***Commentary***

***June Accelerated Revision Posting***

**June 28, 2024**

In accordance with USP's *Rules and Procedures of the Council of Experts ("Rules")*, and except as provided in Section 9.02 *Accelerated Revision Processes*, USP publishes proposed revisions to the *United States Pharmacopeia and the National Formulary* (*USP–NF*) for public review and comment in the *Pharmacopeial Forum (PF),* USP's free bimonthly journal for public notice and comment. After comments are considered and incorporated as the Expert Committee (EC) deems appropriate, the proposal may advance to official status or be re-published in *PF* for further notice and comment, in accordance with the Rules. In cases when proposals advance to official status, a summary of comments received and the appropriate Expert Committee's responses, as well as Expert Committee-initiated changes, are published in the Proposal Status/Commentary section of USPNF.com at the time the official revision is published.

The *Commentary* is not part of the official text and is not intended to be enforceable by regulatory authorities. Rather, it explains the basis of Expert Committees' responses to public comments on proposed revisions. If there is a difference or conflict between the contents of the *Commentary* and the official text, the official text prevails.

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**Monograph/Section(s):** Clonidine Transdermal System / Organic Impurities
**Expert Committee:** Small Molecules 2
**No. of Commenters:** 1

**Comment Summary #1:** The commenter comments that the removal of the *Organic Impurities* test and limit for clonidine related compound B, does a disservice to prospective generic manufacturers. The commenter requests the test not be deleted and suggests to revise the acceptance criteria as total clonidine related compound B per Transdermal System.
**Response:** Comment not incorporated. The IRA is addressing the urgent regulatory concerns regarding acceptance criteria for *Organic Impurities*. USP will engage with stakeholders to explore new ways of including information regarding specified impurities/degradation products within the public standard in a manner that will not impede generic development.

**Monograph/Sections:** Norgestimate/Organic impurities
**Expert Committee:** Chemical Medicines Monographs 5
**No. of Commenters:** 2

**Comment #1:** The commenter recommended tightening the limit for “Any unspecified impurity” to be consistent with ICH Q3A in the test for organic impurities.
**Response:** Comment not incorporated. The comment is out of scope of this revision USP will consider this recommendation in a future revision of the monograph.
**Comment Summary #2:** The commenter recommended removing the reporting threshold in the test for Organic Impurities as it will vary based on product-specific factors.
**Response:** Comment not incorporated. General Chapter ⟨477⟩ User-Determined Reporting Thresholds was published in USP-NF 2024 Issue 1; this chapter supports a flexible reporting Commentary for Interim Revision Announcements published on January 26, 2024 threshold to accommodate product-specific factors. The Expert Committee may consider incorporating this new approach in future revisions.