
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—Text proposed for deletion or replacement is indicated by a strikethrough the affected text. New text (if any) follows, and is enclosed in symbols and set off from the current official text by a paragraph break and by larger type (print edition only), as shown in the examples below:

- ◦new text◦ if slated for an *Interim Revision Announcement*;
- ▲new text▲ if slated for *USP 33–NF 28*; and
- ■new text■ if slated for a *Supplement* to *USP–NF*

Recent revisions that are already official are indicated by the same symbols but do not have the extra paragraph break and there is no increase in type size on the enclosing text. Where the symbols appear together with no enclosed text, such as ◦◦ or ■■ or ▲▲, 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 particular *IRA* or *Supplement* or indicates the *USP* or *NF* as the publication where the revision will appear if approved. For example, ◦₂ indicates that the revision is proposed for the *Interim Revision Announcement* that will appear in issue 2 of a given *PF* volume, ■_{25 (USP32)} indicates that the proposed revision is slated for the *Second Supplement* to *USP 32*, and ▲_{USP33} and ▲_{NF28} indicate that the revisions are proposed for *USP 33* and *NF 28*, respectively.

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 31–NF 26*. 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.

INTERIM REVISION ANNOUNCEMENT	249
MONOGRAPHS (USP)	253
Galantamine Tablets	253
ERRATA LIST FOR <i>USP 32–NF 27</i>	254

INTERIM REVISION
ANNOUNCEMENT
to *USP 31* and to *NF 26*

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Prepared by the Council of Experts and published by the Board of Trustees*

John W. Mauger, *Chair*
USP Board of Trustees

Roger L. Williams, M.D., *Executive Vice President, CEO,*
and Chairman, USP Council of Experts

Darrell R. Abernethy, M.D., Ph.D., *Chief Science Officer*
William F. Koch, Ph.D., FACB, *Chief Metrology Officer*

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All inquiries and comments regarding *USP 31* text and *NF 26* 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 31* or *NF 26* 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)
 USP Mibolerone RS (November 1, 2008)
 USP Narasin RS (November 1, 2008)
 USP Powdered St. John's Wort Extract RS (November 1, 2008)

Unavailable First-Time Official USP Reference Standards

The official dates of any *USP 31* or *NF 26* 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 December 1, 2008. Please refer to the current USP Catalog for a more up-to-date availability list. The USP Catalog can be accessed online at <http://www.uspcatalog.com>.

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 RS
 USP Valrubicin Related Compound A RS
 USP Vasopressin RS

MONOGRAPHS (USP)

Galantamine Tablets

Change to read:

Related compounds—

Buffer solution, Solution A, Solution B, Mobile phase, and Diluent—Prepare as directed in the Assay.

Resolution solution—Prepare a solution of USP Galantamine Hydrobromide Related Compounds Mixture RS in Diluent having a concentration of 0.6 mg per mL.

Standard solution—Use the Standard preparation, prepared as directed in the Assay.

Test solution—Use the Assay preparation.

Chromatographic system—Prepare as directed in the Assay. Chromatograph about 20 µL of the Resolution solution, and record the responses as directed for Procedure. Identify the

impurities using the approximate relative retention times given in Table 1: the resolution, *R*, between 6β-hexahydrogalantamine and 6β-octahydrogalantamine is not less than 1.5. Chromatograph the Standard solution, and record the responses as directed for Procedure: the relative standard deviation for replicate injections is not more than 2.0% for the galantamine peak.

Procedure—Separately inject equal volumes (about 20 µL) of the Standard solution and the Test solution into the chromatograph, record the chromatograms, and measure the peak responses. [NOTE—Ignore the peak due to bromide near the void volume.] Calculate the percentage of each of the galantamine related compounds in the portion of Tablets taken by the formula:

$$100(C_s / C_u)(r_u / r_s)(1/F)$$

in which *C_s* and *C_u* are the concentrations, in mg per mL, of galantamine in the Standard solution and Test solution, respectively; *r_u* is the peak area of each impurity obtained from the Test solution; *r_s* is the peak area of galantamine obtained from the Standard solution; and *F* is the Relative Response Factor (see Table 1 for values) for each of the impurities relative to galantamine.

•Table 1

Compound Name	Relative Retention Time (RRT)	Relative Response Factor (<i>F</i>)	Limit (%)
<i>N</i> -Desmethylgalantamine ¹	0.41	1.0	0.5
<i>O</i> -Desmethylgalantamine ²	0.56	1.0	0.5
6β-Hexahydrogalantamine (also known as galantamine <i>N</i> -oxide) ³	0.73	1.1	0.75
6β-Octahydrogalantamine (also known as lycoramine) ^{†4}	0.86	—	—
Galantamine hydrobromide	1.00	1.0	—
6α-Hexahydrogalantamine (also known as epigalantamine) ⁵	1.15	1.0	0.5
Tetrahydrogalantamine ^{†6}	2.09	—	—
Individual unspecified degradation product	—	1.0	0.2
Total impurities	—	—	1.5

[NOTE—The impurities marked with “†” are not quantified and are intended for system suitability evaluation only.]

¹ (4*aS*,6*R*,8*aS*)-4*a*,5,9,10,11,12-Hexahydro-3-methoxy-6*H*-benzofuro[3*a*,3,2-*ef*][2]benzazepin-6-ol.

² (4*aS*,6*R*,8*aS*)-4*a*,5,9,10,11,12-Hexahydro-11-methyl-6*H*-benzofuro[3*a*,3,2-*ef*][2]benzazepin-3,6-diol.

³ [4*aS*-(4*a*α,6β,8*aR**)]-4*a*,5,9,10,11,12-Hexahydro-3-methoxy-11-methyl-6*H*-benzofuro[3*a*,3,2-*ef*][2]benzazepin-6-ol, *N*-oxide.

⁴ [4*aS*-(4*a*α,6β,8*aR**)]-4*a*,5,7,8,9,10,11,12-Octahydro-3-methoxy-11-methyl-6*H*-benzofuro[3*a*,3,2-*ef*][2]benzazepin-6-ol.

⁵ [4*aS*-(4*a*α,6α,8*aR**)]-4*a*,5,9,10,11,12-Hexahydro-3-methoxy-11-methyl-6*H*-benzofuro[3*a*,3,2-*ef*][2]benzazepin-6-ol.

⁶ [4*aS*-(4*aR**,8*aR**)]-9,10,11,12-Tetrahydro-3-methoxy-11-methyl-4*aH*-benzofuro[3*a*,3,2-*ef*][2]benzazepine.