In accordance with USP’s Rules and Procedures of the Council of Experts, USP publishes all 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 bimonthly journal for public notice and comment. After comments are considered and incorporated as the Expert Committee deems appropriate, the proposal may advance to official status or be republished in *PF* for further notice and comment, in accordance with the Rules and Procedures. In cases when proposals advance to official status without republication in *PF*, a summary of comments received and the appropriate Expert Committee’s responses are published in the *Revisions and Commentary* section of the USP Web site at the time the 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. 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/Multitple 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