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# INTERIM REVISION ANNOUNCEMENT

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In this section readers will find the following:

- The list of new USP Reference Standards that have become available
- The list of assays or tests that are adopted but held in abeyance pending availability of required USP Reference Standards
- Newly adopted (official) revisions to the *USP–NF* that become official before the official date of the next *Supplement* or that were not ready for adoption by the closing date for the upcoming *Supplement*. (The official date for these revisions is stated on the next page.)
- Errata

Readers should review this section to determine if they are affected by any of the changes.

**Symbols**—New text is enclosed in symbols and set off from the current official text as shown in the following example:  
•new text•

Where the symbols appear together with no enclosed text, such as ••, it means that text has been deleted and no new text was proposed to replace it. In all revisions, the closing symbol is accompanied by an identifier that indicates the issue of a given *PF* volume.

**Errata**—Errata are considered to be text, erroneously published in the *USP–NF* or its *Supplements*, that does not accurately reflect the intended official requirements of the Council of Experts. Beginning with *PF 35(2)*, Errata will be published both in the *Pharmacopeial Forum* and on the [usp.org](http://usp.org) website. At the end of the *Interim Revision Announcement* section in this publication is a list of errata and corrections to *USP 32–NF 27*. The page number indicates where the item is found in *USP–NF*. Errata are updated as necessary in each *Pharmacopeial Forum* issue and monthly on the [usp.org](http://usp.org) website. This information will also be cumulative in future *Supplements*, and will appear in its corrected form in the next annual edition of *USP–NF*. The list of Errata has been relocated to [www.usp.org](http://www.usp.org), where updates will be posted monthly.

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INTERIM REVISION  
ANNOUNCEMENT  
to *USP 32* and to *NF 27*

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Duane M. Kirking, Pharm.D., Ph.D.,  
*Chair, USP Board of Trustees,  
USP Trustee At-Large*

Roger L. Williams, M.D., *Chief Executive Officer  
and Chairman, USP Council of Experts*

Susan de Mars, J.D., *Chief Documentary Standards Officer and General Counsel*  
William F. Koch, Ph.D., FACB, *Chief Standards Acquisition and Metrology Officer*

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Inquiries regarding *USP–NF* can be addressed to the USP Executive Secretariat, 12601 Twinbrook Parkway, Rockville, MD 20852, USA ([execsec@usp.org](mailto:execsec@usp.org)).

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## New USP Reference Standards

The following USP Reference Standards, which were not available when the associated monograph was made official, have since become available. The respective official date of each *USP 32* or *NF 27* standard, test, or assay requiring the use of the following USP Reference Standards is indicated in parentheses after the name of the Reference Standard. Note that the official date is six months after publishing in this PF.

USP S-Adenosyl-L-homocysteine RS (March 1, 2010)  
 USP Fludeoxyglucose Related Compound B RS (May 1, 2010)  
 USP Alpha Lipoic Acid RS (March 1, 2010)  
 USP Lypressin RS (March 1, 2010)  
 USP Propylene Glycol Dilaurate RS (May 1, 2010)  
 USP Valrubicin RS (March 1, 2010)  
 USP Vasopressin RS (March 1, 2010)

## Unavailable First-Time Official USP Reference Standards

The official dates of any *USP 32* or *NF 27* standards, tests, or assays requiring the use of the following new USP Reference Standards are postponed until further notice pending availability of the respective Reference Standards. This listing was updated as of August 10, 2009. Please refer to the current USP Catalog for a more up-to-date availability list. The USP Catalog can be accessed on-line at <http://www.uspcatalog.com>.

USP Acarbose RS  
 USP Acarbose System Suitability Mixture RS  
 USP Albumin Human RS  
 USP Alteplase RS  
 USP Amifostine RS  
 USP Amifostine Thiol RS  
 USP Antithrombin III Human RS  
 USP Aprotinin RS  
 USP Aprotinin System Suitability RS  
 USP Copolymer Polypropylene RS  
 USP Diethylstilbestrol Diphosphate RS  
 USP Powdered *Echinacea pallida* Extract RS  
 USP Eucatropine Hydrochloride RS  
 USP Gonadorelin Hydrochloride RS  
 USP Hemoglobin RS  
 USP Maritime Pine Extract RS  
 USP Menotropins RS  
 USP Oleyl Oleate RS  
 USP Sargramostim RS  
 USP Sincalide RS  
 USP Valrubicin Related Compound A RS

## MONOGRAPHS (USP)

### Acitretin Capsules

**Change to read:**

**Assay—**

*Diluent*—Prepare a suitable mixture of methanol and tetrahydrofuran (13:10).

*Mobile phase*—Prepare a filtered and degassed mixture of methanol, water, alcohol, and glacial acetic acid (74:21:5:0.5). Make adjustments if necessary (see *System Suitability* under *Chromatography* (621)).

*Standard preparation*—In a 100-mL volumetric flask, dissolve about 10 mg of USP Acitretin RS, accurately weighed, in 80 mL of *Diluent*, and sonicate for 5 minutes. Add 8 mL of water, and quantitatively dilute with *Diluent* to obtain a solution having a concentration of about 0.1 mg per mL.

*System suitability solution*—Transfer 2 mL of the *Standard preparation* to a clear 4-mL glass vial. After sealing the vial with a teflon-lined silicone septum and cap, place the vial on its side in a light chamber, expose it to 400 foot-candles of fluorescent light for 5 minutes, and then completely wrap the vial with aluminum foil. [NOTE—Exposure to the fluorescent light allows for the formation of two degradation products: acitretin related compound A and the 9-*cis* isomer [(*E,E,Z,E*)-9-(4-methoxy-2,3,6-trimethylphenyl)-3,7-dimethyl-2,4,6,8-nonate-traenoic acid].]

*Assay preparation*—\*Open not fewer than 20 Capsules, composite the Capsule fill, and mix well. Transfer the Capsule fill, equivalent to 10 mg of acitretin, into a 100-mL volumetric flask. Add 8 mL of water to wet the sample, and sonicate for 5 minutes. Dilute with *Diluent* to volume, and sonicate for 5 minutes. Cool to room temperature. Pass the suspension through a suitable filter having a porosity of 0.5 μm, and use the clear filtrate. [NOTE—Inject the *Sample solution* within an hour of preparation.]

*Chromatographic system* (see *Chromatography* (621))—The liquid chromatograph is equipped with a 365-nm detector and a 4.6-mm × 15-cm column that contains 5-μm L1 packing. The flow rate is about 1.0 mL per minute. Chromatograph the *System suitability solution*, and record the peak responses as directed for *Procedure*: the resolution, *R*, between acitretin related compound A (relative retention time of about 0.84) and acitretin is not less than 3.0; the resolution, *R*, between the 9-*cis* isomer (relative retention time of about 1.09) and acitretin is not less than 1.8. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure*: the relative standard deviation for replicate injections of acitretin is not more than 2.0%.

*Procedure*—Separately inject equal volumes (about 25 μL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of acitretin (C<sub>21</sub>H<sub>26</sub>O<sub>3</sub>) in the portion of Capsules taken by the formula:

$$100 \times C \times (r_U/r_S)$$

in which *C* is the concentration, in mg per mL, of USP Acitretin RS in the *Standard preparation*; and *r<sub>U</sub>* and *r<sub>S</sub>* are the peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.

### Docusate Sodium

**Change to read:**

**Residue on ignition** (281): between 15.5% and 16.5%, calculated on the anhydrous basis.

\**Procedure*—Transfer about 1 g, accurately weighed, to a tared crucible, ignite until thoroughly charred, and cool. Moisten the ash with 1 mL of sulfuric acid, and complete the ignition by heating at 800 ± 25° for 15-minute periods to constant weight.

### Propranolol Hydrochloride Extended-Release Capsules

**Change to read:**

**Dissolution** (711)—

TEST 1—If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 1*.

*pH 1.2 Buffer solution*—Dissolve 2.0 g of sodium chloride in water, add 7.0 mL of hydrochloric acid, dilute with water to 1 L, and mix.

*pH 6.8 Buffer solution*—Dissolve 21.72 g of anhydrous dibasic sodium phosphate and 4.94 g of citric acid monohydrate in water, dilute with water to 1 L, and mix.

*Media*—Proceed as directed under *Method B* for *Delayed-Release Dosage Forms*, using 900 mL of *pH 1.2 Buffer solution* during the *Acid stage*, and conduct the test for 1.5 hours. For the *Buffer stage*, use 900 mL of *pH 6.8 Buffer solution*, conduct the test for 2.5 hours (this is the 4-hour time point: 1.5 hours in *Acid stage* plus 2.5 hours in *Buffer stage*), conduct the test for the additional time points, always considering *T*<sub>1</sub> = 1.5 hours, and use the acceptance criteria given under *Tolerances*.

*Apparatus 1*: 100 rpm.

*Times*: 1.5, 4, 8, 14, and 24 hours.

*Procedure*—Using filtered portions of the solution under test, diluted if necessary, determine the amount of C<sub>16</sub>H<sub>21</sub>NO<sub>2</sub>·HCl dissolved, using UV absorbances at the wavelength of maximum absorbance at about 320 nm, with respect to a baseline drawn from 355 nm through 340 nm, by comparison with a Standard solution in water having a known concentration of USP Propranolol Hydrochloride RS.

*Tolerances*—The percentages of the labeled amount of C<sub>16</sub>H<sub>21</sub>NO<sub>2</sub>·HCl dissolved at the times specified conform to *Acceptance Table 2*.

Time (hours)	Amount dissolved
1.5	not more than 30%
4	between 35% and 60%
8	between 55% and 80%
14	between 70% and 95%
24	between 81% and 110%

TEST 2—If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.

*pH 1.2 Buffer solution*—Dissolve 2.0 g of sodium chloride in water, add 7.0 mL of hydrochloric acid, dilute with water to 1 L, and mix.

*pH 7.5 Buffer solution*—Dissolve 6.8 g of monobasic potassium phosphate and 1.6 g of sodium hydroxide in 900 mL of water, adjust with 1 N sodium hydroxide to a pH of 7.5, dilute with water to 1 L, and mix.

**Media**—Proceed as directed under *Method B* for *Delayed-Release Dosage Forms*, using 900 mL of pH 1.2 Buffer solution during the *Acid stage*, and conduct the test for 1 hour. For the *Buffer stage*, use 900 mL of pH 7.5 Buffer solution, conduct the test for 2 hours (this is the 3-hour time point: 1 hour in *Acid stage* plus 2 hours in *Buffer stage*), conduct the test for the additional time points, always considering  $T_1 = 1$  hour, and use the acceptance criteria given under *Tolerances*.

**Apparatus 1:** 50 rpm.

**Times:** 1, 3, 6, and 12 hours.

**Procedure**—Using filtered portions of the solution under test, diluted if necessary, determine the amount of  $C_{16}H_{21}NO_2 \cdot HCl$  dissolved, using UV absorbances at the wavelength of maximum absorbance at about 320 nm, with respect to a baseline drawn from 355 nm through 340 nm, by comparison with a Standard solution in water having a known concentration of USP Propranolol Hydrochloride RS.

**Tolerances**—The percentages of the labeled amount of  $C_{16}H_{21}NO_2 \cdot HCl$  dissolved at the times specified conform to *Acceptance Table 2*.

Time (hours)	Amount dissolved
1	not more than 20%
3	between 20% and 45%
6	between 45% and 80%
12	not less than 80%

•TEST 3—If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 3*.

**Acid stage medium:** pH 1.2 buffer solution (prepared by dissolving 2.0 g of sodium chloride in water, adding 7.0 mL of hydrochloric acid, and diluting with water to 1000 mL); 900 mL.

**Buffer stage medium:** pH 6.8 phosphate buffer; 900 mL.

**Apparatus 1:** 100 rpm.

**Standard stock solution:** Transfer 50 mg, accurately weighed, of USP Propranolol Hydrochloride RS to a 50-mL volumetric flask, and dilute with water to volume.

**Working standard solution**—Quantitatively dilute the *Standard stock solution* with water to obtain a final concentration of about L/1000 mg per mL, where L is the capsule label claim in mg.

**Procedure**—Conduct the test in *Acid stage medium* for 1.5 hours, sample, and pass through a suitable 0.45- $\mu$ m filter. Replace the *Acid stage medium* with the *Buffer stage medium*, and conduct the test for 2.5 hours (this is the 4-hour time point: 1.5 hours in *Acid stage medium* plus 2.5 hours in *Buffer stage medium*), conduct the test for the additional time points, always considering  $T_1 = 1.5$  hours, and use the acceptance criteria given under *Tolerances*.

Determine the percentage of propranolol hydrochloride dissolved using the spectrophotometric procedure as directed for *Test 1*.

**Tolerances**—The percentages of the labeled amount of  $C_{16}H_{21}NO_2 \cdot HCl$  dissolved at the times specified conform to *Acceptance Table 2*.

Time (hours)	Amount dissolved
1.5	not more than 15%
4	not more than 30%
8	between 25% and 60%
14	between 55% and 85%
24	not less than 75%

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