

Ahmed S. Zidan, Ph.D.,

Visiting Associate

Division of Product Quality and Research, Office of Testing and Research, Office of Pharmaceutical Quality, Center of Drug Evaluation and Research, United States Food and Drug Administration, Silver Spring, MD, USA.

Bibliography

Ahmed S Zidan Ph.D. has earned his Ph.D. degree in Pharmaceutics from the Zagazig University faculty of Pharmacy in 2007 through a scientific mission at School of Pharmacy, Howard University, Washington DC, USA. He has published over 60 peer-reviewed manuscripts, 2 book chapters, and has been invited to give different presentations locally and internationally. Dr. Zidan's research focuses primarily in the area drug formulations design of both solid and transdermal formulations. It encompasses pediatric dosage forms, nanoparticles, modified release dosage forms, particulate engineering, and scientific underpinnings of Quality by Design utilizing novel Process Analytical Technologies. As a coordinator of graduate studies and research at Faculty of pharmacy of both King Abdulaziz University and Zagazig University, Dr. Zidan serves as the faculty advisor on all matters related to planning and conducting research to study the impact on product quality, changes in bulk drug substances, formulation component and composition, and manufacturing equipment and processes. As a recognized expert, Dr. Zidan participates as an editorial board member and reviewer in different international leading journals.

Employment

- Visiting Associate at DPQR/OTR/CDER/FDA, July 2015 to Current.
- Associate Professor of pharmaceutics and industrial pharmacy at King Abdulaziz University, Saudi Arabia September 2013 to July 2015.
- Associate Professor of pharmaceutics and industrial pharmacy at Zagazig University, Egypt; June 2012 to September 2013.
- Visiting Scientist/ORISE Fellow. DPQR/ OTR/OPS, CDER, FDA, USA; June 2008 – October 2011.
- Assistant Professor of pharmaceutics and industrial pharmacy. Faculty of pharmacy, Misr International University, Egypt; Sep 2007 to June 2008 (Part Time).
- Visiting scholar for conducting Ph.D. research. Howard University, School of Pharmacy, Washington DC, USA; April 2005 to Feb 2007. Research internship at DPQR/FDA to perform the dissertation practical part.
- Teaching assistant of Pharmaceutics and industrial pharmacy. Faculty of pharmacy, Zagazig University, Egypt; Oct 2003 to March 2005.
- Demonstrator of Pharmaceutics. Faculty of pharmacy, Zagazig University, Egypt; 1998 – 2003.
- Student internship. Egyptian international pharmaceutical Industries Co., (EIPICo), Egypt; May 1994-Sept 1994.

Research-Review Projects in DPQR/FDA

- Reviewed the Drug Product file of original ANDAs in the Review-Research team:
 1. ANDA 207472, Methylphenidate Hydrochloride Extended Release Tablets, 54 mg by Vintage Pharmaceuticals.
 2. ANDA 206351, Metoprolol Succinate Extended-Release Tablets USP 25 mg, 50 mg, 100 mg and 200 mg by Jubilant Life Sciences Limited
 3. ANDA 204340, Oxymorphone Hydrochloride Extended-Release Tablets, 40 mg by Par Pharmaceutical Inc.
 4. ANDA 206926, Methylphenidate Hydrochloride for Extended Release Oral Suspension 25 mg per 5 mL (5 mg per mL) CII by Par Pharmaceutical Inc.
 5. ANDA 207287, Testosterone Gel, 1.62%, Multi-dose pump (20.25 mg/1.25 g actuation) (CIII) by Sandoz Inc.
 6. ANDA 207194, Clindamycin Phosphate and Benzoyl Peroxide Gel, 1.2% and 2.5% by Tolmar Inc.
- Helped with addressing citizen petition, identification of product problems, post marketing corrections, removal of regulatory hurdle for approvals, and helped train reviewers scientists or consumer safety officers. The following products were directly or indirectly impacted by my research work (please see peer reviewed research articles and book chapter in the publication list):
 1. Effect of permeation enhancers on testosterone permeation from Carbopol gels (2 manuscripts under preparation, 1 technical report)
 2. Risk of subpotency in BD syringes (2 manuscripts under preparation, 2 technical reports).
 3. Lipolysis of oral lipid based products (1 manuscript under preparation, 1 technical report).
 4. Tacrolimus group of products (3 publications).
 5. Unit operations (5 publications).
 6. Oral and Rapid Disintegrating Tablets (5 publications).
 7. Transdermal drug delivery systems (7 publications).
 8. Topical drug delivery systems (3 publications).
 9. Multivariate chemometric modeling of solid and colloidal formulations (7 publications).
 10. Cyclosporine oral self-nanoemulsified capsules (3 publications, 2 technical reports).
 11. Safety-first project: Metoprolol Succinate extended release tablets (3 publications, 2 technical reports)).
 12. Risks associated with Tablet splitting (Citation in FDA guidance for Industry on tablet scoring and Citation in Texas bill for practices on dispensing medications).
 13. Co-crystalline drug products (5 publications).
 14. Colloidal nanoformulations based drug delivery products - Liposomes, Emulsions, Niosomes, Nanoparticles and Microemulsions (15 publications).
 15. Tannate group of products (3 publications, 1 technical report).
 16. Pediatric products and mini-tableting (3 publications, WHO white paper, 1 technical report).

Honors and awards

- “CDER Special Recognition Award ‘Abuse Deterrent Formulations (ADF) Research and Review Team’ for Outstanding research effort on Abuse deterrent Formulations (ADF) and for the first review of generic ADF through a pilot Review-Research team approach by Food and Drug Administration, MD, USA in 2016.

- “CDER Regulatory Science Excellence” Award to ‘Chemometric Methods for Tacrolimus Crystallinity Team’ for the quantification of crystallinity and discriminatory dissolution methods development for the tacrolimus products by Food and Drug Administration, MD, USA in 2014.
- FDA Group recognition award as a member of the 2015 CDER QbD&PAT Workshop committee for the extraordinary effort and team work in developing a state-of-the-art, CE-Credited comprehensive workshop on Quality-by-Design and Process Analytical Technology for FDA staff members.
- ORISE fellowship award by Food and Drug Administration, MD, USA for three year (2008-2011).
- Doctoral candidate Fellowship award from the Ministry of Higher Education of the Egyptian Government for pursuing Doctorate of Pharmacy at Howard University, Washington DC, USA by University Grants Commission, for two years (2005-2006).
- US FDA student internship for pursuing Ph.D. research for 16 months (2005-2006).
- Zagazig University (Zagazig, Egypt) Awards for research publications in international Journals, 2006, 2007, 2008, 2009, 2010, 2011, 2012, 2013 and 2014, \$15,000 for 25 Peer reviewed international publications in ISI journals)
- King Abdulaziz University (Jeddah, Saudi Arabia) Awards for research publications in international Journals, 2013, \$4000 for 4 publications.
- Acdima Inc. Award (Amman, Jordan) of for the best publication in Middle East in the field of Pharmaceutical Technology, 2014, \$15,000.
- “Distinguished CDER Faculty” award during 2015-2016 by Office of Pharmaceutical Quality, Center of Drug Evaluation and Research, United States Food and Drug Administration, USA.

Grants

- PI in a proposal titled as “A quality by design approach to maximize skin permeation of anti-AIDS loaded niosomes” and submitted through the Distinct Research Study plans of King Abdulaziz University, March 2013. Funded with a sum SR 50K.
- PI in a proposal titled as “Assessment of Simvastatin Niosomes for Pediatric Transdermal Drug Delivery” and submitted through the internal path of scientific grants of deanship of Scientific Research of King Abdulaziz University, September 2013. Funded with a sum SR 96.2K.
- Co-PI in a proposal titled as “Rapid disintegrating tablets of simvastatin dispersions for a maximized hypolipidemic efficacy” and submitted through the internal path of scientific grants of deanship of Scientific Research of Umm Al-Qura University, May 2013. Funded with a sum SR 150K.
- PI in a proposal titled as “Taste masked tacrolimus-phospholipid dispersions for improved dissolution and gastric tolerability” and submitted through the Distinct Research Study plans of King Abdulaziz University, November 2014. Funded with a sum SR 50K.
- PI in a proposal titled as “Nicotinamide polymeric nanoemulsified systems: A QbD study for better antimicrobial activity” and submitted through the internal path of scientific grants of deanship of Scientific Research of King Abdulaziz University, August 2014. Funded with a sum SR 82.2K.
- Co-PI in a proposal titled as “Understanding Critical Quality Attributes of Modified Release Formulation Manufactured by Three Dimensional Printers” approved through the Critical Path Initiative Grants of the Center of Drug Evaluation and Research, United States Food and Drug Administration, USA, 2016-2017. Funded with a sum \$ 188K.

Reviewing board of pharmaceutical journals

- Journal of Pharmaceutical Sciences.
- International Journal of Pharmaceutics.
- AAPS PharmSciTech Journal.
- AAPS Journal.
- Abstract reviewer for AAPS Annual Meeting.
- Drug development and Industrial Pharmacy Journal.
- Drug Technology Journal.
- Pharmaceutical development and technology Journal.
- Asian journal of pharmaceutics.
- Journal of Zagazig University.
- ISRN pharmaceutics Journal.
- Pharmaceutical projects submitted for funding from Taif University, KSA, King Abdulaziz University, KSA, and Umm Al-Qura University, KSA.

Editorial board membership of scientific journals

- Editorial board member in Wireless Engineering and Technology Journal.
- Editorial board member in Research Journal of Pharmacy and Technology.
- Editorial board member in ISRN pharmaceutics Journal.
- Editorial board member in International Journal of Pharmaceutical Sciences and Research.
- Editorial board member in Indo-American Journal of Pharma and Bio Sciences.
- Editorial board member in International Journal of Pharmaceutical, Chemical and Biological Sciences.
- Editorial board member in International Journal of Pharmaceutical and Biological Research.

Supervision/mentorship for dissertation/thesis research

- Served as a co-advisor for 3 Master students at Department of Pharmaceutics and Industrial Pharmacy, Faculty of Pharmacy, Zagazig University, Zagazig, Egypt (Sheref Imam, Sara Labib and Mohamed Ebeed).
- Served and mentored four Ph.D. graduate students at Department of Pharmaceutical Sciences, School of Pharmacy, Howard University, Washington DC, USA (Crystal Spinks, David Awotwee, Nahid Deepa, Chintan Bhanushali).
- Serving as principle advisor for 2 Master students at Department of Pharmaceutics, Faculty of Pharmacy, King Abdulaziz University, Jeddah, KSA (Ibrahim Harbi and Fahed Alshammary).

Peer-reviewed publications

- 62 publications in peer reviewed ISI journals.

Oral and Poster Presentations

- 40 presentations in international conferences and meetings.