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⟨1771⟩ OPHTHALMIC PRODUCTS—PERFORMANCE TESTS

INTRODUCTION

This chapter provides information on performance tests to assess drug release from finished ophthalmic products. These tests are applicable to products that have an extended-release mechanism (beyond 1 day); the dissolution/drug release rate is rate limiting for absorption and is expected to provide a controlled therapeutic response. Examples of such products include intraocular matrix-type and polymer-based bioerodible implants, non-bioerodible intraocular matrix and reservoir implants, intraocular injectable suspensions/colloidal systems, intraocular in situ–forming depots and gels, punctal plug-based delivery systems, non-biodegradable drug release devices (e.g., drug-coated stents, drug-coated contact lenses), biodegradable and non-degradable ocular inserts/bioadhesives (for cul-de-sac or conjunctival-sac applications), and other such dosage forms. For products having a localized and immediate response when applied to the eye (e.g., topically applied dosage forms, including dispersed systems, having very short residence time for absorption), a dissolution/drug release test may have no practical value.

Application of a dissolution/drug release test to assess performance as a surrogate for in vivo testing should be considered only with appropriately validated in vivo–in vitro correlations (see *In Vitro and In Vivo Evaluation of Dosage Forms* ⟨1088⟩). Dissolution/drug release tests are used as a quality control tool for specific product attributes (e.g., burst release from matrix-type, biodegradable, polymeric systems). These tests may have the ability to distinguish between different lots of a drug product having one or more formulation and/or process changes.

Changes may be related to the drug substance(s) or excipients present in the formulation, physical and/or chemical attributes of the finished formulation, critical manufacturing variables, shipping and storage effects, aging effects, or other formulation and/or process factors critical to the performance of the ophthalmic product. Such changes may affect the performance characteristics of the dosage form when applied to the eye. Consideration should be given to whether processing or components are intended to provide for prolonged exposure to any part of the eye and whether a dissolution/drug release test could be used to demonstrate this effect.

PERFORMANCE TESTS (DISSOLUTION/DRUG RELEASE)

Depending on the design and release mechanism of the dosage form, the dissolution/drug release test can be developed using any apparatus described in *Dissolution* ⟨711⟩ or *Drug Release* ⟨724⟩. Novel dosage forms may require the use of noncompendial equipment and/or conditions. Any dissolution/drug release test should be discriminative for the intended critical quality attributes of the product and should be properly validated (see *The Dissolution Procedure: Development and Validation* ⟨1092⟩). The test conditions should reasonably mimic the method of administration of the product and in vivo conditions to establish, if possible, an in vivo–in vitro correlation that can be used to predict in vivo performance of the product.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
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