



USP Workshop on Topical and Transdermal Drug Products
September 14-15, 2009
USP Spalding Auditorium
Rockville, Maryland

On-Site Agenda

Two new draft USP General Chapters on Topical and Transdermal Drug Products have been published in *Pharmacopeial Forum (PF)* 35(3) May-June 2009. The General Chapters are <3> *Topical and Transdermal Products—Product Quality Tests* and <725> *Topical and Transdermal Products—Product Performance Tests*. Comments and suggestions for these tests and procedures are invited from interested parties through the routine *PF* comment process.

A variety of chemical, physical tests and in-vitro release tests are used to assess the quality and performance of semisolid dose forms. The chemical and physical quality control tests that USP is proposing for a default monograph on these dose forms is presented in the draft General Chapter <3> *Topical and Transdermal Products—Product Quality Tests*. General Chapter <725> *Topical and Transdermal Products—Product Performance Tests* covers the apparatus and procedures used to evaluate the in vitro drug release and proposes a performance verification test to assess equipment performance. The product performance test is consistent with that proposed in the FDA Guidance for Industry, *Nonsterile Semisolid Dosage Forms, Scale-up and Postapproval Changes: Chemistry, Manufacturing and Controls; In Vitro Release Testing and In Vitro Bioequivalence Documentation (SUPAC-SS)*.

These two General Chapters are part of a series of chapters that will cover product quality and performance tests for the five routes of administration. In addition to the Transdermal route, the other routes of administration include injection, mucosal, inhalation, and gastrointestinal. Draft General Chapter <3> is the first in the default monograph series. For oral dosage forms (gastrointestinal), <711> and Dissolution, <724> Drug Release are examples of product performance chapters.

The Workshop attendees will discuss these two draft General Chapters, with an emphasis on addressing comments received and defining steps toward finalization of these two General Chapters.

Objectives of the Workshop

- Discuss the proposal of two new General Chapters related to topical and transdermal drug products.
- Define product quality tests <3> and product performance tests <725> for topical and transdermal drug products.
- Discuss the selection of the apparatus for the evaluation of in vitro drug release test in <725>.
- Define the need for performance verification test (PVT) and rationale for selection of hydrocortisone cream as PVT standard in <725>.
- Discuss the interpretation and application of in vitro release data.
- Develop a meeting report containing recommendations by the attendees to forward to the USP Performance Tests – Topical Products Ad hoc Advisory Panel.

Scientific Planning Committee

- Clarence Ueda, Ph.D., Chair, Performance Tests – Topical Products Ad hoc Advisory Panel
- Gary Ewing, Ph.D., Schering Plough; Member, Performance Tests – Topical Products Ad hoc Advisory Panel
- Avraham Yacobi, Ph.D., Taro Pharmaceuticals, Inc.; Member, Advisory Panel on Topical-Dermal Performance Tests
- Paul Schwartz, Ph.D., Office of Generic Drugs, FDA
- Larry Ouderkirk, Office of Compliance, FDA
- Prabu Nambiar, Ph.D., MBA., RAC., Vertex Pharmaceuticals, Inc., Chair, Regulatory Science Section, AAPS

DAY ONE: Monday, September 14, 2009

7:30 a.m.	Registration, Continental Breakfast	
8:30 a.m.	Workshop Moderator: Anthony DeStefano, Ph.D.	
8:30 a.m.	1. Opening Remarks	Dr. Williams
8:45 a.m.	2. Overview, History <i>Rationale for the Development of General Chapters <3> and <725></i>	Dr. Ueda
9:00 a.m.	3. Product Quality Tests and Product Performance Tests <i>Rationale for the Development and Selection of Product Performance Tests</i>	Dr. Shah
9:15 a.m.	4. Industry Perspectives	
	a. Consumer Healthcare Products Association	Dr. Elliott, GlaxoSmithKline
	b. Generic Pharmaceutical Association	Mr. Anderson, Nycomed Mr. Houghton, Mylan
10:00 a.m.	Break	
10:30 a.m.	5. Summary of comments received on GC <3> and <725>	Dr. Marques
11:00 a.m.	6. Drug Product Quality Tests—General Chapter <3> <i>Moderators: Dr. Elliott (CHPA) and Dr. Ewing</i>	
	a. Topical semisolid dosage forms: quality issues	Dr. Schwartz
	b. Considerations in the determination of Viscosity	Dr. Ewing
	c. Considerations in the determination of Content Uniformity	Dr. Yacobi
	Q and A	
12:30 p.m.	Lunch	
1:30 p.m.	7. Drug Product Performance Test—General Chapter <725> <i>Moderators: Mr. Johnston (GPhA) and Dr. Ueda</i>	
	a. Vertical Diffusion Cell System <i>Discussion of equipment, set-up, methods and procedures, data analysis, and interpretation</i>	Mr. Shaw
	b. Studies of Performance Testing Using Hydrocortisone Cream	Dr. Hauck
	i. Collaborative studies to evaluate the Performance Verification Test (PVT) Reference Product	
	ii. Justification for using hydrocortisone cream as a PVT Reference Product	
	iii. Acceptance Limit for PVT Reference Product	
	c. Evaluation of Various Vertical Diffusion Cell Operating Parameters using 1% Hydrocortisone Cream	Dr. Kikwai
	d. Industry/CRO view on the use of IVR and application	Dr. Thakker
	Q and A	
3:00 p.m.	Break	

DAY ONE: Monday, September 14, 2009 (continued...)

- 3:30 p.m. **7. Drug Product Performance Test—Discussion (continued)**
- 5:00 p.m. Adjourn
- 5:00 p.m. Reception
- 6:30 p.m. Adjourn for the Day

DAY TWO: Tuesday, September 15, 2009

- 7:30 a.m. Registration, Continental Breakfast
- 8:30 a.m. **8. Transdermal Drug Products <3> and <725>**
Moderators: PhRMA and Dr. Yacobi
- a. Transdermal Dosage Forms (TDS) Dr. Marques
Product Quality and Product Performance Test
- b. TDS Leak Test Dr. Flynn
Rationale for the need for a leak test in transdermal patches
- d. Adhesion and other Product Quality Tests (PQT) Dr. Derdzinski
Rational for the inclusion of additional tests for transdermal patches
- 10:00 a.m. Break
- 10:30 a.m. **8. Comments and Discussion on Transdermal Drug Products <3> and <725>**
- 11:30 a.m. **9. USP Perspectives** Dr. Williams
- 12:00 noon Lunch
- 1:00 p.m. **10. Product Quality and Performance Tests—Clinical Perspectives** Dr. Maibach
- 1:15 p.m. **11. Concluding Session**
Moderators: Dr. Marques and Dr. Shah
- 1:15 p.m. **12. Moderator Reports**
- *Drug Product Quality Tests—General Chapter <3>*
 - *Drug Product Performance Test—General Chapter <725>*
 - *Transdermal Drug Products <3> and <725>*
- 2:00 p.m. General Discussion
- 2:45 p.m. USP's Next Steps Dr. DeStefano
- 3:00 p.m. Adjourn