Personal Information

Email: youssef.naguib@mu.edu.eg youssefwahibnaguib-ibrahim@uiowa.edu naguib@utexas.edu

Phone (Egypt): +2 01282693324

<u>Position:</u> Assistant professor of pharmaceutics, Department of pharmaceutics, Faculty of Pharmacy, Minia University, Minia, Egypt.

Education

2017-2020 Post-doctoral fellowship College of Pharmacy, University of Iowa, Iowa, USA

2015-2016 Post-doctoral fellowship College of Pharmacy, University of Texas at Austin, Texas, USA

2015 Ph.D. College of Pharmacy, University of Texas at Austin, Texas, USA

2009 M. S. Faculty of pharmacy, Minia University, Minia, Egypt.

2003 B. Pharm. (Excellent with honors) Faculty of Pharmacy, Minia University, Minia, Egypt

Awards and research grants

1- Holden Comprehensive Cancer Center (HCCC) Oberely Seed Grant for an amount of \$25,000.

Date: Feb 2019

Grant provider: US National Cancer Institute (NCI) through Holden Comprehensive Cancer Center, University of Iowa, Iowa City, IA, USA

2- Crowley and Vaughn graduate fellowship, The Duane A. Boyle fellowship in Pharmaceutics, and the Max & Mary Anne Burlage Fellowship, for an amount of \$10,000.

Date: May 2014

Fellowship provider: College of Pharmacy, The University of Texas at Austin.

3- Full PhD-Scholarship at the University of Texas at Austin (Targeted nano-carriers for cancer therapy) for an amount of \$220,000.

Date: May 2010

Scholarship provider: Missions Sector, Ministry of Higher Education, Egyptian Government, Egypt.

Summary

I am a highly experienced researcher with a strong background in pharmaceutical formulation design, nanoparticle- and microparticle-based delivery systems, cancer nanomedicine, and pharmacokinetics, in addition to liquid chromatography and other analytical techniques, chemical synthesis, and animal models. Other experience-related assets include excellent presentation skills, and superior communication and writing skills. I also gained extensive teaching experience at the University of Texas at Austin while I participated in pharmacokinetics classes to Pharm. D. students, gave some few lectures to graduate students, and gave several scientific seminars to highly experienced audience at the University of Texas and University of Iowa.

Skills

<u>Pharmaceutical Formulation design</u>: extensive experience in nanoparticle (polymeric and solid lipid nanoparticles) development and characterization, and microspheres development and characterization. Other formulations and drug delivery systems of interest include implants, emulsions, creams, inclusion complexes, and liposomes.

<u>Cell culture:</u> Extensive experience in cell culture techniques including cell culturing and freezing, cytoxicity and viability assays, transfection, cell uptake studies, fluorescence microscopy, and flow cytometry.

<u>Chemical synthesis, pro-drug development, and polymer conjugation</u>: previous experience includes development of gemcitabine pro-drug(s) and conjugate(s), and PLGA/PEG/folic acid conjugation. Expertise include NMR operation and spectra interpretation.

<u>Characterization of pharmaceutical formulations</u>: several techniques including release studies, stability studies, differential scanning calorimetry, particle size analysis, transdermal and corneal permeation studies (using Franz (horizontal) and Ussing (vertical) diffusion cells), and determination of equilibrium solubility, partition coefficient, and plasma protein-binding, in addition to lyophilization, purification, dialysis, ultrafilitration, and ultracentrifugation.

Analytical and separation techniques: Extensive experience in liquid chromatography (HPLC, GPC, and silica gel columns) and TLC. HPLC experience includes development of analytical methods for new drug entities (single or multiple) in pure form, pharmaceutical formulations, and biological samples (including drug extraction from plasma and various tissues, using liquid-liquid extraction, protein precipitation and solid-phase extraction). I was also responsible for instrument repair and maintenance.

Experimental animals: Extensive experience in handling several strains of mice, human and murine tumor challenge in mice (including subcutaneous tumors and orthotopic mammary and pancreatic tumors), intravenous (tail vein and retro-orbital), intraperitoneal and subcutaneous injection (mice and rats). Other skills include IVIS imaging, microneedle application in mice, in addition to blood collection (submandibular bleeding from mice, cardiac puncture in mice, and tail vein collection from rats), and several organ collection (mice and rats). Animal experience also includes conducting pharmacokinetics and biodistribution studies, toxicity evaluation of new active compounds in mice, histological studies and tissue preparation, immunohistochemistry, in addition to some surgical skills (sutures, orthotopic pancreatic tumor challenge and calvarial defects induction in rat skull).

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Professional Experience

Minia University, Faculty of Pharmacy

11/2016 – 11/2017

Position: Assistant professor of pharmaceutics

9/2020 – current

University of Iowa, College of Pharmacy 11/2017 – 8/2020

Position: Post-doctoral fellow (lab of Professor Aliasger Salem)

University of Texas at Austin, College of Pharmacy 6/2015 - 6/2016

Position: Post-doctoral fellow (lab of Professor Zhengrong Cui)

University of Texas at Austin, College of Pharmacy 10/2013 – 6/2016

Position: Lab Manager (lab of Professor Zhengrong Cui)

University of Texas at Austin, College of Pharmacy Spring 2013 and 2015

Position: Teaching assistant

Texas A&M Health Science Center, Rangel College of pharmacy 1/2011 – 8/2011
Position: graduate research assistant (lab of professor Delwar Hussain)

Minia University, Faculty of Pharmacy, Minia, Egypt 2003 – 2010

Position: Teaching assistant (several classes, including pharmacokinetics, industrial pharmacy, physical pharmacy, and formulation).

Retail Pharmacy, Egypt 2004 – 2005

Position: retail pharmacist

Peer reviewing (volunteer contribution) for the following journals:

- i- International Journal of Pharmaceutics, Elsevier, Amsterdam, Netherlands
- ii- AAPS PharmSciTech, Springer Science + Business Media LLC
- iii- Drug Development and Industrial Pharmacy, Informa Healthcare, London, UK.
- iv- Chemistry Letters, Bulletin of the Chemical Society of Japan, Tokyo, Japan.

Teaching and Research Experience

University of Iowa, College of Pharmacy

11/2017 - 9/2020

Research: Research projects include:

- The development of novel nanocarriers for the delivery of nucleic acids to tumors.
- The application of novel combinations for cancer treatment.
- Delivery of new molecular inhibitors to the brain.
- Application of cyclodextrins to improve corneal delivery and oral absorption of hydrophobic drugs
- Pharmacokinetic study of new drug molecules in free form and nanoparticles.

University of Texas at Austin, College of Pharmacy

8/2011 - 6/2016

Research: (A) Post-doc research projects include:

- The development of nanomedicine-based approaches to breach the tumor microenvironment.
- The evaluation of the toxic effects of a new gemcitabine conjugate for pancreatic cancer.

(B) Doctoral research projects:

The development and in vitro/in vivo evaluation of a solid lipid nanoparticle formulation for the improvement of delivery
of docetaxel to solid tumors.

- Development and in vitro/in vivo evaluation of a novel gemcitabine conjugate for pancreatic cancer.
- Microneedle-assisted delivery of 5-fluorouracil for the treatment of skin cancer.

Teaching: Teaching assistant duties of Integrated Basic and Applied Pharmacokinetics (13SP) course in two semesters (Spring 2013 and 2015). I also gave few lectures and seminars to graduate students.

Texas A&M Health Science Center, Rangel College of pharmacy

1/2011 - 8/2011

Research: Research project was focused on the development of polymeric nanoparticles composed of PLGA-PEG-folic acid for the targeted delivery of tanespimycin (17-AAG) to cancer cells that overexpress folic acid receptors.

Minia University, Faculty of Pharmacy, Minia, Egypt Position: Assistant professor of pharmaceutics

11/2016 - 11/2017 9/2020 - current

Research: I participated in the following research projects:

- Development and in vitro/in vivo characterization of oral baclofen gastro-retentive dosage forms.
- Development and characterization of bee propolis-loaded liposomes.
- Microneedle-assisted delivery of anti-inflammatory agent(s) to treat rheumatoid arthritis.

Teaching: I taught the following classes: Basic and clinical pharmacokinetics, physical pharmacy, and controlled-release drug delivery systems.

Minia University, Faculty of Pharmacy, Minia, Egypt
Position: graduate research assistant (Pharmaceutics department)

5/2005 - 5/2009

Research: Master's research project was focused on the development and characterization of biodegradable microsphere-based formulation for the sustained release of prednisolone to treat rheumatoid arthritis in a mouse model.

Teaching: Teaching assistant duties of basic and clinical pharmacokinetics, and dosage forms.

Publications

- 1- Somaya A Abdel-Rahman, Emad I Wafa, Kareem Ebeid, Sean M Geary, **Youssef W Naguib**, Ashraf K El-Damasy, Aliasger K Salem. Thiophene derivative-loaded nanoparticles mediate anticancer activity through the inhibition of kinases and microtubule assembly. **Advanced Therapeutics**, 2021, 4(7):2100058
- 2- Riyad Alzhrani, Haiyue Zhu, Solange Valdes, **Youssef W. Naguib**, Zhengrong Cui, Effect of surface mannosylation on the cytotoxicity and cellular uptake of stearoyl gemcitabine-incorporated, acid-sensitive micelles. **Colloid and Interface Science Communications**, 2021, 43:100441.
- 3- Aml Mekkawy, **Youssef W. Naguib**, et al., Paclitaxel anticancer activity is enhanced by the MEK 1/2 inhibitor PD98059 in vitro and by PD98059-loaded nanoparticles in BRAF V600E melanoma-bearing mice. **International Journal of Pharmaceutics**, 2021. 606:120876
- 4- Youssef W. Naguib, Sanjib Saha, Jessica M. Skeie, Timothy Acri, Kareem Ebeid, Somaya Abdel-Rahman, Sandeep Kesh, Gregory A. Schmidt, Darryl Y. Nishimura, Jeffrey A. Banas, Min Zhu, Mark A. Greiner, and Aliasger K. Salem. A Solubilized ubiquinol for preserving corneal function. **Biomaterials**. 2021, 275:120842
- 5- Youssef W. Naguib, Yang Yu, Shun-guang Wei, Angie Morris, Brittany E. Givens, Aml Mekkawy, Robert M. Weiss, Robert B. Felder, and Aliasger K. Salem. An Injectable Microparticle Formulation Provides Long-Term Inhibition of Hypothalamic ERK1/2 Activity and Sympathetic Excitation in Rats with Heart Failure. Molecular Pharmaceutics. 2020 Sep, 8(9): 3643-3648
- 6- Jessica M. Skeie, Benjamin T. Aldrich, Darryl Y. Nishimura, Gregory A. Schmidt, M. Bridget Zimmerman, Jennifer J. Ling, **Youssef W. Naguib**, Aliasger K. Salem, Mark A. Greiner. Ubiquinol Supplementation of Donor Tissue Enhances Corneal Endothelial Cell Mitochondrial Respiration. <u>Cornea</u>. 2020. 39(10): 1285-1290

- 7- Youssef W. Naguib, Brittany E. Givens, Giang Ho, Yang Yu, Shun-guang Wei, Robert M. Weiss, Robert B. Felder, Aliasger K. Salem. An injectable microparticle formulation for the sustained release of the specific MEK inhibitor PD98059: in vitro evaluation and pharmacokinetics. Drug Delivery and Translational Research. 2020. DOI: 10.1007/s13346-020-00758-9
- 8- Mohamed Ibrahim, Hatem A. Sarhan, **Youssef W. Naguib**, Hamdy Abdelkader. Design, characterization and in vivo evaluation of modified release baclofen floating coated beads. <u>International Journal of Pharmaceutics</u>. 2020. 582:119344
- 9- Hesham Refaat, **Youssef W. Naguib**, Mahmoud M. A. Elsayed, Hatem A. A. Sarhan, Eman Alaaeldin. Modified Spraying Technique and Response Surface Methodology for the Preparation and Optimization of Propolis Liposomes of Enhanced Anti-Proliferative Activity against Human Melanoma Cell Line A375. <u>Pharmaceutics</u>. 2019. 28;11(11):558
- 10- Brittany E. Givens¹, **Youssef W. Naguib**¹, Sean M. Geary, Eric J. Devor, Aliasger K. Salem. Nanoparticle-Based Delivery of CRISPR/Cas9 Genome-Editing Therapeutics. AAPS Journal. 2018. 20(6):108

¹ Equal contribution

- 11- Young K. Cheun, Myong-Chul Koag, **Youssef W. Naguib**, Hala Ouzon-Shubeita, Zhengrong Cui, Danaya Pakotiprapha, and Seongmin Lee. Synthesis, structure, and biological evaluation of a platinum-carbazole conjugate. Chemical Biology & Drug Design, 2018, 91(1): 116-125
- 12- Hannah L. O'Mary, Abdulaziz M. Aldayel, Solange A. Valdes, Youssef W. Naguib, Xu Li, Karun Salvady, and Zhengrong Cui. Acid-Sensitive Sheddable PEGylated, Mannose-Modified Nanoparticles Increase the Delivery of Betamethasone to Chronic Inflammation Sites in a Mouse Model. Molecular Pharmaceutics, 2017, 14(6): 1929-1937
- 13- Xu Li, **Youssef W. Naguib**, and Zhengrong Cui. In Vivo Distribution of Zoledronic Acid in a Bisphosphonate-Metal Complex-Based Nanoparticle Formulation synthesized by a Reverse Microemulsion Method. <u>International Journal of Pharmaceutics</u>, 2017, 526(1-2): 69-76
- 14- Xu Li, **Youssef W. Naguib**, Solange Valdes, Stephanie Hufnagel, and Zhengrong Cui. Reverse Microemulsion-Based Synthesis of (Bis)phosphonate-Metal Materials with Controllable Physical Properties: An Example Using Zoledronic Acid-Calcium Complexes. <u>ACS Applied Materials & Interfaces</u>. 2017, 9(16): 14478-14489
- 15- Solange Valdes, **Youssef W. Naguib**, Rick A. Finch, Wallace B. Baze, Christopher A. Jolly, and Zhengrong Cui. Preclinical Evaluation of the Short-Term Toxicity of 4-(N)-Docosahexaenoyl 2´, 2´- Difluorodeoxycytidine (DHA-dFdC). <u>Pharmaceutical Research</u>, 2017, 34(6): 1224-1232
- 16- Youssef W. Naguib, Hannah L. O'Mary, Zhengrong Cui, and Alan B. Watts. <u>Chapter 6: Injectable Formulations of Poorly Water-Soluble Drugs</u>; In: Robert O. Williams III, Alan B. Watts, and Dave A. Miller (Eds), Formulating Poorly Water Soluble Drugs (2nd Ed.), American Association of Pharmaceutical Scientists (AAPS), Springer-Verlag New York.
- 17- Abdulaziz Aldayel, **Youssef W. Naguib**, Hannah O'Mary, Xu Li, Mengmeng Niu, Tinashe Ruwona, and Zhengrong Cui. Acid-Sensitive Sheddable PEGylated PLGA Nanoparticles Increase the Delivery of TNF-α siRNA in Chronic Inflammation Site. <u>Molecular Therapy: Nucleic acids</u>, 2016, 5(7):e340. doi: 10.1038/mtna.2016.39.
- Mengmeng Niu, Solange Valdes, Youssef W. Naguib, Stephen D. Hursting, and Zhengrong Cui. Tumor-Associated Macrophage (TAM)-Mediated Targeted Therapy of Triple-Negative Breast Cancer. <u>Molecular Pharmaceutics</u>, 2016, 13(6):1833-42
- 19- Youssef W. Naguib, Dharmika Lansakara-P., Laura M. Lashinger, B. Leticia Rodriguez, Mengmeng Niu, Abdulaziz M. Aldayel, Stephen D. Hursting, and Zhengrong Cui. Synthesis, characterizations, and in vitro and in vivo evaluations of a novel gemcitabine derivative with potent and broad spectrum antitumor activity, *Neoplasia*, 2016, 18(1):33-48.
- 20- Yuan-qiang Zheng ¹, **Youssef W. Naguib** ¹, Yixuan Dong, Yan-chun Shi, Shorgan Bou, and Zhengrong Cui. Recombinant BCG in vaccine development and tumor immunotherapy. <u>Expert Reviews of Vaccines</u>, 2015, 14 (9), 1255-1275

¹ Equal contribution.

- 21- Youssef W. Naguib, B. Leticia Rodriguez, Xinran Li, Stephen Hursting, Robert Williams III, and Zhengrong Cui. Solid Lipid Nanoparticle Formulations of Docetaxel Prepared with High Melting Point Triglycerides: In Vitro and in Vivo Evaluation. Molecular Pharmaceutics, 2014, 11 (4): 1239-1249
- 22- **Youssef W. Naguib** and Zhengrong Cui. Nanomedicine: The Promise and Challenges in Cancer Chemotherapy. Advances in Experimental Medicine and Biology, 2014, 811: 207-233
- 23- **Youssef W. Naguib** ¹, Amit Kumar ¹, and Zhengrong Cui. The effect of microneedles on the skin permeability and antitumor activity of topical 5-fluorouracil. <u>Acta Pharmaceutica Sinica B</u>, 2014, 4 (1): 94-99.

¹ Equal contribution

- 24- Mengmeng Niu, **Youssef W. Naguib**, Abdulaziz M. Aldayel, Yan-chun Shi, Stephen D. Hursting, Matthew A. Hersh, Zhengrong Cui. Biodistribution and in vivo activities of tumor-associated macrophage-targeting nanoparticles incorporated with doxorubicin. <u>Molecular Pharmaceutics</u>, 2014, 11: 4425-4436
- 25- Amit Kumar, **Youssef W. Naguib**, Yan-chun Shi, and Zhengrong Cui. A method to improve the efficacy of topical eflornithine hydrochloride cream. Drug Delivery, DOI: 10.3109/10717544.2014.951746
- 26- Vipin Saxena, **Youssef Naguib**, and Delwar Hussain. Folate Receptor Targeted 17-allylamino-17-demethoxygeldanamycin (17-AAG) Loaded Polymeric Nanoparticles for Breast Cancer. <u>Colloids and Surfaces B:</u> Biointerfaces. 2012, 94, 274-280
- 27- Khaled A. Khaled, Hatem A. Sarhan, Mohamed A. Ibrahim, Azza H. Ali, and **Youssef W. Naguib***. Prednisolone-loaded PLGA Microspheres. In vitro Characterization and in vivo Application in Adjuvant-Induced Arthritis in Mice. <u>AAPS PharmSciTech</u>, 2010, 11 (2), 859-869.

* Main researcher.

28- Khaled A. Khaled, Hatem A. Sarhan, Mohamed A. Ibrahim, and **Youssef W. Naguib***. Controlled Release Prednisolone Poly (DL-Lactide) Microspheres: Impact of Formulation Parameters, Characterization, and Release Mechanism. <u>Bulletin of Pharmaceutical Sciences</u>. Assiut University, 2008, 31 (1), 49-67

* Main researcher.

Abstracts

Juliana Quarterman, Kareem Ebeid, **Youssef W. Naguib**, and Aliasger Salem. Formulation and characterization of a degradable drug eluting implant coating for improved osseointegration. AAPS PharmSci 360, November 2019, San Antonio, Texas, USA.

Youssef W. Naguib, et al., Gamma-cyclodextrin complexation improves the antioxidant activity of ubiquinol on human corneal cells and provides high corneal penetrance. Center for Biocatalysis and Bioprocessing (CBB) Annual Conference, October 2019, Iowa Memorial Union (IMU), Iowa City, Iowa, USA.

Youssef W. Naguib, et al., Combination of paclitaxel and ciprofloxacin derivative solution or nanoparticles exhibits synergistic anticancer activity. Holden Comprehensive Cancer Center Annual Scientific Retreat, June 2019, Coralville, Iowa, USA.

Abdulaziz Aldayel, **Youssef W. Naguib**, et al., A Novel TNF-α siRNA Nano-Formulation for Potential Treatment of Arthritis. AAPS Annual Meeting and Exposition, San Diego, California, USA, November 2017

Stephanie J. Hufnagel, Xu Li, **Youssef W. Naguib**, Solange Valdes, and Zhengrong Cui. Zoledronic-Calcium Complex-Based Nanoparticles Decrease Tumor-Associated Macrophages in Tumors. <u>AAPS Annual Meeting and Exposition, San Diego, California, USA, November 2017</u>

Abdulaziz Aldayel, **Youssef W. Naguib**, et al., A Novel Acid-Sensitive TNF-α siRNA Nano-formulation for Potential Treatment of Chronic Inflammation. <u>AAPS Annual Meeting and Exposition, Denver, Colorado, USA</u>, November 2016.

Nancy D. Ebelt, Clint D. J. Taveres, Xuemei Xie, **Youssef W. Naguib**, Jiney Jose, *et al.* KD06 is a novel anti-cancer drug that causes cell death in triple-negative breast cancer cell lines and tumor xenografts. In: <u>Proceedings of the 107th Annual Meeting of the American Association for Cancer Research; April 2016; New Orleans, Louisiana, USA. AACR; Cancer Res 2016; 76 (14 Suppl.): Abstract 3774.</u>

Youssef W. Naguib, et al. Synthesis, characterization, and in vitro and in vivo evaluations of a novel gemcitabine derivative with potent and broad spectrum antitumor activity. AAPS Annual Meeting and Exposition, Orlando, Florida, USA, October 2015

Solange Valdes, **Youssesf Naguib**, Zhengrong Cui. Preliminary Study of the Toxicity of a new gemcitabine derivative with Potent Broad Spectrum Antitumor Activity. <u>AAPS Annual Meeting and Exposition, Orlando, Florida, USA, October 2015</u>

Youssef W. Naguib ¹, Amit Kumar ¹, and Zhengrong Cui. Enhancing the Skin Permeability and Antitumor Efficacy of 5-fluorouracil Cream Using Microneedles. AAPS Annual Meeting and Exposition, San Diego, California, USA, November 2014

¹ Equal contribution

Mengmeng Niu, **Youssef W. Naguib**, Abdulaziz M. Aldayel, and Zhengrong Cui. Efficient Targeting of Tumor-Associated Macrophages (TAMs) Using a Polymeric Nanoplatform Surface-Functionalized with Mannose and Acid-Sensitive Sheddable PEG. AAPS Annual Meeting and Exposition, San Diego, California, USA, November 2014

Youssef W. Naguib, B. Leticia Rodriguez, Xinran Li, and Zhengrong Cui. In vitro and In vivo Evaluations of the Antitumor Activity of a Solid Lipid Nano-Scale Formulation of Docetaxel. <u>AAPS Annual Meeting and Exposition, San Antonio, Texas, USA, November 2013.</u>

Youssef Naguib, Vipin Saxena, and Delwar Hussain. Design and Evaluation of Polymeric Nanoparticles of Tanespimycin (17-AAG) for Cancer Therapy. <u>16th Annual Student Research Symposium, Texas A&M Health Science Center, Bryan, Texas, USA, May, 2011.</u>

Khaled A. Khaled, Hatem A. Sarhan, Mohamed A. Ibrahim, and **Youssef W. Naguib***. Preparation and Characterization of Prednisolone-Loaded PLA microspheres. The 30th Egyptian Pharmaceutical Society Conference, Nasr City, Cairo, Egypt, 2006.

* Main researcher.

Patents

Provisional Application (US Patent) No. 62/813,559 Provisional Application (US Patent) No. 63/004,975, Filed: March 4, 2019 Filed: April 3, 2020

References

Aliasger Salem, PhD

Lyle and Sharon Bighley Endowed Chair and Professor in Pharmaceutical Sciences

Department of Pharmaceutical Sciences and Experimental Therapeutics

The University of Iowa, Iowa City, Iowa 52246, USA

E-mail: aliasger-salem@uiowa.edu

Zhengrong Cui, PhD

Professor, Division of Molecular Pharmaceutics

The University of Texas at Austin, Austin, Texas 78712, USA

E-mail: zhengrong.cui@austin.utexas.edu

Mark Greiner, MD

Medical Director, Iowa Lions Eye Bank.

Robert and Joell Brightfelt Professor of Cornea Research

Fellowship Director, Cornea, External Diseases and Refractive Surgery

E-mail: mark-greiner@uiowa.edu

Robert O. Williams III, PhD

Professor, Division of Molecular Pharmaceutics Chairman

Johnson & Johnson Centennial Chair in Pharmacy.

The University of Texas at Austin, Austin, Texas 78712, USA

Editor-in-chief: AAPS PharmSciTech

E-mail: bill.williams@austin.utexas.edu

Salomon Stavchansky, PhD

Professor, Division of Molecular Pharmaceutics

Alcon Centennial Professor

The University of Texas at Austin, Austin, Texas 78712, USA

E-mail: stavchansky@austin.utexas.edu

Hugh Smyth, PhD

Professor, Division of Molecular Pharmaceutics

University of Texas at Austin, Austin, Texas 78712, USA

Editor-in-chief: Drug Development & Industrial Pharmacy

E-mail: hugh.smyth@austin.utexas.edu