



Designation: F3142 – 16

Standard Guide for Evaluation of *in vitro* Release of Biomolecules from Biomaterials Scaffolds for TEMPs¹

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1. Scope

1.1 To describe general principles of developing and/or using an *in vitro* assay to evaluate biomolecule release from biomaterials scaffolds for TEMPs, with examples from the literature

1.2 The guide will address scaffolds that do not contain seeded cells; general principles may still apply but may need to be modified if cells are part of the TEMPs.

1.3 *In vitro* release assessment of biomolecules from matrices is a valuable tool for screening biomolecule-scaffold interactions, as well as characterization, and/or quality control.

1.4 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.5 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards*:²

F2312 Terminology Relating to Tissue Engineered Medical Products

F2809 Terminology Relating to Medical and Surgical Materials and Devices

F2902 Guide for Assessment of Absorbable Polymeric Implants

2.2 *United States Pharmacopeia (USP) General Chapters*:³

USP<1> Injections and Implanted Drug Products (Parenterals)—Product Quality Tests

USP <711> Dissolution

USP <724> Drug Release

USP <785> Osmolality and Osmolarity

USP <1092> The Dissolution Procedure: Development and Validation

2.3 *European Pharmacopeia (Ph. Eur.)*:⁴

Ph. Eur. 2.9.3 Dissolution Test for Solid Dosage Forms

Ph. Eur. 2.9.4 Dissolution Test for Transdermal Patches

Ph. Eur. 2.9.25 Dissolution Test for Medicated Chewing Gums

2.4 *FDA Document*:⁵

FDA Guidance for Industry Bioanalytical Method Validation (2001)

3. Terminology

3.1 The present document uses the definitions of Terminologies F2809 and F2312.

4. Significance and Use

4.1 The European Pharmacopoeia (Ph. Eur.) as well as the United States Pharmacopeia (USP) describe several dissolution and drug release setups for tablets, capsules, transdermal patches and suppositories (USP <711>, USP <724>, Ph. Eur. 2.9.3, Ph. Eur. 2.9.4). However, up to this point no pharmacopoeia standardized *in-vitro* release test has been established for parenteral dosage forms which provide sustained drug release, for example, implants.

4.2 An appropriately designed *in-vitro* release test would be favorable in the early stage of development of biomolecule-releasing scaffolds for TEMPs, as well as in quality control, and may help to reduce the number of animal experiments.

4.3 Appendix X1 provides a tabulated overview of published *in-vitro* release studies performed with biomaterial scaffolds loaded with biomolecules.

4.4 One goal of *in-vitro* release studies is to simulate the *in-vivo* conditions as closely as possible, but with sufficiently

¹ This test method is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.42 on Biomaterials and Biomolecules for TEMPs.

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² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

³ Available from U.S. Pharmacopeial Convention (USP), 12601 Twinbrook Pkwy., Rockville, MD 20852-1790, <http://www.usp.org>.

⁴ Available from EDQM Council of Europe, 7 allée Kastner, CS 30026, F-67081 Strasbourg, France, or visit the website, www.edqm.eu.

⁵ Available from Drug Information Branch (HDF-210), Center for Drug Evaluation and Research (CDER), 5600 Fishers Lane, Rockville, MD 20857, or visit the website, <http://www.fda.gov/cder/guidance/index>.