

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*. Errata reports are posted at www.usp.org/USPNF/newOfficialText. The following 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; please call 1-800-822-USPC.

Page Number	Title	Section	Description
<i>USP35–NF30</i>			
1118	DESCRIPTION AND SOLUBILITY	<i>Ethylcellulose Dispersion Type B</i>	Lines 3 and 4: Change “in toluene, in chloroform, and in ethyl acetate; insoluble in water, in glycerin, and in propylene glycol.” to: in tetrahydrofuran, and in ethyl acetate; insoluble in water and in chloroform.
1705	<i>Bentonite</i>	IDENTIFICATION A. X-Ray Diffraction (941)	Line 4 of <i>Acceptance criteria</i> : Change “from the pattern of <i>Sample B</i> is 1.492 and 1.504 Å.” to: from the pattern of <i>Sample B</i> is between 1.492 and 1.504 Å.
1719	<i>Tribasic Calcium Phosphate</i>	IDENTIFICATION Test A	Line 1 of the <i>Sample solution</i> : Change “Dissolve 100 mg in 5 mL of diluted nitric acid.” to: A solution in a slight excess of nitric acid
1724	<i>Calcium Sulfate</i>	ASSAY <i>Procedure</i>	Line 5 of <i>Titrimetric system</i> : Delete the subsection “Blank: 100 mL of water and 4 mL of 3 N hydrochloric acid”
			Line 11 of <i>Analysis</i> : Delete the sentence “Perform a blank determination.”
			Line 13 of <i>Analysis</i> : Change “Result = [(V – B) × N × F × 100]/W” to: Result = [(V × N × F)/W] × 100
			Line 15 of <i>Analysis</i> : Delete “B = volume of titrant consumed by the Blank (mL)”
1746	<i>Microcrystalline Cellulose</i>	IDENTIFICATION B. Procedure	4th formula of <i>Analysis</i> : Change “Result = (95) × [η] _c /W _s × [(100 – %LOD)/100]” to: Result = [(95) × [η] _c]/W _s × [(100 – %LOD)/100]
1847	<i>Magnesium Stearate</i>	IMPURITIES <i>Chloride and Sulfate, Sulfate</i> (221)	Line 3: Change “0.020 N sulfuric acid (1.0%)” to: 0.020 M sulfuric acid (1.0%)
1865	<i>Methyl Alcohol</i>	ASSAY <i>Procedure</i>	Line 9 of <i>System suitability</i> : Change “Tailing factor: NLT 1.5 for methyl alcohol, <i>System suitability solution</i> ” to: Tailing factor: NMT 1.5 for methyl alcohol, <i>System suitability solution</i>
1906	<i>Polyethylene Oxide</i>	IMPURITIES <i>Organic Impurities, Procedure: Limit of Free Ethylene Oxide</i>	Line 2 of <i>System suitability</i> : Change “Samples: Standard stock solution and Standard solution C” to: Sample: Standard solution C
1919	<i>Polysorbate 20</i>	SPECIFIC TESTS <i>Acid Value</i>	Line 1 of <i>Sample</i> : Change “10.0” to: 10.0 g
1920	<i>Polysorbate 60</i>	SPECIFIC TESTS <i>Acid Value</i>	Line 1 of <i>Sample</i> : Change “10.0” to: 10.0 g

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1955	<i>Sodium Hydroxide</i>	ASSAY <i>Procedure</i>	Line 10 of <i>Analysis</i> : Change "Result = $\{[(V_{S1} - V_B) \times N \times F_1]/W\} \times 100$ " to: Result = $\{[(V_{S2} - V_B) \times N \times F_1]/W\} \times 100$ Line 11 of <i>Analysis</i> : Change "V _{S1} " to: V _{S2}
2007	<i>Trehalose</i>	ADDITIONAL REQUIREMENTS <i>USP Reference Standards</i>	Line 2: Delete "USP Glycerin RS"
2019	<i>Zein</i>	IDENTIFICATION <i>C. SDS-Polyacrylamide Gel Electrophoresis</i>	Lines 1 and 2 of the <i>Acceptance criteria</i> : Change "Zein has two major bands: the α band is at 21–25 kDa, and the β band is at 17–18 kDa." to: Zein has two major bands for α -zein at 19–26 kDa.
2063	<i>Acetazolamide for Injection</i>	ASSAY	Line 19: Change "25C(A _U /A _S)" to: 250C(A _U /A _S)
2079	<i>Adenosine</i>	IDENTIFICATION <i>Infrared Absorption (197M)</i>	Line 1: Delete "NMT 0.1%"
2106	<i>Alprazolam Orally Disintegrating Tablets</i>	IMPURITIES <i>Procedure</i>	Change the subsection "Buffer and Diluent: Prepare as directed in the Assay." to: <i>Diluent</i> : Prepare as directed in the Assay. <i>Buffer</i> : 6.8 g/L of monobasic potassium phosphate in water. Adjust with phosphoric acid to a pH of 3.0.
2202	<i>Amoxicillin Tablets</i>	PERFORMANCE TESTS	Line 4 of <i>Analysis</i> : Change "Result = $(r_U/r_S) \times (C_S/L) \times (D/V) \times P \times F \times 100$ " to: Result = $(r_U/r_S) \times (C_S/L) \times V \times D \times P \times F \times 100$ and: Transpose lines 12 and 13 of the variable definition list to match the order in the equation
2628	<i>Chlorophyllin Copper Complex Sodium</i>	SPECIFIC TESTS <i>Loss on Drying</i>	Line 1: Change "150°" to: 105°
3261	<i>Fluticasone Propionate</i>	IMPURITIES <i>Organic Impurities</i>	Line 1 of the <i>Sample solution</i> : Change "2.0 mg/mL" to: 0.2 mg/mL
3319	<i>Ganciclovir Oral Suspension</i>	ASSAY	Line 1 of <i>Internal standard solution</i> : Change "4 mg per mL" to: 0.4 mg per mL
3489	<i>Indinavir Sulfate</i>	OTHER COMPONENTS <i>Procedure 2: Content of Alcohol</i>	Line 6 of <i>Chromatographic system</i> in the subsection <i>Column</i> : Change "G14" to: G16
3830	<i>Metformin Hydrochloride Tablets</i>	<i>Dissolution, Test 3</i>	Lines 6 and 7 of <i>Procedure</i> : Change " $r_U \times C_S \times 900 \times 100/r_S \times D \times LC$ " to: $r_U \times C_S \times 1000 \times 100/r_S \times D \times LC$ Line 11 of <i>Procedure</i> : Change "900 is the volume" to: 1000 is the volume
3905	<i>Metronidazole</i>	<i>Related compounds</i>	Line 19 of <i>Procedure</i> : Change " r_i is the peak response for any unspecified degradation product peak in the <i>Test solution</i> " to: r_i is the peak response for any single unspecified impurity in the <i>Test solution</i>

Page Number	Title	Section	Description
3983	<i>Naftifine Hydrochloride Gel</i>	<i>Content of alcohol</i>	Line 4 of <i>Procedure</i> : Change "Calculate the quantity, in mg, of C ₂ H ₅ OH in the portion of Gel taken by the formula:" to: Calculate the percentage of C ₂ H ₅ OH in the portion of Gel taken by the formula:
4351	<i>Polyvinyl Alcohol</i>	<i>Identification test C</i>	Line 5: Change "Add 10 mL of alcohol to the remaining 5 mL of the polyvinyl alcohol solution, and mix" to: Add 10 mL of alcohol to the remaining 2 mL of the polyvinyl alcohol solution, and mix.
4379	<i>Povidone</i>	IMPURITIES <i>Vinylpyrrolidinone</i>	Line 2 of the Note in <i>Column, Analytical in Chromatographic system</i> : Change "4.0- × 30-mm or a 4.6- × 30-mm guard column" to: 4.0-mm × 30-mm or a 4.6-mm × 30-mm guard column
		IMPURITIES <i>Limit of Aldehydes</i>	Line 15 of <i>Analysis</i> : Change "Result = $10 \times (C/W) \times \{[(A_{U2} - A_{U1}) - (A_{B2} - A_{B1})] / [(A_{S2} - A_{S1}) - (A_{B2} - A_{B1})]\}$ " to: Result = $100 \times (C_S/C_U) \times \{[(A_{U2} - A_{U1}) - (A_{B2} - A_{B1})] / [(A_{S2} - A_{S1}) - (A_{B2} - A_{B1})]\}$ Line 17 of <i>Analysis</i> : Change "C = concentration of acetaldehyde in the <i>Standard solution</i> (mg/mL) W = weight of Povidone taken (g)" to: C _S = concentration of acetaldehyde in the <i>Standard solution</i> (mg/mL) C _U = concentration of <i>Sample solution</i> (mg/mL)
4411	<i>Prilocaine and Epinephrine Injection</i>	<i>Assay for epinephrine</i>	Line 7 of <i>Procedure</i> : Change "183.21/333.30" to: 183.20/333.29
			Line 8 of <i>Procedure</i> : Change "183.21 and 333.30" to: 183.20 and 333.29
4544	<i>Ribavirin Tablets</i>	ASSAY <i>Procedure</i>	Line 5 of <i>System suitability</i> in subsection <i>Tailing factor</i> : Change "NLT 2.0" to: NMT 2.0
4976	<i>Tyrosine</i>	IMPURITIES <i>Heavy Metals (231)</i>	Line 1: Change "Method I" to: <i>Method II</i>
5027	<i>Vinorelbine Tartrate</i>	ASSAY <i>Procedure</i>	Line 1 of <i>Relative standard deviation</i> in <i>System suitability</i> : Change "NLT 2.0%" to: NMT 2.0%
5068	<i>Zinc Carbonate</i>	IMPURITIES <i>Iron (241)</i>	Line 1 of <i>Sample solution</i> : Change "Sample solution: Dissolve 1.0 g in 20 mL of water and 3 mL of hydrochloric acid." to: <i>Test preparation</i> : Dissolve 0.5 g in 20 mL of water and 3 mL of hydrochloric acid.
First Supplement to USP35–NF30			
5154	(698) <i>Deliverable Volume</i>	ACCEPTANCE CRITERIA <i>For Multiple-Unit Containers</i>	<i>Figure 1</i> , right branch, left box: Change "Volume of 1 more containers is less than 95% LV" to: Volume of 1 or more containers is less than 95% LV

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5460	<i>Divalproex Sodium Extended-Release Tablets</i>	PERFORMANCE TESTS <i>Dissolution (711), Test 3</i>	Line 2 of <i>Analysis</i> : Change " <i>Samples: Acid stage standard solution, Buffer stage standard solution, Acid stage sample solutions, and Buffer stage sample solutions</i> " to: <i>Samples: Acid stage standard solution, Buffer stage standard solution, and Sample solutions</i>
5473	<i>Esomeprazole Magnesium Delayed-Release Capsules</i>	IMPURITIES <i>Organic Impurities</i>	Line 1 of <i>Sample solution</i> : Change "Transfer a portion of the powdered pellets, from the Capsule content, equivalent to 80–90 mg of esomeprazole, to a 200-mL volumetric flask, add 20 mL of methanol, and shake for 30 s." to: Transfer a portion of the powdered pellets (about 80–90 mg), from the Capsule content, to a 200-mL volumetric flask, add 20 mL of methanol, and shake for 30 s.
		PERFORMANCE TESTS <i>Dissolution</i>	Line 4 of <i>Medium</i> : Change "...and adjust with 2 N hydrochloric acid or 2 N sodium, if necessary, to a pH..." to: ...and adjust with 2 N hydrochloric acid or 2 N sodium hydroxide, if necessary, to a pH...
5524	<i>Omega-3-Acid Ethyl Esters Capsules</i>	SPECIFIC TESTS <i>Microbial Enumeration Tests (61) and Tests for Specified Microorganisms (62)</i>	Line 2: Change "10 ³ " to: 10 ³ cfu/mL
			Line 3: Change "10 ² " to: 10 ² cfu/mL
			Line 6: Change " <i>Salmonella</i> in 10 g." to: <i>Salmonella</i> species in 10 g.
5538	<i>Tacrolimus</i>	IMPURITIES <i>Procedure 2</i>	Footnote h of <i>Table 3</i> : Change "(3 <i>S</i> ,4 <i>R</i> ,5 <i>S</i> ,8 <i>S</i> ,9 <i>E</i> ,12 <i>S</i> ,14 <i>S</i> ,15 <i>R</i> ,16 <i>S</i> ,18 <i>R</i> ,19 <i>R</i> ,26 <i>aS</i>)-5,6,8,11,12,13,14,15,16,17,18,19,24,25,26,26a-hexadecahydro-5,19-dihydroxy-3-((<i>E</i>)-2-[(1 <i>R</i> ,3 <i>R</i> ,4 <i>R</i>)-4-hydroxy-3-methoxycyclohexyl]-1-methylvinyl)-14,16-dimethoxy-4,10,12,18-tetramethyl-15,19-epoxy-8-propyl-3 <i>H</i> -pyrido[2,1- <i>c</i>][1,4]oxaazacyclotricosine-1,7,20,21(4 <i>H</i> ,23 <i>H</i>)-tetrone." to: (3 <i>S</i> ,4 <i>R</i> ,5 <i>S</i> ,8 <i>R</i> ,9 <i>E</i> ,12 <i>S</i> ,14 <i>S</i> ,15 <i>R</i> ,16 <i>S</i> ,18 <i>R</i> ,19 <i>R</i> ,26 <i>aS</i>)-5,6,8,11,12,13,14,15,16,17,18,19,24,25,26,26a-hexadecahydro-5,19-dihydroxy-3-((<i>E</i>)-2-[(1 <i>R</i> ,3 <i>R</i> ,4 <i>R</i>)-4-hydroxy-3-methoxycyclohexyl]-1-methylvinyl)-14,16-dimethoxy-4,10,12,18-tetramethyl-15,19-epoxy-8-propyl-3 <i>H</i> -pyrido[2,1- <i>c</i>][1,4]oxaazacyclotricosine-1,7,20,21(4 <i>H</i> ,23 <i>H</i>)-tetrone.
5541	<i>Tacrolimus Capsules</i>	IMPURITIES <i>Procedure 2</i>	Footnote j of <i>Table 5</i> : Change "(3 <i>S</i> ,4 <i>R</i> ,5 <i>S</i> ,8 <i>S</i> ,9 <i>E</i> ,12 <i>S</i> ,14 <i>S</i> ,15 <i>R</i> ,16 <i>S</i> ,18 <i>R</i> ,19 <i>R</i> ,26 <i>aS</i>)-5,6,8,11,12,13,14,15,16,17,18,19,24,25,26,26a-hexadecahydro-5,19-dihydroxy-3-((<i>E</i>)-2-[(1 <i>R</i> ,3 <i>R</i> ,4 <i>R</i>)-4-hydroxy-3-methoxycyclohexyl]-1-methylvinyl)-14,16-dimethoxy-4,10,12,18-tetramethyl-15,19-epoxy-8-propyl-3 <i>H</i> -pyrido[2,1- <i>c</i>][1,4]oxaazacyclotricosine-1,7,20,21(4 <i>H</i> ,23 <i>H</i>)-tetrone." to: (3 <i>S</i> ,4 <i>R</i> ,5 <i>S</i> ,8 <i>R</i> ,9 <i>E</i> ,12 <i>S</i> ,14 <i>S</i> ,15 <i>R</i> ,16 <i>S</i> ,18 <i>R</i> ,19 <i>R</i> ,26 <i>aS</i>)-5,6,8,11,12,13,14,15,16,17,18,19,24,25,26,26a-hexadecahydro-5,19-dihydroxy-3-((<i>E</i>)-2-[(1 <i>R</i> ,3 <i>R</i> ,4 <i>R</i>)-4-hydroxy-3-methoxycyclohexyl]-1-methylvinyl)-14,16-dimethoxy-4,10,12,18-tetramethyl-15,19-epoxy-8-propyl-3 <i>H</i> -pyrido[2,1- <i>c</i>][1,4]oxaazacyclotricosine-1,7,20,21(4 <i>H</i> ,23 <i>H</i>)-tetrone.

Page Number	Title	Section	Description
<i>Second Supplement to USP35–NF30</i>			
5633	(232) <i>Elemental Impurities—Limits</i>	DRUG PRODUCTS <i>Large Volume Parenterals</i>	Row 13 of <i>Column 4 of Table 1</i> : Change “250” to: 10
		DRUG SUBSTANCE AND EXCIPIENTS	Rows 11 and 15 of <i>Column 2 of Table 2</i> : Change “100” to: 10
			Rows 11 and 15 of <i>Column 3 of Table 2</i> : Change “10” to: 1.0
			Row 11 of <i>Column 4 of Table 2</i> : Change “1.5” to: 0.15
			Row 13 of <i>Column 4 of Table 2</i> : Change “25” to: 1.0
			Row 15 of <i>Column 4 of Table 2</i> : Change “30” to: 3.0
		ANALYTICAL TESTING	Line 6: Change “Pd” to: Pb
5634	(233) <i>Elemental Impurities—Procedures</i>	INTRODUCTION <i>Definition</i>	Line 2 of <i>Target Elements</i> : Change “Pd” to: Pb
5910	<i>Azithromycin for Injection</i>	IMPURITIES <i>Limit of Azithromycin N-Oxide, Desosaminylazithromycin, and N-Demethylazithromycin</i>	Line 5 of <i>Analysis</i> : Change “Result = $(r_U/r_S) \times (C_S/C_U) \times P \times F \times 100$ ” to: Result = $(r_U/r_S) \times (C_S/C_U) \times P \times 100$
		IMPURITIES <i>Limit of Aminoazithromycin, Formamido Analog, Methylformamido Analog, and 3'-De(dimethylamino)-3'-oxoazithromycin</i>	Row 11 of <i>Table 2</i> : Change “3'-Demethyl-3'-N-[(4-methylphenyl)sulfonyl]azithromycin” to: 3'-N-Demethyl-3'-N-[(4-methylphenyl)sulfonyl]azithromycin