
INTERIM REVISION ANNOUNCEMENT

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 effective before the effective date of the next *Supplement* or that were not ready for adoption by the closing date for the upcoming *Supplement*. (The effective date for these revisions is stated on the next page.)

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 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 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, where updates will be posted monthly.

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

*By authority of the United States Pharmacopeial Convention, Inc.
Prepared by the Council of Experts and published by the Board of Trustees*

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All inquiries and comments regarding *USP 32* text and *NF 27* text should be addressed to the Executive Secretariat, *USP–NF*, 12601 Twinbrook Parkway, Rockville, MD 20852 (execsec@usp.org).

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.

USP 23-Epi-26-deoxyactein RS (January 1, 2009)

USP Actein RS (January 1, 2009)

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 February 6, 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 S-Adenosyl-L-homocysteine 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 Fludeoxyglucose Related Compound B RS
 USP Gonadorelin Hydrochloride RS
 USP Hemoglobin RS
 USP Alpha Lipoic Acid RS
 USP Maritime Pine Extract RS
 USP Menotropins RS
 USP Oleyl Oleate RS
 USP Propylene Glycol Dilaurate RS
 USP Sargramostim RS
 USP Sincalide RS
 USP Valrubicin Related Compound A RS
 USP Vasopressin RS

MONOGRAPHS (USP)

Amantadine Hydrochloride Capsules

Add the following:

•Labeling—When more than one *Dissolution Test* is given, the labeling states the *Dissolution Test* used only if *Test 1* is not used.●₃

Change to read:

Dissolution ●₃(711)—

•TEST 1—*Procedure for a Pooled Sample*.●₃

Medium: water; 900 mL.

Apparatus 1: 100 rpm.

Time: 45 minutes.

Internal standard solution—Dissolve an accurately weighed quantity of naphthalene in hexane to obtain a solution having a known concentration of about 0.054 mg per mL.

Standard solution—Dissolve an accurately weighed quantity of USP Amantadine Hydrochloride RS in water to obtain a solution having a known concentration of about 0.1 mg per mL. Pipet 15.0 mL of this solution into a 50-mL screw-capped test tube, add 5.0 mL of 5 N sodium hydroxide and 10.0 mL of *Internal standard solution*, and shake for 60 minutes. Collect the hexane layer.

Test solution—Filter 15.0 mL of the solution under test and place into a 50-mL screw-capped test tube. Pipet 5.0 mL of 5 N sodium hydroxide and 10.0 mL of the *Internal standard solution* into the test tube, and shake for 60 minutes. Collect the hexane layer (*Test solution*).

Chromatographic system—Proceed as directed in the *Assay*.

Procedure—Separately inject equal volumes (about 2.5 μL) of the *Standard solution* and the *Test solution*. Record the chromatograms, and measure the responses for the major peaks. Calculate the amount of C₁₀H₁₇N · HCl dissolved.

Tolerances—Not less than 75% (Q) of the labeled amount of C₁₀H₁₇N · HCl is dissolved in 45 minutes.

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

Medium: water; 900 mL.

Apparatus 2: 75 rpm, with sinkers. [NOTE—A suitable sinker is available as catalog number CAPWHT-2S from www.QLA-LLC.com or www.tabletdissolution.com or www.labhut.com.]

Time: 45 minutes.

Standard stock solution—Dissolve an accurately weighed quantity of USP Amantadine Hydrochloride RS in *Medium* to obtain a solution with a final concentration of about 0.12 mg per mL.

Internal standard solution—Dissolve an accurately weighed quantity of naphthalene in hexanes to obtain a solution having a final concentration of about 0.06 mg per mL.

Working standard solution—Transfer 60.0 mL of the *Standard stock solution* to a 200-mL volumetric flask. Add 20 mL of 5 N sodium hydroxide and 40.0 mL of *Internal standard solution*. Shake the flask for approximately 10 minutes, and allow the layers to separate. Use the top layer for injection. The final concentration is about 0.18 mg per mL.

Test solution—Transfer 3.0 mL of the solution under test to a centrifuge tube. Add 1.0 mL of 5 N sodium hydroxide and 2.0 mL of *Internal standard solution*. Shake the tube for approximately 10 minutes, and allow the layers to separate. Use the top layer for injection.

Chromatographic system (see *Chromatography* (621))—The gas chromatograph is equipped with a flame-ionization detector and a 0.32-mm × 30-m column that contains

0.25-μm film of phase G1. The oven temperature is set at 100° for 3 minutes, then increased at a rate of 10° per minute to 200°, and held at 200° for 2 minutes. The injector temperature is maintained at 250°, and the detector at 300°. The carrier gas is helium flowing at a rate of 1.4 mL per minute, and the split flow rate is 20 mL per minute. Chromatograph the *Working standard solution*, and record the peak responses as directed for *Procedure*: the resolution, *R*, between naphthalene and amantadine hydrochloride is not less than 2; the tailing factor for the amantadine hydrochloride peak is not more than 2.0; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 2 μL) of the *Working standard solution* and the *Test solution* into the chromatograph, record the chromatograms, and measure the peak responses for all the peaks. Calculate the percentage of C₁₀H₁₇N · HCl dissolved by the formula:

$$\frac{A_U \times C_S \times 900 \times 100}{A_S \times L}$$

in which *A_U* is the ratio of the peak areas obtained from the *Test solution*; *C_S* is the concentration, in mg per mL, of amantadine hydrochloride in the *Standard stock solution*; *A_S* is the average ratio of the peak areas obtained from the *Working standard solution*; 900 is the volume, in mL, of *Medium*; 100 is the conversion factor to percentage; and *L* is the Capsule label claim in mg.

Tolerances—Not less than 75% (Q) of the labeled amount of C₁₀H₁₇N · HCl is dissolved in 45 minutes.●₃

Bupropion Hydrochloride Extended-Release Tablets

Change to read:

Dissolution (711)—

FOR PRODUCTS LABELED FOR DOSING EVERY 12 HOURS—

TEST 1—

Medium: water; 900 mL.

Apparatus 2: 50 rpm.

Times: 1, 4, and 8 hours.

Procedure—Determine the amount of C₁₃H₁₈ClNO · HCl dissolved by employing UV absorption at the wavelength of maximum absorbance at about 298 nm, using a 1.0-cm cell, on filtered portions of the solution under test, suitably diluted with *Medium*, if necessary, in comparison with a *Standard solution* having a known concentration of USP Bupropion Hydrochloride RS in the same *Medium*.

Tolerances—The percentages of the labeled amount of C₁₃H₁₈ClNO · HCl dissolved at the times specified conform to *Acceptance Table 2*.

Time (hours)	Amount dissolved
1	between 25% and 45%
4	between 60% and 85%
8	not less than 80%

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

Medium: 0.1 N hydrochloric acid, pH 1.5 (prepared by transferring about 50 mL of concentrated hydrochloric acid to 6000 mL of water, adding about 18 g of sodium hydroxide, mixing, and adjusting with either diluted sodium hydroxide or hydrochloric acid to a pH of 1.5 ± 0.05); 900 mL, deaerated.

Apparatus 1: 50 rpm.

Times: 1, 2, 4, and 6 hours.

Determine the percentages of the labeled amount of $C_{13}H_{18}ClNO \cdot HCl$ dissolved by employing the following method.

Buffer solution—Dissolve 3.45 g of monobasic sodium phosphate monohydrate in 996 mL of water, add 4.0 mL of triethylamine, and mix. Adjust with phosphoric acid to a pH of 2.80 ± 0.05 .

Mobile phase—Prepare a filtered and degassed mixture of *Buffer solution* and methanol (65 : 35). Make adjustments if necessary (see *System Suitability* under *Chromatography* (621)).

Standard solution—Dissolve an accurately weighed quantity of USP Bupropion Hydrochloride RS in *Medium*, and dilute quantitatively, and stepwise if necessary, with *Medium* to obtain a solution having a known concentration similar to the one expected in the *Test solution*.

Test solution—Use portions of the solution under test, and pass through a 0.45- μ m nylon filter.

Chromatographic system (see *Chromatography* (621))—The liquid chromatograph is equipped with a 298-nm detector and a 4.6-mm \times 15-cm column that contains packing L1. The flow rate is about 1.0 mL per minute. Chromatograph the *Standard solution*, and record the peak responses as directed for *Procedure*: the column efficiency is not less than 2000 theoretical plates; the tailing factor is not more than 2.0; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 20 μ L) of the *Standard solution* and the *Test solution* into the chromatograph, record the chromatograms, and measure the peak responses. Calculate the percentage of bupropion hydrochloride dissolved at each time point.

Tolerances—The percentages of the labeled amount of $C_{13}H_{18}ClNO \cdot HCl$ dissolved at the times specified conform to *Acceptance Table 2*.

Time (hours)	Amount dissolved
1	between 25% and 50%
2	between 40% and 65%
4	between 65% and 90%
6	not less than 80%

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

Medium, Apparatus, and Procedure—Proceed as directed for *Test 1*, except using the wavelength of about 250 nm.

Times: 1, 2, 4, and 6 hours.

Tolerances: The percentages of the labeled amount of $C_{13}H_{18}ClNO \cdot HCl$ dissolved at the times specified conform to *Acceptance Table 2*.

Time (hours)	Amount dissolved
1	between 30% and 55%
2	between 50% and 75%
4	between 70% and 90%
6	not less than 80%

TEST 5—If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 5*.

Medium and Procedure—Proceed as directed for *Test 1*.

Apparatus—Proceed as directed for *Test 1*, except to use a 0.5-cm cell.

Times: 1, 3, and 6 hours.

Tolerances—The percentages of the labeled amount of $C_{13}H_{18}ClNO \cdot HCl$ dissolved at the times specified conform to *Acceptance Table 2*.

Time (hours)	Amount dissolved
1	between 35% and 55%
3	between 65% and 85%
6	not less than 80%

•TEST 7—If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 7*.

Medium, Apparatus 1, and Times—Proceed as directed for *Test 2*, including the quantitative chromatographic method, but using as the *Mobile phase* a mixture of *Buffer solution* with methanol (55 : 45).

Tolerances—The percentages of the labeled amount of $C_{13}H_{18}ClNO \cdot HCl$ dissolved at the times specified conform to *Acceptance Table 2*.

Time (hours)	Amount dissolved
1	between 25% and 50%
2	between 45% and 70%
4	not less than 70%
6	not less than 80%

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FOR PRODUCTS LABELED FOR DOSING EVERY 24 HOURS—

TEST 4—If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 4*.

Medium: 0.1 N hydrochloric acid; 900 mL, deaerated.

Apparatus 1: 75 rpm.

Time: 2, 4, 8, and 16 hours.

Procedure—Determine the amount of $C_{13}H_{18}ClNO \cdot HCl$ dissolved by employing UV absorption at the wavelength of maximum absorbance at about 252 nm, using a 1.0-mm cell, on filtered portions of the solution under test, suitably diluted with *Medium*, if necessary, in comparison with a Standard solution having a known concentration of USP Bupropion Hydrochloride RS in the same *Medium*.

Tolerances—The percentages of the labeled amount of $C_{13}H_{18}ClNO \cdot HCl$ dissolved at the times specified conform to *Acceptance Table 2*.

Time (hours)	Amount dissolved
2	not more than 20%
4	between 20% and 45%
8	between 65% and 90%
16	not less than 80%

TEST 6—If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 6*.

Medium and Apparatus: Proceed as directed for *Test 4*.

Times: 1, 2, 4, 8, and 12 hours.

Procedure—Determine the amount of $C_{13}H_{18}ClNO \cdot HCl$ dissolved by employing UV absorption at the wavelength of maximum absorbance at about 298 nm, using a 1.0-cm cell, on filtered portions of the solution under test, suitably diluted with *Medium*, if necessary, in comparison with a Standard solution having a known concentration of USP Bupropion Hydrochloride RS in the same *Medium*.

Tolerances—The percentages of the labeled amount of $C_{13}H_{18}ClNO \cdot HCl$ dissolved at the times specified conform to *Acceptance Table 2*.

Time (hours)	Amount dissolved
1	between 15% and 35%
2	between 25% and 50%
4	between 40% and 65%
8	between 65% and 90%
12	not less than 80%

•TEST 8—If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 8*.

Medium: 0.1 N hydrochloric acid; 900 mL.

Apparatus 1: 75 rpm.

Times: 2, 4, 8, and 16 hours.

Standard solution—

FOR TABLETS LABELED TO CONTAIN 150 MG—Prepare a solution containing about 0.1667 mg of USP Bupropion Hydrochloride RS per mL in *Medium*.

FOR TABLETS LABELED TO CONTAIN 300 MG—Prepare a solution containing about 0.3333 mg of USP Bupropion Hydrochloride RS per mL in *Medium*.

Test solution—Pass a portion of the solution under test through a suitable filter having a porosity of 0.45 μm .

Procedure—Determine the percentage of bupropion hydrochloride dissolved by employing UV absorption at the wavelength of maximum absorbance at about 298 nm on portions of the *Test solution* in comparison with the *Standard solution*, using *Medium* as the blank.

Tolerances—The percentages of the labeled amount of $\text{C}_{13}\text{H}_{18}\text{ClNO} \cdot \text{HCl}$ dissolved at the times specified conform to *Acceptance Table 2*.

Time (hours)	Amount dissolved
2	not more than 10%
4	between 10% and 35%
8	between 45% and 75%
16	not less than 80%

•3