



**Commentary – *Pharmacopeial Forum* 36(5) Sept.-Oct. 2010  
Interim Revision Announcements to USP 33-NF 28 Reissue**

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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. If there is a difference between the contents of the *Commentary* and the official text, the official text prevails. In case of a dispute or question of interpretation, the language of the official text, alone and independent of the *Commentary*, shall prevail.

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**Monograph/Section(s):** Cephalexin/Multiple Sections

**Expert Committee(s):** Monograph Development - Antibiotics

**No. of Commenter(s):** 1

**Comment Summary #1:** The commenter requested revising the limits in the test for *Organic Impurities* to tighten and including limits for specified and unspecified impurities.

**Response:** Comment not incorporated. The Expert Committee is willing to consider future changes to the monograph upon receipt of supporting data.

**Comment Summary #2:** The commenter requested adding a limit for *Residue on Ignition*.

**Response:** Comment not incorporated. The Expert Committee is willing to consider future changes to the monograph upon receipt of supporting data.

**Reason for Revision #1:** Because 1-hydroxybenzotriazole is banned in the United States for safety reasons, it is proposed to revise the Assay to delete the requirement for this reagent. USP has data supporting the proposed revision. The calculation formula for the Assay was updated accordingly.

**Reason for Revision #2:** *Identification* tests *B* and *C* in the *Cephalexin* monograph are replaced by a single identification test based on the chromatographic retention times in the Assay.

**Monograph/Section(s):** Cephalexin Hydrochloride/Assay and Identification

**Expert Committee(s):** Monograph Development - Antibiotics

**No. of Commenter(s):** 0

**Reason for Revision #1:** Because 1-hydroxybenzotriazole is banned in the United States for safety reasons, it is proposed to revise the Assay to delete the requirement for this reagent. USP has data supporting the proposed revision. The calculation formula for the Assay was updated accordingly.

**Reason for Revision #2:** *Identification* tests *B* and *C* in the *Cephalexin Hydrochloride* monograph are replaced by a single identification test based on the chromatographic retention times in the Assay.

**Monograph/Section(s):**

Cephalexin Capsules/Multiple Sections

Cephalexin for Oral Suspension/Multiple Sections

Cephalexin Tablets/Multiple Sections

Cephalexin Tablets for Oral Suspension/Multiple Sections

**Expert Committee(s):** Monograph Development - Antibiotics

**No. of Commenter(s):** 0

**Reason for Revision #1:** Because 1-hydroxybenzotriazole is banned in the United States for safety reasons, it is proposed to revise the Assay to delete the requirement for this reagent. USP has data supporting the proposed revision. The calculation formula for the Assay was updated accordingly.

**Reason for Revision #2:** The thin-layer chromatographic *Identification* test is replaced with a test based on the chromatographic retention time in the Assay.

**Reason for Revision #3:** The test for *Water Determination* is deleted per current USP style to eliminate this test from drug product monographs.

**Monographs/Section(s):** Protamine Sulfate

Protamine Sulfate for Injection

Protamine Sulfate Injections

**Expert Committee:** Biologics and Biotechnology - Blood and Blood Products

**No. of Commenters:** 0

**Reason for Revision to all three monographs:** The monographs were revised by the following:

1. Replacing the current sheep plasma clotting Assay by a new potency Assay. The new Assay eliminates the need for a wire loop, which is no longer commercially available, and is harmonized with the potency assay for Protamine Sulfate in the *European Pharmacopoeia 6.0*.
2. The new potency Assay is supported by a new reference standard, USP Heparin Sodium for Assays RS, which is the new potency RS for all USP heparin and protamine monographs