

Commentary – Pharmacopeial Forum 36(1) Jan.-Feb. 2010 Interim Revision Announcements to USP 33-NF 28 Reissue

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.

For further information, contact: USP Executive Secretariat United States Pharmacopeia 12601 Twinbrook Parkway Rockville, MD 20852-1790 USA execsec@usp.org

Monograph/Section(s): Acitretin Capsules/Assay

Expert Committee(s): Monograph Development-Ophthalmology Oncology and

Dermatology

No. of Commenter(s): 0

Reason for Revision: The *Assay preparation* in the monograph was revised to indicate that only the contents of the Capsules are used, rather than the entire Capsule including the shells. The acitretin concentration of the *Assay preparation* was also specified.

Monograph/Section(s): Docusate Sodium/Residue on ignition

Expert Committee: Monograph Development-Gastrointestinal, Renal, and

Endocrine

No. of Commenters: 0

Reason for Revision: The monograph was revised by specifying that the test for *Residue on ignition* be performed at 800±25°, which is also consistent with the specifications in the *Food Chemicals Codex*.

Monograph/Section(s): Propranolol Hydrochloride Extended-release

Capsules/Dissolution

Expert Committee: Biopharmaceutics

No. of Commenters: 0

Reason for Revision: The monograph was revised to clarify how to measure time when running *Dissolution Test 1* and *Test 2*. In addition a *Dissolution Test 3* for a new generic product was added.