ERRATA

Following is a list of errata and corrections to *USP–NF*. The page number indicates where the item is found and in which official or pending official publication of *USP–NF*. This list will be updated with the posting of errata reports on www.usp.org/USPNF/newOfficialText. This information will appear in its corrected form in a future annual edition of *USP–NF*. An erratum consists of content erroneously published that does not accurately reflect the intended official or effective requirements as approved by the Council of Experts. USP staff is available to respond to questions regarding the accuracy of a particular requirement by calling 1-800-822-USPC.

Page Number	Title	Section	Description
Revision Bulletin, December 1, 2011			
Online	*Divalproex Sodium Delayed-Release Capsules*	PERFORMANCE TESTS *Dissolution, Test 3*	Line 1 of *Buffer*: Change "pH 7.5 phosphate buffer (0.25 g/L of citric acid monohydrate, 0.2 g/L of anhydrous dibasic sodium phosphate, 3.4 g/L of monobasic potassium phosphate, and 0.85 g/L of sodium hydroxide in water)" to: 0.25 g/L of citric acid monohydrate, 0.2 g/L of anhydrous dibasic sodium phosphate, 3.4 g/L of monobasic potassium phosphate, and 0.85 g/L of sodium hydroxide in water
USP35–NF30			
1106	*Description and Solubility*	*Carbomer Copolymer*	Line 3: Change "7.9 to 7.8" to: 7.3 to 7.8
1841	*Lecithin*	SPECIFIC TESTS *Peroxide Value*	Line 3 of *Analysis*: Change "acetic acid (2:1)" to: glacial acetic acid (2:1)
1960	*Sodium Stearyl Fumarate*	SPECIFIC TESTS *Fats and Fixed Oils, Saponification Value* ⟨401⟩	Line 12 of *Analysis*: Change "Result = $[(V_S - V_B) \times N \times F]/W$ V_S = volume of the *Titrant* consumed by the *Sample* (mL) V_B = volume of the *Titrant* consumed by the *Blank* (mL)" to: Result = $[(V_B - V_S) \times N \times F]/W$ V_B = volume of the *Titrant* consumed by the *Blank* (mL) V_S = volume of the *Titrant* consumed by the *Sample* (mL)
1989	*Stearic Acid*	SPECIFIC TESTS *Acidity*	Line 3 of *Analysis*: Change "0.05" to: 0.05 mL
1995	*Sucrose*	SPECIFIC TESTS *Optical Rotation, Specific Rotation* ⟨781S⟩	Line 1 of *Sample solution*: Change "Previously dried Sucrose at 105° for 2 h. Prepare a solution of 260 mg/mL of Sucrose in water." to: 260 mg/mL
			Line 1 of *Acceptance criteria*: Change "+66.3 to +67.0" to: +66.3 to +67.0 at 20°
2001	*Sunflower Oil*	SPECIFIC TESTS *Limit of Peroxide*	Line 4 of *Potassium iodide solution*: Change "iodine-free starch TS" to: iodide-free starch TS
			Line 5 of *Analysis*: Change "iodine-free starch TS" to: iodide-free starch TS

2060	*Acetaminophen and Tramadol Hydrochloride Tablets*	OTHER COMPONENTS *Limit of p-Aminophenol*	Line 1 of *Basic ferricyanide solution*: Change "sodium ferricyanide" to: sodium nitroferricyanide
2097	*Alfuzosin Hydrochloride*	*Assay*	Line 3: Change "Titrate with 0.1 M perchloric acid, determining the endpoint potentiometrically. Each mL of 0.1 M perchloric acid is equivalent to 42.59 mg of $C_{19}H_{27}N_5O_4 \cdot HCl$." to: Titrate with 0.1 N perchloric acid VS, determining the endpoint potentiometrically. Each mL of 0.1 N perchloric acid VS is equivalent to 42.59 mg of $C_{19}H_{27}N_5O_4 \cdot HCl$.
2318	*Benzethonium Chloride Concentrate*	*Identification*	Line 1: Change "Evaporate a volume of Concentrate, equivalent to about 200 mg of benzethonium chloride, on a steam bath: the residue so obtained meets the requirements of the tests for *Identification* under *Benzethonium Chloride*." to: A. Evaporate a volume of Concentrate, equivalent to 200 mg of benzethonium chloride, on a steam bath. To the residue add 2 mL of alcohol, 0.5 mL of 2 N nitric acid, and 1 mL of silver nitrate TS. A white precipitate, which is insoluble in 2 N nitric acid but soluble in 6 N ammonium hydroxide, is formed. B. Evaporate a volume of Concentrate, equivalent to 200 mg of benzethonium chloride, on a steam bath. The residue so obtained forms precipitate with 2 N nitric acid and with mercuric chloride TS, both of which dissolve upon the addition of alcohol. C. Evaporate a volume of Concentrate, equivalent to 200 mg of benzethonium chloride, on a steam bath. To the residue add 0.1 g of potassium nitrate, and heat on a steam bath for 3 min. Cautiously dilute the solution with water to 10 mL, add 0.5 g of granulated zinc, and warm the mixture for 10 min. Cool. Add 0.2 g of sodium nitrite to 1 mL of the clear liquid, and add this mixture to 20 mg of naphthol dipotassium disulfonate or naphthol disodium disulfonate in 1 mL of ammonium hydroxide. The solution turns orange-red, and a brown precipitate may be formed.

2318	*Benzethonium Chloride Topical Solution*	IDENTIFICATION	Line 1: Change "The residue obtained by evaporating, on a steam bath, a volume of Topical Solution, equivalent to about 200 mg of benzethonium chloride, responds to the *Identification* tests under *Benzethonium Chloride*." to: A. Evaporate a volume of Topical Solution, equivalent to 200 mg of benzethonium chloride, on a steam bath. To the residue add 2 mL of alcohol, 0.5 mL of 2 N nitric acid, and 1 mL of silver nitrate TS. A white precipitate, which is insoluble in 2 N nitric acid but soluble in 6 N ammonium hydroxide, is formed. B. Evaporate a volume of Topical Solution, equivalent to 200 mg of benzethonium chloride, on a steam bath. The residue so obtained forms precipitate with 2 N nitric acid and with mercuric chloride TS, both of which dissolve upon the addition of alcohol. C. Evaporate a volume of Topical Solution, equivalent to 200 mg of benzethonium chloride, on a steam bath. To the residue add 0.1 g of potassium nitrate, and heat on a steam bath for 3 min. Cautiously dilute the solution with water to 10 mL, add 0.5 g of granulated zinc, and warm the mixture for 10 min. Cool. Add 0.2 g of sodium nitrite to 1 mL of the clear liquid, and add this mixture to 20 mg of naphthol dipotassium disulfonate or naphthol disodium disulfonate in 1 mL of ammonium hydroxide. The solution turns orange-red, and a brown precipitate may be formed.
2453	*Calcium Gluconate*	DEFINITION	Line 6: Change "calcium gluconate" to: calcium gluconate monohydrate
			Line 8: Change "calcium gluconate" to: calcium gluconate monohydrate
		ASSAY	Line 1 of *Acceptance criteria*: Change "Anhydrous form, 98.0%–102.0%" to: Anhydrous form, 98.0%–102.0% on the dried basis
2702	*Clindamycin Hydrochloride*	IMPURITIES *Organic Impurities*	Line 16 of *Analysis*: Change "*P* = potency of USP Lincomycin RS (µg/mg)" to: *P* = potency of USP Lincomycin Hydrochloride RS (µg/mg)

2744	*Clotrimazole Topical Solution*	*Identification*	Line 1: Change "Transfer a volume of Topical Solution, equivalent to about 10 mg of clotrimazole, to a screw-capped, 50-mL centrifuge tube, and add 5 mL of dilute ammonium hydroxide (1 in 100) and 10 mL of chloroform. Shake vigorously, centrifuge to obtain a clear chloroform phase, and proceed as directed in the *Identification* test under *Clotrimazole Cream*." to: In a suitable chromatographic chamber, arranged for thin-layer chromatography (see *Chromatography* ⟨621⟩) and containing 200 mL of ether, place a beaker containing 25 mL of ammonium hydroxide. Cover the chamber, and allow to equilibrate for 2 hours. Transfer a volume of Topical Solution, equivalent to about 10 mg of clotrimazole, to a screw-capped, 50-mL centrifuge tube, and add 5 mL of dilute ammonium hydroxide (1 in 100) and 10 mL of chloroform. Shake vigorously, and centrifuge to obtain a clear chloroform phase. Apply 20 µL of the lower chloroform phase and 20 µL of a solution of USP Clotrimazole RS in chloroform containing 1 mg per mL to a suitable thin-layer chromatographic plate (see *Chromatography* ⟨621⟩) coated with a 0.25-mm layer of chromatographic silica gel mixture. Develop the chromatogram until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber, mark the solvent front, and allow the solvent to evaporate. Locate the spots on the plate by examination under short-wavelength UV light: the R_F value of the principal spot from the *Test solution* corresponds to that obtained from the *Standard solution*. Dissolve 3 g of bismuth subnitrate and 30 g of potassium iodide in 10 mL of dilute hydrochloric acid (1 in 4), dilute with water to 100 mL, mix, and prepare a spray reagent by diluting 10 mL of this solution and 5 mL of dilute hydrochloric acid (1 in 4) with water to 200 mL, and mixing. Spray the plate evenly with this spray reagent: the principal spots from the *Test solution* and the *Standard solution* are orange.

2744	*Clotrimazole Vaginal Inserts*	*Identification*	Line 1: Change "Place an amount of finely powdered Vaginal Inserts, equivalent to about 50 mg of clotrimazole, in a screw-capped, 50-mL centrifuge tube. Add 10 mL of chloroform, and shake vigorously for about 2 minutes. Centrifuge to clarify. [NOTE—The supernatant may remain slightly turbid.] Proceed as directed in the *Identification* test under *Clotrimazole Cream*, except to use a Standard solution of USP Clotrimazole RS in chloroform containing 5 mg per mL." to: In a suitable chromatographic chamber, arranged for thin-layer chromatography (see *Chromatography* ⟨621⟩ and containing 200 mL of ether, place a beaker containing 25 mL of ammonium hydroxide. Cover the chamber, and allow to equilibrate for 2 hours. Place an amount of finely powdered Vaginal Inserts, equivalent to about 50 mg of clotrimazole, in a screw-capped, 50-mL centrifuge tube. Add 10 mL of chloroform, and shake vigorously for about 2 minutes. Centrifuge to clarify. [NOTE—The supernatant may remain slightly turbid.] Apply 20 µL of the lower chloroform phase and 20 µL of a solution of USP Clotrimazole RS in chloroform containing 5 mg per mL to a suitable thin-layer chromatographic plate (see *Chromatography* ⟨621⟩) coated with a 0.25-mm layer of chromatographic silica gel mixture. Develop the chromatogram until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber, mark the solvent front, and allow the solvent to evaporate. Locate the spots on the plate by examination under short-wavelength UV light: the R_F value of the principal spot from the *Test solution* corresponds to that obtained from the *Standard solution*. Dissolve 3 g of bismuth subnitrate and 30 g of potassium iodide in 10 mL of dilute hydrochloric acid (1 in 4), dilute with water to 100 mL, mix, and prepare a spray reagent by diluting 10 mL of this solution and 5 mL of dilute hydrochloric acid (1 in 4) with water to 200 mL, and mixing. Spray the plate evenly with this spray reagent: the principal spots from the *Test solution* and the *Standard solution* are orange.
2994	*Drospirenone*	ASSAY	Line 3 of *Analysis*: Change "Calculate the percentage of the labeled quantity of drospirenone" to: Calculate the percentage of drospirenone
3639	*Lanolin*	*Foreign substances*	Line 13 of *Chromatographic system I*: Change "40 minutes" to: 40 mL per minute

3660	*Levetiracetam Tablets*	*USP Reference Standards* ⟨11⟩	Line 4: Change "(*S*)-2-Aminobutanamide. $C_4H_{10}N_2O$ 102.13" to: (*S*)-2-Aminobutanamide hydrochloride. $C_4H_{10}N_2O \cdot HCl$ 138.60
3706	*Lopinavir*	IMPURITIES *Organic Impurities, Procedure 1*	Column 2, row 1 of *Impurity Table 1*: Change "Relative Retention Time[o]" to: Relative Retention
			Column 1, row 13 of *Impurity Table 1*: Change "Lopinavir D-leucine diastereomer[k]" to: Lopinavir D-valine diastereomer[k]
			Footnote [o] of *Impurity Table 1*: Delete "[o] (See *Chromatography* ⟨621⟩, *Interpretation of Chromatograms*.)"
		IMPURITIES *Organic Impurities, Procedure 2*	Column 2, row 1 of *Impurity Table 2*: Change "Relative Retention Time[g]" to: Relative Retention
			Footnote [g] of *Impurity Table 2*: Delete "[g] (See *Chromatography* ⟨621⟩, *Interpretation of Chromatograms*.)"
3720	*Lorazepam Tablets*	*USP Reference standards* ⟨11⟩	Line 3: Add "USP Lorazepam Related Compound A RS 7-Chloro-5-*o*-chlorophenyl)-1,3-dihydro-3-acetoxy-2*H*-1,4-benzodiazepin-2-one. $C_{17}H_{12}Cl_2N_2O_3$ 363.20"
4379	*Povidone*	IMPURITIES *Vinylpyrrolidinone*	Line 6 of *Column*: Change "L7" to: L1
			Line 7 of *Column*: Change "L7" to: L1

4781	*Temazepam Capsules*	*Assay*	Line 2: Change "*Buffer solution*, *Mobile phase*, *Internal standard solution*, *Standard preparation*, *Chromatographic system*, and *Procedure*—Proceed as directed in the *Assay* under *Temazepam*." to: *Buffer solution*—Dissolve 5.444 g of monobasic potassium phosphate in 2000 mL of water. Adjust with phosphoric acid to a pH of 3.0. *Mobile phase*—Prepare a filtered and degassed mixture of *Buffer solution* and acetonitrile (53:47). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩). *Internal standard solution*—Dissolve an accurately weighed quantity of benzophenone in a mixture of methanol and water (9:1), and dilute quantitatively and stepwise with the same solvent to obtain a solution having a concentration of 0.2 mg per mL. *Standard preparation*—Dissolve an accurately weighed quantity of USP Temazepam RS in *Internal standard solution* to obtain a solution having a known concentration of 0.2 mg per mL. *Assay preparation*—Weigh the contents of not less than 20 Capsules, and calculate the average weight per Capsule. Mix the combined contents, and transfer an accurately weighed portion of the Capsule contents, equivalent to about 40 mg of temazepam, to a 200-mL volumetric flask, add 150 mL of *Internal standard solution*, and shake the mixture by mechanical means for 30 minutes. Dilute with *Internal standard solution* to volume, and mix. Allow the contents of the flask to settle, and filter, discarding the first 5 mL of the filtrate. *Chromatographic system* (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and a 4-mm × 25-cm column that contains packing L16. The flow rate is about 2 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure*: the column efficiency is not less than 800 theoretical plates; the tailing factor is not more than 2; the resolution, *R*, between the temazepam peak and any other peak is not less than 1, and the relative standard deviation for replicate injections is not more than 2.0%. *Procedure*—Separately inject equal volumes (about 10 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. The relative retention times are about 1.0 for temazepam and 2.0 for benzophenone. Calculate the quantity, in mg, of $C_{16}H_{13}ClN_2O_2$ in the portion of Tablets taken by the formula: $200C(R_U / R_S)$ in which C is the concentration, in mg per mL, of USP Temazepam RS in the *Standard preparation*; and R_U and R_S are the peak response ratios obtained from the *Assay preparation* and the *Standard preparation*, respectively.

4989	*Valganciclovir Tablets*	*Related compounds*	Line 26 of *Procedure*: Change "not more than 0.2% of each unidentified individual impurity is found; not more than 0.5% of total unidentified impurities/degradants is found; and not more than 3.5% of total impurities including all the degradation products is found." to: not more than 0.2% of each individual unidentified degradation product is found; not more than 0.5% of total individual unidentified degradation products is found; and not more than 3.5% of total degradation products is found.