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
USP34–NF29			
263	*Auxiliary Packaging Components* ⟨670⟩	*PHARMACEUTICAL COIL* *Polyester Pharmaceutical Coil*	Line 4 of *Identification* test *A*: Change "400 cm^{-1} (2.5 to 25 μm)" to: 650 cm^{-1} (2.5 to 15 μm)
			Line 17: Change "*Acidity or Alkalinity and Other Foreign Matter*" to: *Acidity or Alkalinity*
			Line 2 of *Loss on Drying*: Change "NMT 0.5%" to: NMT 1.0%
1495	*Copovidone*	ASSAY *K-value*	Line 4 of *Analysis*: Change $$\text{Result} = \left[\sqrt{300c\ \log z + (c + 1.5c\ \log z)^2} + 1.5c\ \log z - c/0.15\ c + 0.003\ c^2\right] \times (100/K_U)$$ to: $$\text{Result} = \left[\sqrt{300c\ \log z + (c + 1.5c\ \log z)^2} + 1.5c\ \log z - c\right]/(0.15\ c + 0.003\ c^2) \times (100/K_U)$$
1678	*Stannous Chloride*	*Limit of sulfate*	Line 5: Change "*Potassium sulfate solution*—Dissolve 1.8 g of potassium sulfate with *30% Alcohol* to make 1000 mL. *Standard solution*—Mix 3 mL of barium chloride solution (250 g per L) and 4.5 mL of *Potassium sulfate solution*. Shake, and let stand for 1 min. To 2.5 mL of this solution, add 15 mL of *Potassium sulfate solution* and 0.5 mL of *Acetic acid solution*. Allow to stand for 5 min. *Test solution*—Use 15 mL of the solution prepared in *Identification A*. *Procedure*—Mix 3 mL of barium chloride solution (250 g per L) and 4.5 mL of *Potassium sulfate solution*. Shake, and let stand for 1 min. To 2.5 mL of this solution, add the *Test solution* and 0.5 mL of *Acetic acid solution*. Allow to stand for 5 min. Any opalescence in the *Test solution* is not more intense than that in the *Standard solution* (500 ppm)." to: *Potassium sulfate solution 1*—Dissolve 1.8 g of potassium sulfate with *30% Alcohol* to make 1000 mL. Immediately before use, dilute 1 mL of the resulting solution with *30% Alcohol* to make 100 mL. This solution contains the equivalent of 18 μg/mL.

	Stannous Chloride	*Limit of sulfate (continued)*	*Potassium sulfate solution 2*—Dissolve 1.8 g of potassium sulfate with water to make 1000 mL. Immediately before use, dilute 1 mL of the resulting solution with water to make 100 mL. This solution contains the equivalent of 18 µg/mL. *Standard solution*—Mix 3 mL of barium chloride solution (250 mg/mL) and 4.5 mL of *Potassium sulfate solution 1*. Shake, and let stand for 1 min. To 2.5 mL of this solution, add 15 mL of *Potassium sulfate solution 2* and 0.5 mL of *Acetic acid solution*. Allow to stand for 5 min. *Test solution*—Use 15 mL of the solution prepared in *Identification A*. *Procedure*—Mix 3 mL of barium chloride solution (250 mg/mL) and 4.5 mL of *Potassium sulfate solution 1*. Shake, and let stand for 1 min. To 2.5 mL of this solution, add the *Test solution* and 0.5 mL of *Acetic acid solution*. Allow to stand for 5 min. Any opalescence in the *Test solution* is not more intense than that in the *Standard solution* (500 ppm).
1876	*Ferric Ammonium Citrate*	*Mercury*	Line 2 of *Standard solutions*: Change "*Mercury Stock Solution*" to: *Standard Mercury Solution*
1901	*Amprolium*	*CAS Number*	Change "[*121-25-5*]" to: [*137-88-2*]
2364	*Clarithromycin Extended-Release Tablets*	*Dissolution* ⟨711⟩, *Test 3*	Line 6 of the second paragraph of *Procedure*: Change "900" to: 1000
2453	*Cyclophosphamide*	IMPURITIES *Organic Impurities, Procedure 2: Limit of Degradation Products*	Line 19 of *Analysis*: Change "and leave the plate in the tank for 15 min" to: and leave the plate in the tank for at least 15 min
2455	*Cyclophosphamide Tablets*	*Assay*	Line 1: "*Mobile phase*, *Internal standard solution*, and *Standard preparation*—Prepare as directed in the *Assay* under *Cyclophosphamide*. *Assay preparation*—Transfer not fewer than 10 Tablets to a volumetric flask of suitable size so that the final concentration is about 1 mg of anhydrous cyclophosphamide per mL. Fill about half full with water, shake for 30 minutes, dilute with water to volume, and mix. Filter through fast, fluted filter paper, discarding the first 40 to 50 mL of the filtrate. Pipet 25 mL of the filtrate and 5 mL of *Internal standard solution* into a 50-mL volumetric flask, dilute with water to volume, and mix. *Chromatographic system*—Proceed as directed for *Chromatographic system* in the *Assay* under *Cyclophosphamide*. *Procedure*—Proceed as directed for *Procedure* in the *Assay* under *Cyclophosphamide*. Calculate the quantity, in mg, of $C_7H_{15}Cl_2N_2O_2P$ per Tablet taken by the formula: $(2CV/N)(R_U / R_S)$ in which C is the concentration, in mg per mL, of anhydrous cyclophosphamide in the *Standard preparation*, as determined from the concentration of USP Cyclophosphamide RS corrected for moisture by a titrimetric water determination; V is the volume, in mL, of the volumetric flask to which the N Tablets were transferred; N is the number of Tablets taken; and R_U and R_S are the ratios of the peak responses of cyclophosphamide to those of the internal standard in the *Assay preparation* and the *Standard preparation*, respectively."

	Cyclophosphamide Tablets	*Assay (continued)*	to: *Mobile phase*—Prepare a suitable, degassed solution of water and acetonitrile (70:30). *Internal standard solution*—Dissolve 185 mg of ethylparaben in 250 mL of alcohol in a 1000-mL volumetric flask, dilute with water to volume, and mix. *Standard preparation*—Transfer an accurately weighed quantity of USP Cyclophosphamide RS, equivalent to about 25 mg of anhydrous cyclophosphamide, to a 50-mL volumetric flask, add about 25 mL of water, and shake to dissolve the USP Reference Standard. Add 5.0 mL of *Internal standard solution*, dilute with water to volume, and mix to obtain a *Standard preparation* having a known concentration of about 0.5 mg of anhydrous cyclophosphamide per mL. *Assay preparation*—Transfer not fewer than 10 Tablets to a volumetric flask of suitable size so that the final concentration is about 1 mg of anhydrous cyclophosphamide per mL. Fill about half full with water, shake for 30 minutes, dilute with water to volume, and mix. Filter through fast, fluted filter paper, discarding the first 40 to 50 mL of the filtrate. Pipet 25 mL of the filtrate and 5 mL of *Internal standard solution* into a 50-mL volumetric flask, dilute with water to volume, and mix. *Chromatographic system* (see *Chromatography* ⟨621⟩)—The liquid chromatography is equipped with a 195-nm detector and a 3.9-mm × 30-cm column that contains packing L1. The flow rate is about 1.5 mL per minute. Chromatograph six replicate injections of the *Standard preparation*, and record the peak responses as directed for *Procedure*: the relative standard deviation is not more than 2%, and the resolution factor between cyclophosphamide and ethylparaben is not less than 2. *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. The relative retention times are about 0.7 for cyclophosphamide and 1.0 for ethylparaben. Calculate the quantity, in mg, of $C_7H_{15}Cl_2N_2O_2P$ per Tablet taken by the formula: $(2CV/N)(R_U / R_S)$ in which C is the concentration, in mg per mL, of anhydrous cyclophosphamide in the *Standard preparation*, as determined from the concentration of USP Cyclophosphamide RS corrected for moisture by a titrimetric water determination; V is the volume, in mL, of the volumetric flask to which the N Tablets were transferred; N is the number of Tablets taken; and R_U and R_S are the ratios of the peak responses of cyclophosphamide to those of the internal standard in the *Assay preparation* and the *Standard preparation*, respectively.
2455	*Cyclophosphamide for Injection*	*Assay*	Line 1: Change "*Mobile phase*, *Internal standard solution*, and *Standard preparation*—Prepare as directed in the *Assay* under *Cyclophosphamide*. *Assay preparation*—Accurately weigh a portion of Cyclophosphamide for Injection, equivalent to about 200 mg of anhydrous cyclophosphamide, and proceed as directed for *Assay preparation* in the *Assay* under *Cyclophosphamide*. *Chromatographic system*—Proceed as directed for *Chromatographic system* in the *Assay* under *Cyclophosphamide*.

	Cyclophosphamide for Injection	*Assay* *(continued)*	*Procedure*—Proceed as directed for *Procedure* in the *Assay* under *Cyclophosphamide*. Calculate the quantity, in mg, of $C_7H_{15}Cl_2N_2O_2P$ in the portion of Cyclophosphamide for Injection taken by the formula: $400C(R_U / R_S)$ in which the terms are as defined therein." to: *Mobile phase*—Prepare a suitable, degassed solution of water and acetonitrile (70:30). *Internal standard solution*—Dissolve 185 mg of ethylparaben in 250 mL of alcohol in a 1000-mL volumetric flask, dilute with water to volume, and mix. *Standard preparation*—Transfer an accurately weighed quantity of USP Cyclophosphamide RS, equivalent to about 25 mg of anhydrous cyclophosphamide, to a 50-mL volumetric flask, add about 25 mL of water, and shake to dissolve the USP Reference Standard. Add 5.0 mL of *Internal standard solution*, dilute with water to volume, and mix to obtain a *Standard preparation* having a known concentration of about 0.5 mg of anhydrous cyclophosphamide per mL. *Assay preparation*—Accurately weigh a portion of Cyclophosphamide for Injection, equivalent to about 200 mg of anhydrous cyclophosphamide, to a 200-mL volumetric flask, add about 50 mL of water, and shake for about 5 minutes, dilute with water to volume, and mix. Pipet 25 mL of this solution and 5 mL of *Internal standard solution* into a 50-mL volumetric flask, dilute with water to volume, and mix. *Chromatographic system* (see *Chromatography* ⟨621⟩)—The liquid chromatography is equipped with a 195-nm detector and a 3.9-mm × 30-cm column that contains packing L1. The flow rate is about 1.5 mL per minute. Chromatograph six replicate injections of the *Standard preparation*, and record the peak responses as directed for *Procedure*: the relative standard deviation is not more than 2%, and the resolution factor between cyclophosphamide and ethylparaben is not less than 2. *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. The relative retention times are about 0.7 for cyclophosphamide and 1.0 for ethylparaben. Calculate the quantity, in mg, of $C_7H_{15}Cl_2N_2O_2P$ in the portion of Cyclophosphamide for Injection taken by the formula: $400C(R_U / R_S)$ in which C is the concentration, in mg per mL, of anhydrous cyclophosphamide in the *Standard preparation*, as determined from the concentration of USP Cyclophosphamide RS corrected for moisture by a titrimetric water determination; and R_U and R_S are the ratios of the peak responses of cyclophosphamide to those of the internal standard in the *Assay preparation* and the *Standard preparation*, respectively.
2627	*Donepezil Hydrochloride*	IMPURITIES *Organic Impurities, Procedure*	Line 1 of *Relative standard deviation*: Change "NLT 5.0%" to: NMT 5.0%
2786	*Etodolac Extended-Release Tablets*	*Assay*	Line 4 of *Chromatographic system*: Change "L1" to: L7
			Line 5 of *Chromatographic system*: Change "L1" to: L7
2823	*Fexofenadine Hydrochloride*	*Heavy Metals, Method II* ⟨231⟩	Line 1: Change "0.002%" to: NMT 0.002%

2846	*Fludarabine Phosphate*	*Limit of alcohol*	Line 11 of *Chromatographic system*: Change "Chromatograph the *Standard solution*" to: Chromatograph the *Standard solution* (about 1.0 mL)
			Line 15 of *Chromatographic system*: Change "Chromatograph the *Blank solution*" to: Chromatograph the *Blank solution* (about 1.0 mL)
			Line 5 of *Procedure*: Change "Record the chromatograms, and measure the peak area for alcohol." to: Separately inject equal volumes (about 1.0 mL) of the *Blank solution*, the *Standard solution*, and the *Test solution*. Record the chromatograms, and measure the peak area for alcohol.
		Chromatographic purity, Test A (Early-Eluting Impurities)	Line 1 of *Procedure*: Change "Separately inject equal volumes (about 10 µL) of the *Standard solution* and the *Test solution*, record the chromatograms" to: Inject about 10 µL of the *Test solution*, record the chromatogram
		Chromatographic purity, Test B (Late-Eluting Impurities)	Line 1 of *Procedure*: Change "Separately inject equal volumes (about 10 µL) of the *Standard solution* and the *Test solution*, record the chromatograms" to: Inject about 10 µL of the *Test solution*, record the chromatogram
2850	*Fludarabine Phosphate for Injection*	*Related compounds, Test A (Early-Eluting Impurities)*	Line 1 of *Test solution*: Change "water" to: *Mobile phase*
			Line 3 of *Test solution*: Change "using water rinses" to: using *Mobile phase* rinses
			Line 1 of *Procedure*: Change "Separately inject equal volumes (about 10 µL) of the *Standard solution* and the *Test solution*, record the chromatograms" to: Inject about 10 µL of the *Test solution*, record the chromatogram
		Related compounds, Test B (Late-Eluting Impurities)	Line 1 of *Procedure*: Change "Separately inject equal volumes (about 10 µL) of the *Standard solution* and the *Test solution*, record the chromatograms" to: Inject about 10 µL of the *Test solution*, record the chromatogram
		USP Reference standards ⟨11⟩	Line 2: Add "USP Endotoxin RS"
2932	*Gabapentin Tablets*	*Assay*	Line 1 of *Mobile phase*: Change "Acetonitrile and *Diluent* (3:47)" to: Dissolve 1.2 g of monobasic potassium phosphate in 940 mL of water. Adjust with 5 N potassium hydroxide to a pH of 6.9. Add 60 mL of acetonitrile, and stir. Filter and degas.
3275	*Letrozole Tablets*	PERFORMANCE TESTS *Dissolution* ⟨711⟩	Line 1 of *Analysis*: Change "Inject a filtered portion" to: Inject a centrifuged portion
3433	*Mesna*	IMPURITIES *Organic Impurities, Procedure*	Third formula of *Analysis*: Change "Result = $(r_U/r_S) \times (C_S/C_U) \times F \times 100$" to: Result = $(r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$

3468	*Methotrexate Injection*	*Assay*	Line 1: Change "*pH 6.0 Buffer solution*, *Mobile phase*, *System suitability solution*, *System suitability test*, and *Standard preparation*—Proceed as directed in the *Assay* under *Methotrexate*. *Assay preparation*—Transfer an accurately measured volume of Injection, equivalent to about 25 mg of methotrexate, to a 250-mL volumetric flask, dilute with *Mobile phase* to volume, and mix. *Procedure*—Proceed as directed for *Procedure* in the *Assay* under *Methotrexate*. Calculate the quantity, in mg, of methotrexate ($C_{20}H_{22}N_8O_5$) in each mL of the Injection taken by the formula: $250(C/V)(P_U / P_S)$ in which C is the concentration, in mg per mL, of USP Methotrexate RS in the *Standard preparation*; V is the volume, in mL, of Injection taken; and P_U and P_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively." to: *pH 6.0 Buffer solution*—Prepare a mixture of 0.2 M dibasic sodium phosphate and 0.1 M citric acid (630:370). Adjust if necessary with 0.1 M citric acid or 0.2 M dibasic sodium phosphate to a pH of 6.0. *Mobile phase*—Prepare a filtered and degassed solution of *pH 6.0 Buffer solution* and acetonitrile (90:10). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩). *Standard preparation*—Dissolve an accurately weighed quantity of USP Methotrexate RS in *Mobile phase* to obtain a solution having a known concentration of about 100 µg per mL. *Assay preparation*—Transfer an accurately measured volume of Injection, equivalent to about 25 mg of methotrexate, to a 250-mL volumetric flask, dilute with *Mobile phase* to volume, and mix. *System suitability solution*—Prepare a solution in *Mobile phase* containing about 0.1 mg per mL each of USP Methotrexate RS and folic acid. *Chromatographic system* (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 302-nm detector and a 4.6-mm × 25-cm column that contains packing L1. The flow rate is about 1.2 mL per minute. Chromatograph the *System suitability solution*, and record the peak responses as directed for *Procedure*: the relative retention times are about 0.35 for folic acid and 1.0 for methotrexate, the resolution, R, between the folic acid and methotrexate peaks is not less than 8.0, and the relative standard deviation for replicate injections is not more than 2.5% for methotrexate. *Procedure*—Separately inject equal volumes (about 10 µL) of the *Assay preparation* and the *Standard preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of methotrexate ($C_{20}H_{22}N_8O_5$) in each mL of the Injection taken by the formula: $250(C/V)(P_U / P_S)$ in which C is the concentration, in mg per mL, of USP Methotrexate RS in the *Standard preparation*; V is the volume, in mL, of Injection taken; and P_U and P_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.

3468	*Methotrexate for Injection*	*Assay*	Line 1: Change "*pH 6.0 Buffer solution*, *Mobile phase*, *System suitability solution*, *System suitability test*, and *Standard preparation*—Proceed as directed in the *Assay* under *Methotrexate*. *Assay preparation*—Dissolve the contents of 1 container of Methotrexate for Injection in an accurately measured volume of *Mobile phase* to obtain a solution having a known concentration of about 0.1 mg per mL. *Procedure*—Proceed as directed for *Procedure* in the *Assay* under *Methotrexate*. Calculate the quantity, in mg, of methotrexate ($C_{20}H_{22}N_8O_5$) in the container of Methotrexate for Injection taken by the formula: $C(L/D)(r_U/r_S)$ in which C is the concentration, in mg per mL, of USP Methotrexate RS, corrected for water content, in the *Standard preparation*; L is the labeled quantity of Methotrexate in the container; D is the concentration, in mg per mL, of Methotrexate in the *Assay* preparation on the basis of the labeled quantity in the container and the extent of dilution; and r_U and r_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively." to: *pH 6.0 Buffer solution*—Prepare a mixture of 0.2 M dibasic sodium phosphate and 0.1 M citric acid (630:370). Adjust if necessary with 0.1 M citric acid or 0.2 M dibasic sodium phosphate to a pH of 6.0. *Mobile phase*—Prepare a filtered and degassed solution of *pH 6.0 Buffer solution* and acetonitrile (90:10). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩). *Standard preparation*—Dissolve an accurately weighed quantity of USP Methotrexate RS in *Mobile phase* to obtain a solution having a known concentration of about 100 µg per mL. *Assay preparation*—Dissolve the contents of 1 container of Methotrexate for Injection in an accurately measured volume of *Mobile phase* to obtain a solution having a known concentration of about 0.1 mg per mL. *System suitability solution*—Prepare a solution in *Mobile phase* containing about 0.1 mg per mL each of USP Methotrexate RS and folic acid. *Chromatographic system* (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 302-nm detector and a 4.6-mm × 25-cm column that contains packing L1. The flow rate is about 1.2 mL per minute. Chromatograph the *System suitability solution*, and record the peak responses as directed for *Procedure*: the relative retention times are about 0.35 for folic acid and 1.0 for methotrexate, the resolution, R, between the folic acid and methotrexate peaks is not less than 8.0, and the relative standard deviation for replicate injections is not more than 2.5% for methotrexate. *Procedure*—Separately inject equal volumes (about 10 µL) of the *Assay preparation* and the *Standard preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of methotrexate ($C_{20}H_{22}N_8O_5$) in the container of Methotrexate for Injection taken by the formula: $C(L/D)(r_U/r_S)$ in which C is the concentration, in mg per mL, of

	Methotrexate for Injection	*Assay (continued)*	USP Methotrexate RS, corrected for water content, in the *Standard preparation*; *L* is the labeled quantity of methotrexate in the container; *D* is the concentration, in mg per mL, of methotrexate in the *Assay preparation* on the basis of the labeled quantity in the container and the extent of dilution; and r_U and r_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.
3469	*Methotrexate Tablets*	*Assay*	Line 1: Change "*pH 6.0 Buffer solution*, *Mobile phase*, *System suitability solution*, *System suitability test*, and *Standard preparation*—Proceed as directed in the *Assay* under *Methotrexate*. *Assay preparation*—Weigh and finely powder not less than 20 Tablets. Weigh accurately a portion of the powder, equivalent to about 25 mg of methotrexate, and transfer to a 250-mL volumetric flask. Add about 200 mL of *Mobile phase*, and dissolve the methotrexate using a mechanical shaker or ultrasonic bath. Dilute with *Mobile phase* to volume, and mix. *Procedure*—Proceed as directed for *Procedure* in the *Assay* under *Methotrexate*. Calculate the quantity, in mg, of methotrexate ($C_{20}H_{22}N_8O_5$) in the portion of Tablets taken by the formula: $250C(P_U / P_S)$ in which C is the concentration, in mg per mL, of USP Methotrexate RS in the *Standard preparation*; and P_U and P_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively." to: *pH 6.0 Buffer solution*—Prepare a mixture of 0.2 M dibasic sodium phosphate and 0.1 M citric acid (630:370). Adjust if necessary with 0.1 M citric acid or 0.2 M dibasic sodium phosphate to a pH of 6.0. *Mobile phase*—Prepare a filtered and degassed solution of *pH 6.0 Buffer solution* and acetonitrile (90:10). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩). *Standard preparation*—Dissolve an accurately weighed quantity of USP Methotrexate RS in *Mobile phase* to obtain a solution having a known concentration of about 100 µg per mL. *Assay preparation*—Weigh and finely powder not less than 20 Tablets. Weigh accurately a portion of the powder, equivalent to about 25 mg of methotrexate, and transfer to a 250-mL volumetric flask. Add about 200 mL of *Mobile phase*, and dissolve the methotrexate using a mechanical shaker or ultrasonic bath. Dilute with *Mobile phase* to volume, and mix. *System suitability solution*—Prepare a solution in *Mobile phase* containing about 0.1 mg per mL each of USP Methotrexate RS and folic acid. *Chromatographic system* (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 302-nm detector and a 4.6-mm × 25-cm column that contains packing L1. The flow rate is about 1.2 mL per minute. Chromatograph the *System suitability solution*, and record the peak responses as directed for *Procedure*: the relative retention times are about 0.35 for folic acid and 1.0 for methotrexate, the resolution, *R*, between the folic acid and methotrexate peaks is not less than 8.0, and the relative standard deviation for replicate injections is not more than 2.5% for methotrexate.

	Methotrexate Tablets	*Assay (continued)*	*Procedure*—Separately inject equal volumes (about 10 µL) of the *Assay preparation* and the *Standard preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of methotrexate ($C_{20}H_{22}N_8O_5$) in the portion of Tablets taken by the formula: $250C(P_U / P_S)$ in which C is the concentration, in mg per mL, of USP Methotrexate RS in the *Standard preparation*; and P_U and P_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.
4017	*Probucol*	*USP Reference standards* ⟨11⟩	Line 3 of *USP Probucol Related Compound B RS*: Change "$C_{28}H_{42}O_2$ 474.78" to: $C_{28}H_{42}O_2S_2$ 474.76
4041	*Propafenone Hydrochloride*	IMPURITIES *Organic Impurities, Procedure*	Line 5 of *Analysis*: Change "$(r_U/r_S) \times 100$" to: $(r_U/r_S) \times (C_S/C_U) \times 100$
			Line 10 of *Analysis*: Add "C_S = concentration of USP Propafenone Hydrochloride RS in the *Standard solution* C_U = concentration of Propafenone Hydrochloride in the *Sample solution*"
4106	*Quinine Sulfate*	*Limit of dihydroquinine sulfate*	Line 2 of *System suitability preparation*: Change "quinine sulfate" to: USP Quinine Sulfate RS
4475	*Tramadol Hydrochloride*	ASSAY *Procedure*	Line 1 of *Solution A*: Change "0.5 mL" to: 2 mL
4615	*Zidovudine*	*Assay*	Line 12 of *Chromatographic system*: Change "the tailing factor is not more than 1.5; and the relative standard deviation for replicate injections is not more than 2.0%" to: the tailing factor is not more than 1.5 for the zidovudine peak; and the relative standard deviation for replicate injections is not more than 2.0% for the zidovudine peak
4616	*Zidovudine Capsules*	*Assay*	Line 11 of *Chromatographic system*: Change "the tailing factor is not more than 2.0; and the relative standard deviation for replicate injections is not more than 2.0%" to: the tailing factor is not more than 2.0 for the zidovudine peak; and the relative standard deviation for replicate injections is not more than 2.0% for the zidovudine peak
4617	*Zidovudine Injection*	*Assay*	Line 11 of *Chromatographic system*: Change "the tailing factor is not more than 1.5; and the relative standard deviation for replicate injections is not more than 2.0%" to: the tailing factor is not more than 1.5 for the zidovudine peak; and the relative standard deviation for replicate injections is not more than 2.0% for the zidovudine peak

4620	*Zidovudine Tablets*	*Uniformity of dosage units* ⟨905⟩	Line 6 of *Chromatographic system*: Change "the tailing factor is not more than 2.0; and the relative standard deviation for replicate injections is not more than 2.0%" to: the tailing factor is not more than 2.0 for the zidovudine peak; the relative standard deviation for replicate injections is not more than 2.0% for the zidovudine peak
		Related compounds	Line 6 of *Procedure*: Change "$100(1/F)\ (r_i\ /\ r_S)$ in which F is the relative response factor and is equal to 1.7 for zidovudine related compound C, and is equal to 1.00 for all other peaks; r_i is the peak response for each impurity obtained from the *Test solution;* and r_S is the peak response for zidovudine obtained from the *Standard solution*" to: $(r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$ in which r_U is the peak response of each impurity from the *Sample solution*; r_S is the peak response of zidovudine from the *Standard solution*; C_S is the concentration of USP Zidovudine RS in the *Standard solution* (mg/mL); C_U is the nominal concentration of Zidovudine in the *Sample solution* (mg/mL); and F is the relative response factor and is equal to 1.7 for zidovudine related compound C, and is equal to 1.00 for all other peaks
		Assay	Line 11 of *Chromatographic system*: Change "the relative standard deviation for replicate injections is not more than 2.0%" to: the relative standard deviation for replicate injections is not more than 2.0% for the zidovudine peak
Revision Bulletin (Official July 1, 2011)			
Online	*Ondansetron Tablets*	PERFORMANCE TESTS *Dissolution* ⟨711⟩, *Test 6*	Line 1 of *Column*: Change "4.6-mm × 5-cm" to: 4.6-mm × 15-cm
First Supplement to USP34–NF29			
4941	*Divalproex Sodium Extended-Release Tablets*	PERFORMANCE TESTS *Dissolution* ⟨711⟩, *Test 1*	Line 15 of *Analysis*: Change "$C_t = (r_U/r_S) \times (C_S \times D_U) \times 2$" to: $C_t = (r_U/r_S) \times (C_S \times D_U)$
5010	*Olanzapine and Fluoxetine Capsules*	IMPURITIES *Organic Impurities, Procedure*	Line 3 of *Analysis*: Change "[NOTE—Peaks eluting before a relative retention time of 0.63 and after a relative retention time of 1.0 are related to olanzapine.]" to: [NOTE—Peaks eluting before a relative retention time of 0.63 and after a relative retention time of 1.0, excluding any peak with relative retention times of 0.22, 0.30, and 0.31, are olanzapine related degradation products.]
			Line 20 of *Analysis*: Change "[NOTE—Peaks eluting between a relative retention time of 0.63 and 1.0 are related to fluoxetine.]" to: [NOTE—Peaks eluting at relative retention times of 0.22, 0.30, and 0.31, and any peaks between a relative retention time of 0.63 and 1.0, are fluoxetine related degradation products.]
5043	*Terazosin Capsules*	ASSAY *Procedure*	Line 3 of *Mobile phase*: Change "0.20 mL" to: 0.20 mL/L
5045	*Terazosin Tablets*	ASSAY *Procedure*	Line 3 of *Mobile phase*: Change "0.20 mL" to: 0.20 mL/L

5049	*Topiramate*	IMPURITIES *Organic Impurities*	Line 2: Change "[NOTE—On the basis of the synthetic route, perform either *Procedure 2* or *Procedure 3*. If *N*-methyltopiramate is a potential related compound, *Procedure 1* and *Procedure 3* are recommended.]" to: [NOTE—On the basis of the synthetic route, perform either *Procedure 2* or *Procedure 3*. If *N*-methyltopiramate is a potential related compound, *Procedure 1* or *Procedure 3* is recommended.]
Interim Revision Announcement (Official September 1, 2011)			
Online	*Modafinil*	ASSAY *Procedure*	Line 2 of *System suitability solution*: Change "50 µg/mL " to: 10 µg/mL
Second Supplement to USP34–NF29			
5417	*Ethynodiol Diacetate and Ethinyl Estradiol Tablets*	IDENTIFICATION	Line 1: Delete "*Thin Layer Chromatographic Identification Test* ⟨201⟩"
USP35–NF30			
1689	*Purified Stearic Acid*	*Other requirements*	Line 1 of *Other requirements*: Change "It meets the requirements for *Residue on ignition*, *Heavy metals*, *Mineral acid*, *Neutral fat or paraffin*, and *Assay* under *Stearic Acid*." to: *Residue on Ignition* ⟨281⟩: not more than 4 mg, determined on a 4-g portion (0.1%). *Heavy metals, Method II* ⟨231⟩: 0.001%. *Mineral acid*—Shake 5 g of melted Purified Stearic Acid with an equal volume of hot water for 2 minutes, cool, and filter: the filtrate is not reddened by the addition of 1 drop of methyl orange TS. *Neutral fat or paraffin*—Add 1 g of Purified Stearic Acid to 30 mL of anhydrous sodium carbonate solution (1 in 60) in a flask, and boil the mixture: the resulting solution, while hot, shows not more than a faint opalescence. *Assay*—Place about 100 mg of Purified Stearic Acid in a small conical flask fitted with a suitable reflux attachment. Place about 50 mg of USP Stearic Acid RS and about 50 mg of USP Palmitic Acid RS in a similar flask. Treat each flask as follows. Add 5.0 mL of a solution prepared by dissolving 14 g of boron trifluoride in methanol to make 100 mL, swirl to mix, and reflux for 15 minutes or until the solid is dissolved. Cool, transfer the reaction mixture with the aid of 10 mL of chromatographic solvent hexane to a 60-mL separator, and add 10 mL of water and 10 mL of saturated sodium chloride solution. Shake, allow to separate, then drain and discard the lower, aqueous layer. Pass the hexane layer through 6 g of anhydrous sodium sulfate (previously washed with chromatographic solvent hexane) into a suitable flask. Using a syringe fitted with a suitable needle, introduce a 1-µL to 2-µL portion of the assay preparation (which contains the Purified Stearic Acid) into a suitable gas chromatograph equipped with a flame-ionization detector. The column preferably is of glass, 1.5 m in length and 3 mm in inside diameter, and it is packed with 15% G4 on support S1A. The carrier gas is helium, passed through a bed of molecular sieve for drying, if necessary. The temperatures of the port and the detector are maintained at 210°, and the column temperature is maintained at 165°.

	Purified Stearic Acid	*Other requirements (continued)*	*System suitability*—In a suitable chromatogram, the resolution factor, *R* (see *Chromatography* ⟨621⟩), is not less than 2.0 between the peaks from methyl palmitate and methyl stearate (located by comparison with the chromatogram of the standard preparation), and five replicate injections of a single sample show a coefficient of variation of not more than 1.5% in the percentage of methyl stearate and methyl palmitate, respectively. Measure the peak areas of the fatty acid esters in the chromatogram, and determine the percentage of $C_{18}H_{36}O_2$ in the portion of Purified Stearic Acid taken by the formula: $100(A / B)$ in which *A* is the area due to the methyl stearate peak, and *B* is the sum of the areas of all of the fatty acid ester peaks in the chromatogram. Similarly, determine the percentage of $C_{16}H_{32}O_2$.
2440	*Calcium Acetate Tablets*	IMPURITIES *Limit of Aluminum*	Line 1 of *Blank*: Change "*Blank*" to: *Blank solution*
			Line 2 of *Analysis*: Change "*Blank*" to: *Blank solution*
2445	*Calcium Carbonate Tablets*	PERFORMANCE TESTS *Dissolution* ⟨711⟩	Line 7 of *Analysis*: Change "C_S" to: *C*
First Supplement to USP35–NF30			
5485	*Esterified Estrogens Tablets*	ASSAY *Procedure*	Line of 5 *Analysis*: Change "Conjugated Estrogens" to: Esterified Estrogens