

# U.S. Pharmacopeia (USP) Update on Performance Tests

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General Chapters

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# General Chapter (GC) <1724>



## <1724> SEMISOLID DRUG PRODUCTS— PERFORMANCE TESTS

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### SCOPE

The scope of this general chapter is to provide general information for performance testing of semisolid drug products, various types of equipment employed for such testing, and potential applications of the performance testing.

### PURPOSE

This chapter provides general information about performance testing of semisolid drug products the theory and applications of such testing, information about the availability of appropriate equipment, and likely developments in performance testing of semisolid drug products. General chapter [Topical and Transdermal Drug Products—Product Quality Tests \(3\)](#) provides information related to product quality tests for topical and transdermal dosage forms, [Drug Release \(724\)](#) provides procedures and details for testing drug release from transdermal systems, and this chapter (1724) provides procedures for determining drug release from semisolid dosage forms.

### INTRODUCTION

This chapter provides general information for in vitro testing of semisolid drug products. Semisolid dosage forms include creams, ointments, gels, and lotions. Semisolid dosage forms may be considered extended-release preparations, and their drug release depends largely on the formulation and manufacturing process. The release rate of a given product from different manufacturers is likely to be different.

### Drug Product Quality and Performance Tests

A USP drug product monograph contains tests, analytical procedures, and acceptance criteria. Drug product tests are divided into two categories: (1) those that assess general quality attributes, and (2) those that assess product performance, e.g., in vitro release of the drug substance from the



- In-vitro Release Test (synthetic membrane)
- Product development
- Post-approval changes (SUPAC)



- ▶ FDA guidance

GUIDANCE DOCUMENT

**Maximal Usage Trials for Topically Applied  
Active Ingredients Being Considered for  
Inclusion in an Over-The -Counter Monograph:  
Study Elements and Considerations**

MAY 2019

- <https://www.fda.gov/media/125080/download>



## **Effect of Sunscreen Application on Plasma Concentration of Sunscreen Active Ingredients** A Randomized Clinical Trial

Murali K. Matta, PhD<sup>1</sup>; Jeffrey Florian, PhD<sup>1</sup>; Robbert Zusterzeel, MD, PhD, MPH<sup>1</sup>; [et al](#)

› [Author Affiliations](#) | [Article Information](#)

*JAMA*. 2020;323(3):256-267. doi:10.1001/jama.2019.20747

- <https://jamanetwork.com/journals/jama/fullarticle/2759002>



## ▶ **Current version**

- In-vitro release testing (IVRT)
  - Synthetic membranes

## ▶ **Revision**

- Inclusion of In-vitro permeation testing (IVPT)
  - Human skin

# Expert Panel



- Kailas Thakker (chair) - consultant
- Ashvin Patel - Teledyne
- George Crist - consultant
- John Heaney - QLA LLC
- Kevin Warner – Alucent Biomedical Inc.
- Leandro Santos - Incyte
- Robert Graham Buice - Chattem
- Vivek Shah - Sotax
- Vivek Joshi – Millipore
- Tapash Gosh – FDA
- Sam Raney - FDA

- **<1002> Filters and membranes**
  - Synthetic membranes and human and animal skin
  - Only for analytical procedures
    - Chromatography
    - Dissolution
    - Particles and Foreign Matter
    - Microbiology
    - In-vitro Release and In-vitro Permeation Tests



# New GC <1002> Filters and Membranes



- Filtration procedures
- Material of construction
- Pore size
- Adsorption
- Leachables and Extractables
- Selection
- Validation/Qualification/Integrity

# Pharmacopeial Forum



- <https://online.usppf.com/usppf>
- Every two months
- 90-days for public comments

A screenshot of the USP PF Online website dashboard. The top navigation bar is dark brown and contains the USP logo, the text 'PF Online', a search bar with the placeholder text 'Search for a Monograph, Chapter Number, etc...', and user information 'Hi, Margareth' with a dropdown arrow. Below the search bar are 'Bookmarks' and 'Resources' dropdown menus. A secondary navigation bar below the search bar contains a home icon and several menu items: 'START HERE', 'GENERAL NOTICES', 'STIMULI', 'GENERAL CHAPTERS', 'MONOGRAPHS', 'REAGENTS AND REFERENCE TABLES', and 'HELP'. The main content area features a heading 'New PF Dashboard' with a help icon. Below the heading is a welcome message: 'Welcome to the new PF starting with PF45(1)!'. A light blue box at the bottom contains the text: 'CURRENT ISSUE: PF 47(3) May 3, 2021 to July 31, 2021' and 'Commenting open for 67 more days' with a comment icon.

# Contact



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# Questions



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