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

Margareth R. C. Marques, M.Sc., Ph. D. Principal Scientist
General Chapters

August, 2021

General Chapter (GC) <1724>

(1724) SEMISOLID DRUG PRODUCTS— PERFORMANCE TESTS



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 <u>Topical and Transdermal Drug Products—Product Quality Tests (3)</u> provides information related to product quality tests for topical and transdermal dosage forms, <u>Drug Release (724)</u> provides procedures and details for testing drug release from transdermal systems, and this chapte (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

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In-vitro Release Test (synthetic membrane)

Product development

Post-approval changes (SUPAC)

Products Applied to the Skin



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

FDA Study: Sunscreens



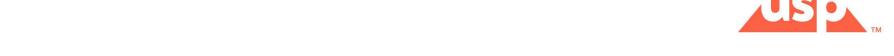
Effect of Sunscreen Application on Plasma Concentration of Sunscreen Active Ingredients A Randomized Clinical Trial

Murali K. Matta, PhD1; Jeffry Florian, PhD1; Robbert Zusterzeel, MD, PhD, MPH1; 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

<1724> Semisolid Drug Products—Performance Tests



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

New general chapter



<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



Contact



Margareth R. C. Marques

E-mail mrm@usp.org

Questions



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