

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

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Expert Committee: General Chapters—Dosage Form

In accordance with section 7.04(c) of the 2015–2020 Rules and Procedures of the Council of Experts, this is to provide notice that the USP General Chapters—Dosage Form Expert Committee intends to revise the recently published General Chapter <1> Injections and Implanted Drug Products (Parenterals)—Product Quality Tests to narrow the General Chapter’s scope.

General Chapter <1> Injections and Implanted Drug Products (Parenterals)—Product Quality Tests, which will become official May 1, 2016, was intended to support existing monographs, as well as, the development of new monographs. Comments were received indicating that the dual purpose of this General Chapter could lead to confusion and application of the General Chapter requirements to products not intended by the Expert Committee. In response to these comments the Expert Committee intends to revise General Chapter <1> to clarify its purpose and application to eliminate potential compliance issues.

Furthermore, USP will be reviewing all of the Product Quality General Chapters (Injections and Implanted Drug Products <1>, Oral Drug Products—Product Quality Tests <2>, Topical and Transdermal Drug Products—Product Quality Tests <3>, Mucosal Drug Products—Product Quality Tests <4>, and Inhalation and Nasal Drug Products—General Information and Product Quality Tests <5>) to determine whether the current format and content is appropriate.

It is anticipated that the revision will be posted as a Revision Bulletin on March 25, 2016 and incorporated in *USP 40–NF 35*.

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