Considerations for and Alternatives to Comparative Clinical Endpoint and Pharmacodynamic Bioequivalence Studies for Generic Orally Inhaled Drug Products

Public Workshop
April 20-21, 2023

Agenda

FDA recommendations for establishing bioequivalence (BE) with local drug delivery for orally inhaled drug products (OIDPs) often involve study designs for conducting comparative clinical endpoint (CCEP) and pharmacodynamic (PD) BE studies. Considering the difficulties that these studies can present for generic drug developers, FDA product-specific guidance (PSG) recommendations for some OIDPs have included alternative BE approaches that do not involve CCEP BE studies. However, understanding what studies may be suitable as part of an alternative BE approach can be difficult when developing generics for certain inhalation products with complex formulations, such as suspension-based metered dose inhalers (MDIs) and dry powder inhalers (DPIs).

The purpose of this two-day OIDP workshop is to discuss the current scientific and regulatory perspectives for using in vitro, in vivo, and in silico studies as alternatives to CCEP and PD BE studies, and to explore potential designs for alternative BE approaches that can address the particular challenges associated with establishing local drug delivery equivalence for suspension-based MDIs and DPIs. The workshop will begin with a reflection on the successes, limitations, and challenges with BE approaches that include CCEP, and PD BE studies. Next, two parallel sessions will provide focused discussion on the in vitro, in vivo, and in silico studies that may serve as alternatives to CCEP, and PD BE studies, where these interactive sessions will allow for small group discussions centered on the technical and practical aspects of these studies when used across OIDPs. The workshop will conclude with panel discussions for MDIs and DPIs that will provide participants the opportunity to discuss their study designs and issues with applying alternative BE approaches in lieu of CCEP and PD BE studies, with the goal of identifying where consensus can be achieved between collaborators from government, industry, and academia on what may constitute adequate alternative BE approaches for complex OIDPs.

GENERAL TOPICS THAT WILL BE THE FOCUS OF THE WORKSHOP:

- Reviewing successes with the use of CCEP and PD BE studies to establish BE for locally acting OIDPs, and discussing relevant challenges
- Evaluating alternative BE approaches that utilize in vitro, in vivo, and in silico studies, instead of CCEP and PD BE studies, and discussing relevant technical and practical issues when used with different OIDPs
- Discussing the integration of multiple alternative in vitro, in vivo, and in silico studies to form cohesive alternative BE approaches in lieu of CCEP or PD BE studies for MDIs and DPIs

Day 1 — April 20, 2023

8:30 AM – 8:40 AM	**Welcome**	
	Anna Schwendeman, PhD	Co-Director, CRCG
8:40 AM – 8:50 AM	**Opening Remarks**	
	Robert Lionberger, PhD	Director, ORS, OGD, CDER, FDA
8:50 AM – 8:55 AM	***Workshop Day 1 Overview***	
	Elizabeth Bielski, MS, PhD	Senior Pharmacologist, DTP-I, ORS, OGD, CDER, FDA
Symposium I:	**Successes and Challenges Associated with the Use of Comparative Clinical Endpoint and Pharmacodynamic Bioequivalence Studies for Locally Acting Orally Inhaled Drug Products** In this symposium, FDA presenters will provide an overview on where the use of CCEP BE studies and PD BE studies have been successful for supporting locally acting generic OIDPs. This will be followed by presentations from industry on the encountered challenges with these in vivo BE studies, and potential ways for addressing them.	
8:55 AM – 9:00 AM	***Speaker Introductions***	
	Paramjeet Kaur, PhD	Pharmacologist, DB-II, OB, OGD, CDER, FDA
9:00 AM – 9:25 AM	***Challenges and General Considerations of Conducting Pharmacodynamic Equivalence Studies for Albuterol Sulfate Metered Dose Inhalers***	
	Ke Ren, PhD	Deputy Director, DB-III, OB, OGD, CDER, FDA
9:25 AM – 9:50 AM	***Challenges and Recommendations in Comparative Clinical Endpoint Bioequivalence Studies in Dry Powder Inhaler Products***	
	Stephanie Soukup, MD	Physician, DCR, OSCE, OGD, CDER, FDA
9:50 AM – 10:20 AM	***Coffee Break***	
10:20 AM – 10:45 AM	***Considerations for FEV1-based Comparative Clinical Endpoint or Pharmacodynamic Bioequivalence Studies for Orally Inhaled Drug Products***	
	Yuqing Gong, PhD	Pharmacologist, DQMM, ORS, OGD, CDER, FDA
10:45 AM – 11:10 AM	***Implementing a Clinical Endpoint BE Study for Wixela Inhub: An Industry Viewpoint***	
	Jonathan Ward, BA (Hons), PhD	VP & Head of Global Clinical, Respiratory, Viatris
11:10 AM – 11:50 AM	***Q&A Session with Panel***	
Moderator:	**Michael Spagnola, MD**	Lead Physician, OCSE, OGD, CDER, FDA
Panelists:	**Yuqing Gong, PhD**	Pharmacologist, DQMM, ORS, OGD, CDER, FDA
	Ke Ren, PhD	Deputy Director, DB-III, OB, OGD, CDER, FDA
	Stephanie Soukup, MD	Physician, DCR, OSCE, OGD, CDER, FDA
	Jonathan Ward, BA (Hons), PhD	VP & Head of Global Clinical, Respiratory, Viatris
11:50 AM – 12:50 PM	***Lunch Break***	
Symposium II:	**Integration of Alternative In Vitro, In Vivo, and In Silico Studies to Establish Bioequivalence of Locally Acting Orally Inhaled Drug Products in Lieu of Comparative Clinical Endpoint and Pharmacodynamic Bioequivalence Studies** This symposium will be comprised of three sessions that facilitate in-depth discussions on the various alternative in vitro, in vivo, and in silico studies that may be used for alternative BE approaches in lieu of CCEP and PD BE studies for locally acting OIDPs. These sessions will cover the scientific and technical challenges of these approaches along with the potential ways they may be used together for more complex OIDPs. Sessions 1 and 2 will run in parallel followed by Session 3.	
12:50 PM – 12:55 PM	***Speaker Introduction***	
	Elizabeth Bielski, MS, PhD	Senior Pharmacologist, DTP-I, ORS, OGD, CDER, FDA
12:55 PM – 1:25 PM	***Plenary Talk: Designing Alternatives to Comparative Clinical Endpoint and Pharmacodynamic Bioequivalence Studies – Does One Approach Fit All for Generic Orally Inhaled Drug Products?***	
	Bryan Newman, PhD	Lead Pharmacologist, DTP-I, ORS, OGD, CDER, FDA

The parallel breakout sessions in Symposium II, Session 1, and Session 2, are listed below sequentially. Both sessions will be held concurrently.

Session 1:	**In Vitro Studies that May Contribute to Alternative Bioequivalence Approaches for Locally Acting Orally Inhaled Drug Products** This session will run in parallel with Session 2 and will cover various in vitro alternative studies, including dissolution studies, realistic aerodynamic particle size distribution (APSD), particle morphology and other advanced characterization methods. The scientific and practical challenges with using these approaches for different OIDPs will be discussed.	
1:25 PM – 1:35 PM	***Speaker Introduction Session 1***	
	Nicholas Holtgrewe, PhD	Chemist, DCDA, OTR, OPQ, CDER, FDA
	Bryan Newman, PhD	Lead Pharmacologist, DTP-I, ORS, OGD, CDER, FDA
1:35 PM – 1:55 PM	***Considerations and Challenges for Dissolution Testing of Orally Inhaled Drug Products (OIDPs)***	
	Elizabeth Bielski, MS, PhD	Senior Pharmacologist, DTP-I, ORS, OGD, CDER, FDA
1:55 PM – 2:15 PM	***Dissolution Tests for OIDPs: Opportunities and Challenges***	
	Guenther Hochhaus, PhD	Professor, Pharmaceutics, College of Pharmacy, University of Florida
2:15 PM – 2:35 PM	***Considerations for Conducting More Realistic Aerodynamic Particle Size Distribution Testing for Orally Inhaled Drug Products***	
	Susan Boc, PhD	Pharmacokineticist, DTP-I, ORS, OGD, CDER, FDA
2:35 PM – 2:55 PM	***Which Test and Handling Factors Affect the MDI Performance?***	
	Mårten Svensson, PhD	CEO, Emmace Consulting AB
2:55 PM – 3:00 PM	***Plenary Closing Remarks for Virtual Attendees on Day 1***	
	Markham Luke, MD, PhD, FAAD	Director, DTP-I, ORS, OGD, CDER, FDA
3:00 PM – 3:30 PM	***Coffee Break***	
3:30 PM – 4:10 PM	***Small Group Discussions – Dissolution (in person only) Session 1***	
	Nicholas Holtgrewe, PhD	Chemist, DCDA, OTR, OPQ, CDER, FDA
	Bryan Newman, PhD	Lead Pharmacologist, DTP-I, ORS, OGD, CDER, FDA
4:10 PM – 4:30 PM	***Sub-Session Summary – Dissolution (in person only) Session 1***	
	Nicholas Holtgrewe, PhD	Chemist, DCDA, OTR, OPQ, CDER, FDA
	Bryan Newman, PhD	Lead Pharmacologist, DTP-I, ORS, OGD, CDER, FDA
4:30 PM – 4:40 PM	***Break***	
4:40 PM – 5:10 PM	***Small Group Discussions – Realistic APSD (in person only) Session 1***	
	Nicholas Holtgrewe, PhD	Chemist, DCDA, OTR, OPQ, CDER, FDA
	Bryan Newman, PhD	Lead Pharmacologist, DTP-I, ORS, OGD, CDER, FDA
5:10 PM – 5:30 PM	***Sub-Session Summary – Realistic APSD (in person only) Session 1***	
	Nicholas Holtgrewe, PhD	Chemist, DCDA, OTR, OPQ, CDER, FDA
	Bryan Newman, PhD	Lead Pharmacologist, DTP-I, ORS, OGD, CDER, FDA

Session 2:	**In Vivo and In Silico Studies that May Contribute to Alternative Bioequivalence Approaches for Locally Acting Orally Inhaled Drug Products** This session will run in parallel with Session 1 and will introduce various in vivo and in silico alternative studies, including alternative pharmacokinetic (PK) studies. The challenges with proper study design, model selection, purpose and validation will be discussed.	
1:25 PM – 1:35 PM	***Speaker Introduction Session 2***	
	Rukia Mchumo, PhD	Pharmacologist, DB-II, OB, OGD, CDER, FDA
	Ross Walenga, PhD	Chemical Engineer, DQMM, ORS, OGD, CDER, FDA
1:35 PM – 1:55 PM	***Total and Regional Lung Delivery of Salbutamol in Subjects with Idiopathic Pulmonary Fibrosis (IPF)***	
	Omar S. Usmani, MBBS, PhD, FHEA, FRCP, FERS	Professor, Respiratory Medicine & Consultant Physician, National Heart, Lung Institute, Imperial College London, Royal Brompton Hospital, St. Mary's
1:55 PM – 2:15 PM	***Biopharmaceutical Characterization of Orally Inhaled Drug Products Using Scintigraphy in Combination with Charcoal Block - Case Study Ciprofloxacin Dry Powder for Inhalation***	
	Heino Stass, PhD	Senior Clinical Pharmacology Consultant, Bayer AG
2:15 PM – 2:35 PM	***Model Purpose and Selection for Supporting Development and Approval of Generic Locally-Acting Orally Inhaled***	

	Drug Products in the United States	
	Ross Walenga, PhD	Chemical Engineer, DQMM, ORS, OGD, CDER, FDA
2:35 PM – 2:55 PM	***Determining the Role of In Silico Methods for OINDP Generic Biowaivers***	
	William Ganley, MChem, PhD	Head of Computational Pharmaceutics, Nanopharm Ltd.
2:55 PM – 3:00 PM	***Plenary Closing Remarks for Virtual Attendees on Day 1***	
	Markham Luke, MD, PhD	Director, DTP I, ORS, OGD, CDER, FDA
3:00 PM – 3:30 PM	***Coffee Break***	
3:30 PM – 4:10 PM	***Small Group Discussions – Alternative PK Studies (in person only) Session 2***	
	Rukia Mchumo, PhD	Pharmacologist, DB-II, OB, OGD, CDER, FDA
	Ross Walenga, PhD	Chemical Engineer, DQMM, ORS, OGD, CDER, FDA
4:10 PM – 4:30 PM	***Sub-Session Summary – Alternative PK Studies (in person only) Session 2***	
	Rukia Mchumo, PhD	Pharmacologist, DB-II, OB, OGD, CDER, FDA
	Ross Walenga, PhD	Chemical Engineer, DQMM, ORS, OGD, CDER, FDA
4:30 PM – 4:40 PM	***Break***	
4:40 PM – 5:10 PM	***Small Group Discussions – Model Selection and Model Purpose (in person only) Session 2***	
	Rukia Mchumo, PhD	Pharmacologist, DB-II, OB, OGD, CDER, FDA
	Ross Walenga, PhD	Chemical Engineer, DQMM, ORS, OGD, CDER, FDA
5:10 PM – 5:30 PM	***Sub-Session Summary – Model Selection and Model Purpose (in person only) Session 2***	
	Rukia Mchumo, PhD	Pharmacologist, DB-II, OB, OGD, CDER, FDA
	Ross Walenga, PhD	Chemical Engineer, DQMM, ORS, OGD, CDER, FDA

Day 2 April 21, 2023

8:25 AM – 8:30 AM	***Workshop Day 2 Overview***	
	Ross Walenga, PhD	Chemical Engineer, DQMM, ORS, OGD, CDER, FDA

The parallel breakout sessions in Symposium II, Session 1, and Session 2, are listed below sequentially. Both sessions will be held concurrently.

Session 1 (Continued): **In Vitro Studies that May Contribute to Alternative Bioequivalence Approaches for Locally Acting Orally Inhaled Drug Products**

This session will run in parallel with Session 2 and will cover various in vitro alternative studies, including dissolution studies, realistic aerodynamic particle size distribution (APSD), particle morphology and other advanced characterization methods. The scientific and practical challenges with using these approaches for different OIDPs will be discussed.

8:35 AM – 8:45 AM	***Speaker Introduction Session 1***	
	Nicholas Holtgrewe, PhD	Chemist, DCDA, OTR, OPQ, CDER, FDA
	Bryan Newman, PhD	Lead Pharmacologist, DTP-I, ORS, OGD, CDER, FDA
8:45 AM – 9:05 AM	***Alternative Bioequivalence Approach Using Morphologically-Directed Raman Spectroscopy (MDRS) on Nasal Spray Suspensions***	
	Nicholas Holtgrewe, PhD	Chemist, DCDA, OTR, OPQ, CDER, FDA
9:05 AM – 9:25 AM	***Understanding Time-Evolved Changed in Morphology of Pharmaceutical Aerosol Systems***	
	Jag Shur, PhD	Vice President - Science and Technology, Nanopharm Ltd.
9:25 AM – 9:45 AM	***Laser and Optical Diagnostics for Characterization of DPIs***	
	Agisilaos Kourmatzis, PhD, CEng	Associate Professor, School of Aerospace, Mechanical and Mechatronic Engineering, The University of Sydney
9:45 AM – 10:05 AM	***The Use of In Vitro Characterization Techniques to Support the Demonstration of Bioequivalence of Generic Orally Inhaled Products Designed to Be Bioequivalent to Their Reference Listed Drugs***	
	Xian-Ming Zeng, MSc, PhD	CEO, Transpire Bio Inc.
10:05 AM – 10:35 AM	***Coffee Break***	

10:35 AM – 11:15 AM	***Small Group Discussions – Morphology (in person only), Session 1***	
	Nicholas Holtgrewe, PhD	Chemist, DCDA, OTR, OPQ, CDER, FDA
	Bryan Newman, PhD	Lead Pharmacologist, DTP-I, ORS, OGD, CDER, FDA
11:15 AM – 11:35 AM	***Sub-Session Summary – Morphology (in person only) Session 1***	
	Nicholas Holtgrewe, PhD	Chemist, DCDA, OTR, OPQ, CDER, FDA
	Bryan Newman, PhD	Lead Pharmacologist, DTP-I, ORS, OGD, CDER, FDA
11:35 AM – 11:45 AM	***Break***	
11:45 AM – 12:25 PM	***Small Group Discussions – Other In Vitro Techniques (in person only), Session 1***	
	Nicholas Holtgrewe, PhD	Chemist, DCDA, OTR, OPQ, CDER, FDA
	Bryan Newman, PhD	Lead Pharmacologist, DTP-I, ORS, OGD, CDER, FDA
12:25 PM – 12:45 PM	***Sub-Session Summary – Other In Vitro Techniques (in person only) Session 1***	
	Nicholas Holtgrewe, PhD	Chemist, DCDA, OTR, OPQ, CDER, FDA
	Bryan Newman, PhD	Lead Pharmacologist, DTP-I, ORS, OGD, CDER, FDA

Session 2 (Continued): **In Vivo and In Silico Studies that May Contribute to Alternative Bioequivalence Approaches for Locally Acting Orally Inhaled Drug Products**

This session will run in parallel with Session 1 and will introduce various in vivo and in silico alternative studies, including alternative (PK) studies. The challenges with proper study design, model selection, purpose and validation will be discussed.

8:35 AM – 8:45 AM	***Speaker Introduction Session 2***	
	Rukia Mchumo, PhD	Pharmacologist, DB-II, OB, OGD, CDER, FDA
	Ross Walenga, PhD	Chemical Engineer, DQMM, ORS, OGD, CDER, FDA
8:45 AM – 9:05 AM	***Acceptability of Using Alternative PK Metrics from Systemic Pharmacokinetic (PK) Data of Generic OIDPs via Population PK***	
	Kairui (Kevin) Feng, PhD	Reviewer, DQMM, ORS, OGD, CDER, FDA
9:05 AM – 9:25 AM	***Feasibility of Predicting Regional Lung Exposure from Systemic Pharmacokinetic (PK) Data of Generic OIDPs via Population PK***	
	Jürgen Bulitta, PhD	Professor, Department of Pharmacotherapy and Translational Research, College of Pharmacy, University of Florida
9:25 AM – 9:45 AM	***Patient-Specific Aerosol Deposition Assessment – Technology and Validation***	
	Jan De Backer, PhD	CEO, Fluidda Inc.
9:45 AM – 10:05 AM	***Cluster-Informed In Silico and In Vivo Regional Deposition Assessments***	
	Ching-Long Lin, PhD	Edward M. Mielnik and Samuel R. Harding Professor and Department Executive Officer, Department of Mechanical Engineering, University of Iowa
10:05 AM – 10:35 AM	***Coffee Break***	
10:35 AM – 11:15 AM	***Small Group Discussions – PK Metrics to Inform Regional Deposition (in person only), Session 2***	
	Rukia Mchumo, PhD	Pharmacologist, DB-II, OB, OGD, CDER, FDA
	Ross Walenga, PhD	Chemical Engineer, DQMM, ORS, OGD, CDER, FDA
11:15 AM – 11:35 AM	***Sub-Session Summary – PK Metrics to Inform Regional Deposition (in person only) Session 2***	
	Rukia Mchumo, PhD	Pharmacologist, DB-II, OB, OGD, CDER, FDA
	Ross Walenga, PhD	Chemical Engineer, DQMM, ORS, OGD, CDER, FDA
11:35 AM – 11:45 AM	***Break***	
11:45 AM – 12:25 PM	***Small Group Discussions – Regional Deposition Prediction Validation (in person only), Session 2***	
	Rukia Mchumo, PhD	Pharmacologist, DB-II, OB, OGD, CDER, FDA
	Ross Walenga, PhD	Chemical Engineer, DQMM, ORS, OGD, CDER, FDA
12:25 PM – 12:45 PM	***Sub-Session Summary – Regional Deposition Prediction Validation (in person only) Session 2***	
	Rukia Mchumo, PhD	Pharmacologist, DB-II, OB, OGD, CDER, FDA
	Ross Walenga, PhD	Chemical Engineer, DQMM, ORS, OGD, CDER, FDA

At this point in the agenda the two parallel breakout sessions rejoin for the final plenary session.

12:45 PM – 1:45 PM	***Lunch Break***	
Session 3:	**Holistic Alternative Bioequivalence Approaches in Lieu of Comparative Clinical Endpoint and Pharmacodynamic Bioequivalence Studies for Metered Dose Inhalers and Dry Powder Inhalers** This session will provide an opportunity for participants to hear discussion summaries from Sessions 1 and 2 along with in-depth panel discussions on where alternative BE approaches may be possible for MDIs and DPIs with complex formulations. Session summary presentations will be presented by FDA, while the panel discussions will include representatives from FDA, academia, and industry.	
1:45 PM – 1:50 PM	***Speaker Introductions***	
	Ping Du, PhD	Reviewer, OB, DB-II, OGD, CDER, FDA
1:50 PM – 2:05 PM	***Summary of Session 1***	
	Nicholas Holtgrewe, PhD	Chemist, DCDA, OTR, OPQ, CDER, FDA
	Bryan Newman, PhD	Lead Pharmacologist, DTP-I, ORS, OGD, CDER, FDA
2:05 PM – 2:20 PM	***Summary of Session 2***	
	Rukia Mchumo, PhD	Pharmacologist, DB-II, OB, OGD, CDER, FDA
	Ross Walenga, PhD	Chemical Engineer, DQMM, ORS, OGD, CDER, FDA
2:20 PM – 3:20 PM	***Q&A Session with Panel on MDIs***	
Moderator:	**Diana Vivian, PhD**	Associate Director, DB-II, OB, OGD, CDER, FDA
Panelists:	**Per Bäckman, PhD**	Senior Adviser - Inhalation Science, Per Backman/Emmace Consulting AB
	William Ganley, MChem, PhD	Head of Computational Pharmaceutics, Nanopharm Ltd.
	Mark Lepore, MD	Chief Medical Officer, Transpire Bio
	Markham Luke, MD, PhD, FAAD	Director, DTP-I, ORS, OGD, CDER, FDA
	Qing Liu, PhD	Deputy Director, OB, OGD, CDER, FDA
	Gur Jai Pal Singh, PhD	Senior Vice President, Cipla Respiratory Center of Excellence
	Yu Chung Tsang, BSc, PhM, PhD	Chief Scientific Office, Biopharmaceutics & Biostatistics, Global Regulatory Affairs, Apotex Inc.
	Liang Zhao, PhD	Director, DQMM, ORS, OGD, CDER, FDA
3:20 PM – 3: 50 PM	***Break***	
3:50 PM – 4:50 PM	***Q&A Session with Panel on DPIs***	
Moderator:	**Darby Kozak, PhD**	Deputy Director, DTP-I, ORS, OGD, CDER, FDA
Panelists:	**William Ganley, MChem, PhD**	Head of Computational Pharmaceutics, Nanopharm Ltd.
	Abhishek Gupta, PhD, PMP	Chief Scientific Officer and Interim Chief Corporate Dev Officer, Transpire Bio
	Mark Banaszak Holl, PhD	Professor and Associate Dean, Mechanical and Materials Engineering, Division of Pulmonology, Allergy, and Critical Care Medicine, University of Alabama at Birmingham
	Markham Luke, MD, PhD, FAAD	Director, DTP-I, ORS, OGD, CDER, FDA
	Gur Jai Pal Singh, PhD	Senior Vice President, Cipla Respiratory Center of Excellence
	Diana Vivian, PhD	Associate Director, DB-II, OB, OGD, CDER, FDA
	Xian-Ming Zeng, MSc, PhD	CEO, Transpire Bio
	Liang Zhao, PhD	Director, DQMM, ORS, OGD, CDER, FDA
4:50 PM – 5:00 PM	***Closing Remarks***	
	Bing Li, PhD	Associate Director for Science, OB, OGD, CDER, FDA

Appendix of Abbreviations

ANDA	Abbreviated New Drug Application
APSD	Aerodynamic Particle Size Distribution
BE	Bioequivalence
BSc	Bachelor of Science in Chemical Engineering
CCEP	Comparative Clinical Endpoint Products
CDER	Center for Drug Evaluation and Research
CEO	Chief Executive Officer
CRCG	Center for Research on Complex Generics
DB-I	Division of Bioequivalence I
DB-II	Division of Bioequivalence II
DB-III	Division of Bioequivalence III
DCDA	Division of Complex Drug Analysis
DCR	Division of Clinical Review
DPI	Dry Powder Inhalers
DQMM	Division of Quantitative Methods and Modeling
DTP-I	Division of Therapeutic Performance I
FAAD	Fellow of the American Academy of Dermatology
FDA	Food and Drug Administration
FEV1	Forced Expiratory Volume
GDUFA	Generic Drug User Fee Amendments
IND	Investigational New Drug
MD	Doctor of Medicine
MDI	Metered Dose Inhalers
MS	Master of Science
OB	Office of Bioequivalence
OGD	Office of Generic Drugs
OIDP	Orally Inhaled Drug Products
OPQ	Office of Pharmaceutical Quality
ORS	Office of Research and Standards
OSCE	Office of Safety and Clinical Evaluation
OTR	Office of Testing and Research
PD	Pharmacodynamics
PharmD	Doctor of Pharmacy
PhD	Doctor of Philosophy
PK	Pharmacokinetics
PSG	Product-Specific Guidances