compounds to reduce side effects, create new applications and establish proprietary systems.
- Evaluation of anecdotal treatments of diabetes.
- Pancreatic islet cell transplant.

Business Interests

- Manufacturing of therapeutic proteins; biotechnology, genetic engineering: vaccines, therapeutic proteins.
- Technology acquisition; excellent worldwide networking for new technology and NCE acquisition.
- Development of generic equivalent formulations; have established the world's largest resource.
- Worldwide connectivity for most optimal cost of production of biotechnology-based products.
- Ethical botanical line of products; have developed most effective formulations with safety profile.
- Consulting services to the industry, regulatory authorities and profession.