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Đồng Hành Cùng Chất Lượng

200usp
The Standard of trust

<711> Dissolution

Type of Posting: Notice of Intent to Revise

Posting Date: 27-May-2022

Targeted Official Date: 01-May-2023, Interim Revision Announcement

Expert Committee: General Chapters- Dosage Forms Expert Committee

In accordance with the Rules and Procedures of the Council of Experts, this is to provide notice that the Dosage Forms Expert Committee intends to revise General Chapter <711> Dissolution. Based on the comments received, the previously proposed revision, published as an Interim Revision Announcement in Pharmacopeial Forum 48(2) [Mar.–Apr. 2022], has been canceled.

The purpose of this revision is to replace the existing USP Reference Standard Prednisone Tablets with a new USP Dissolution Performance Verification Standard – Prednisone RS, to qualify the Dissolution Apparatus 1 (basket) and Dissolution Apparatus 2 (paddle).

The collaborative testing of the new Reference Standard has been completed, and the results are under evaluation. USP plans to conduct extensive outreach to stakeholders with additional information in preparation for the planned transition to the new RS.

It is anticipated that the proposed revision to General Chapter <711> will be published as an Interim Revision Announcement (IRA) in Pharmacopeial Forum 48(6) [Nov. – Dec 2022] pursuant to the Rules and Procedures of the Council of Experts. The comment period for this revision would end on Jan 31, 2023. In the absence of significant adverse comments, the proposed IRA would become official on May 1, 2023. It is anticipated that the new USP Reference Standard, Dissolution Performance Verification Standard – Prednisone RS will be released in late 2022 to allow additional time to prepare for adoption. Please note that when performing verification testing after the above revision of <711> Dissolution becomes official, only those results obtained using the specified new USP reference standard will be conclusive.

Should you have any questions, please contact Margareth Marques, Senior Principal Scientist (mrm@usp.org) or refer to the FAQs.

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This Notice replaces CN-22-021-01, published on October 29, 2021. It was updated on July 29, 2022 to provide a link to FAQs.