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*. If necessary, this list will be updated with every issue of *PF*. This information will also be available as a cumulative table in future *Supplements* and 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.

***USP32–NF27* Page**	**Title**	**Section**	**Description**
1354	*Stannous Chloride*	*Assay*	Line 6: Change ''0.05 N iodine VS'' to: 0.1 N iodine VS Line 7: Change ''1 mL of 0.05 N iodine VS'' to: 1 mL of 0.1 N iodine VS
1864	*Cefuroxime Axetil for Oral Suspension*	*Identification*	Line 4: Change ''of the *Standard preparation*, both relative to the internal standard, as obtained in the *Assay*.'' to: of the *Standard preparation*, as obtained in the *Assay*.
2305	*Estradiol and Norethindrone Acetate Tablets*	*Identification, B.*	Line 1: Change ''The retention time and UV spectrum of the major peaks'' to: The retention time of the major peaks
		Assay	Line 10 under *Chromatographic system*: Change ''and estrone acetate'' to: and estrone
2755	*Leflunomide Tablets*	*Assay*	Line 4 under *System suitability preparation 2*: Change ''add 1 mL of *System suitability preparation 2*'' to: add 1 mL of *System suitability preparation 1*
3314	*Piperazine Citrate*	*Chromatographic purity*	Line 2 under *Resolution solution*: Change ''triethylamine'' to: triethylenediamine
First Supplement to USP32-NF27			
3926	⟨61⟩ *Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests*	*Growth Promotion Test, Suitability of the Counting Method and Negative Controls*	Table 1, 5th row: Change ''*Aspergillus niger*'' to: *Aspergillus brasiliensis* Lines 9 and 12 under *Preparation of Test Strains*: Change ''*A. niger*'' to: *A. brasiliensis*
3934	⟨71⟩ *Sterility Tests*	*Culture Media and Incubation Temperatures*	Line 15 under *Growth Promotion Test of Aerobes, Anaerobes, and Fungi*: Change ''*Aspergillus niger*'' to: *Aspergillus brasiliensis*
Second Supplement to USP32-NF27			
4211	*Oleoyl Polyoxylglycerides*	*Identification*	Line 15 under test *B*: Change ''It meets the requirements of the test for Fatty acid composititon.'' to: **C:** It meets the requirements of the test for *Fatty acid composititon*.

As part of the monograph redesign, complete procedure information is being included in each monograph, rather than directing the user to another monograph (cross-references) as were utilized in the classic format. As a result of the recall and reissuance of *USP 33–NF 28*, some official monographs appear in the redesigned format while others remain in the classic format. There are cases where cross-references from monographs in the classic format to monographs in the redesigned format are no longer operable. The following table shows the correction of these cross references.

***USP32–NF27* Page**	**Title**	**Section**	**Description**
1319	*Polysorbate 20*	*Identification*	Replace "**A:** It meets the requirements of *Identification* test *A* and *C* under *Polysorbate 80*." with: Tests *A* and *C* from *Polysorbate 80*, as follows: **A:** To 5 mL of a solution (1 in 20) add 5 mL of sodium hydroxide TS. Boil for a few minutes, cool, and acidify with 3 N hydrochloric acid: the solution is strongly opalescent. **C:** A mixture of 60 volumes of it and 40 volumes of water yields a gelatinous mass at normal and lower than normal room temperatures.
		Other requirements	Replace "**Other requirements**—It meets the requirements for *Water, Residue on ignition, Heavy metals,* and *Acid value* under *Polysorbate 80*." with: Sections *Acid value, Water, Residue on ignition,* and *Heavy metals* from *Polysorbate 80*, as follows: **Acid value**—Weigh 10.0 g into a wide-mouth, 250-mL conical flask, and add 50 mL of neutralized alcohol. Heat on a steam bath nearly to boiling, shaking thoroughly occasionally while heating. Invert a beaker over the mouth of the flask, cool under running water, add 5 drops of phenolphthalein TS, and titrate with 0.1 N sodium hydroxide VS: not more than 4 mL of 0.100 N sodium hydroxide is required, corresponding to an acid value of 2.2. **Water,** *Method I* ⟨921⟩: not more than 3.0%. **Residue on ignition** ⟨281⟩: not more than 0.25%. **Heavy metals,** *Method II* ⟨231⟩: 0.001%.
1319	*Polysorbate 40*	*Identification*	Replace "**A:** It meets the requirements of *Identification* test *A* and *C* under *Polysorbate 80*." with: Tests *A* and *C* from *Polysorbate 80*, as follows: **A:** To 5 mL of a solution (1 in 20) add 5 mL of sodium hydroxide TS. Boil for a few minutes, cool, and acidify with 3 N hydrochloric acid: the solution is strongly opalescent. **C:** A mixture of 60 volumes of it and 40 volumes of water yields a gelatinous mass at normal and lower than normal room temperatures.
		Other requirements	Replace "**Other requirements**—It meets the requirements for *Water, Residue on ignition, Heavy metals,* and *Acid value* under *Polysorbate 80*." with: Sections *Acid value, Water, Residue on ignition,* and *Heavy metals* from *Polysorbate 80*, as follows: **Acid value**—Weigh 10.0 g into a wide-mouth, 250-mL conical flask, and add 50 mL of neutralized alcohol. Heat on a steam bath nearly to boiling, shaking thoroughly occasionally while heating. Invert a beaker over the mouth of the flask, cool under running water, add 5 drops of phenolphthalein TS, and titrate with 0.1 N sodium hydroxide VS: not more than 4 mL of 0.100 N sodium hydroxide is required, corresponding to an acid value of 2.2. **Water,** *Method I* ⟨921⟩: not more than 3.0%. **Residue on ignition** ⟨281⟩: not more than 0.25%. **Heavy metals,** *Method II* ⟨231⟩: 0.001%.

***USP32–NF27* Page**	**Title**	**Section**	**Description**
1319	*Polysorbate 60*	*Identification*	Replace ''**A:** It meets the requirements of *Identification* test *A* and *C* under *Polysorbate 80*.'' with: Tests *A* and *C* from *Polysorbate 80*, as follows: **A:** To 5 mL of a solution (1 in 20) add 5 mL of sodium hydroxide TS. Boil for a few minutes, cool, and acidify with 3 N hydrochloric acid: the solution is strongly opalescent. **C:** A mixture of 60 volumes of it and 40 volumes of water yields a gelatinous mass at normal and lower than normal room temperatures.
		Other requirements	Replace ''**Other requirements**—It meets the requirements for *Water, Residue on ignition, Heavy metals,* and *Acid value* under *Polysorbate 80*.'' with: Sections *Acid value, Water, Residue on ignition,* and *Heavy metals* from *Polysorbate 80*, as follows: **Acid value**—Weigh 10.0 g into a wide-mouth, 250-mL conical flask, and add 50 mL of neutralized alcohol. Heat on a steam bath nearly to boiling, shaking thoroughly occasionally while heating. Invert a beaker over the mouth of the flask, cool under running water, add 5 drops of phenolphthalein TS, and titrate with 0.1 N sodium hydroxide VS: not more than 4 mL of 0.100 N sodium hydroxide is required, corresponding to an acid value of 2.2. **Water,** *Method I* ⟨921⟩: not more than 3.0%. **Residue on ignition** ⟨281⟩: not more than 0.25%. **Heavy metals,** *Method II* ⟨231⟩: 0.001%.

USP32–NF27 Page	Title	Section	Description
1969	*Clindamycin Palmitate Hydrochloride for Oral Solution*	*Assay*	Change ''*Internal standard solution* and *Standard preparation*—Prepare as directed in the *Assay* under *Clindamycin Palmitate Hydrochloride.* *Assay preparation*—Constitute the Clindamycin Palmitate Hydrochloride for Oral Solution as directed in the labeling, and transfer 5.0 mL of the constituted solution to a glass-stoppered, 15-mL conical centrifuge tube. Add 5.0 mL of *Internal standard solution* and 1 mL of sodium carbonate solution (3 in 10), and proceed as directed for *Standard preparation* in the *Assay* under *Clindamycin Palmitate Hydrochloride* beginning with ''Insert the stopper, shake vigorously. . .''. *Chromatographic system*—Proceed as directed in the *Assay* under *Clindamycin Palmitate Hydrochloride.* *Procedure*—Proceed as directed in the *Assay* under *Clindamycin Palmitate Hydrochloride*. Calculate the quantity, in mg, of $C_{18}H_{33}ClN_2O_5S$ in each mL of the solution constituted from Clindamycin Palmitate Hydrochloride for Oral Solution taken by the formula: $(F/1000)(W_S/V)(R_U/R_S)$ in which V is the volume, in mL, of constituted solution from Clindamycin Palmitate Hydrochloride for Oral Solution taken, and the other terms are as defined therein.'' to: *Internal standard solution*—Dissolve cholesteryl benzoate in chloroform to obtain a solution containing about 5 mg per mL. *Standard preparation*—Transfer about 150 mg of USP Clindamycin Palmitate Hydrochloride RS, accurately weighed, to a glass-stoppered, 15-mL conical centrifuge tube. Add 5 mL of water, 5.0 mL of *Internal standard solution*, and 1 mL of sodium carbonate solution (3 in 10), and mix. Insert the stopper, shake vigorously for not less than 10 minutes, and centrifuge. Remove the upper aqueous layer, and transfer 1.0 mL of the lower chloroform layer to a 15-mL centrifuge tube. Add 1.0 mL of pyridine and 1.0 mL of acetic anhydride. Agitate the tube to ensure complete mixing, cover the top of the centrifuge tube with a plastic cap through which a small hole has been punched, heat at 100° for 2.5 hours, and allow to cool. Mix, and centrifuge, if necessary. Use the clear solution. *Assay preparation*—Constitute the Clindamycin Palmitate Hydrochloride for Oral Solution as directed in the labeling, and transfer 5.0 mL of the constituted solution to a glass-stoppered, 15-mL conical centrifuge tube. Add 5.0 mL of *Internal standard solution* and 1 mL of sodium carbonate solution (3 in 10), and proceed as directed for *Standard preparation* beginning with ''Insert the stopper, shake vigorously. . .''. *Chromatographic system* (see *Chromatography* ⟨621⟩)—The gas chromatograph is equipped with a flame-ionization detector and contains a 0.6-m × 3-mm glass column packed with 1 percent phase G36 on support S1AB. The column and detector are maintained at about 290° and 320°, respectively. Dry helium is used as the carrier gas at a flow rate of about 60 mL per minute. *Procedure*—Separately inject equal volumes of about 1.0 µL of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. In a suitable chromatogram the resolution of the peaks is complete. The elution order is: cholesteryl benzoate, clindamycin palmitate. Calculate the quantity, in mg, of $C_{18}H_{33}ClN_2O_5S$ in each mL of the solution constituted from Clindamycin Palmitate Hydrochloride for Oral Solution taken by the formula: $(F/1000)(W_S/V)(R_U/R_S)$ in which F is the potency, in µg of clindamycin per mg, of the USP Clindamycin Palmitate Hydrochloride RS; W_S is the weight, in mg, of USP Clindamycin Palmitate Hydrochloride RS in the *Standard preparation*; V is the volume, in mL, of the constituted solution from Clindamycin Palmitate Hydrochloride for Oral Solution; R_U and R_S are the ratios of the peak response of clindamycin palmitate to that of cholesteryl benzoate obtained from the *Assay preparation* and the *Standard preparation*, respectively.

Interim Revision Announcement

Following is a list of errata and corrections to the *USP 33–NF 28 Reissue*. The page number indicates where the item is found.

***USP 33–NF28 Reissue* Page**	**Title**	**CATEGORY Section**	**Description**
R-4	*USP General Notices and Requirements*	8.240. Weights and Measures	Row 22, column 1, in *Symbols and units table*: Change ''pg = pictogram'' to: pg = picogram
R-89	⟨941⟩ *Characterization of Crystalline and Partially Crystalline Solids by X-ray Powder Diffraction (XRPD)*	SPECIMEN PREPARATION AND MOUNTING Specimen Mounting	Line 12 under *Effect of Specimen Displacement*: Move the expression ''[cos$\theta \simeq 1$]'' to line 5 above, to read: (typically of the order of 0.01° in 2θ at low angles [cos$\theta \simeq 1$] for a displacement D = 15 μm)
R-316	*Oil- and Water-Soluble Vitamins with Minerals Capsules*	STRENGTH Biotin, Method 2	Line 1 under *Cystine-tryptophan solution*: Change ''Suspend 4.0 g of L-cystine in 1.0 g of L-tryptophan'' to: Suspend 4.0 g of L-cystine and 1.0 g of L-tryptophan
		STRENGTH Thiamine, Method 2	Line 1 under *Analysis, Samples*: Change ''*Standard solution* and *Standard solution*'' to: *Standard solution* and *Sample solution*
R-341	*Oil- and Water-Soluble Vitamins with Minerals Tablets*	STRENGTH Biotin, Method 2	Line 1 under *Cystine-tryptophan solution*: Change ''Suspend 4.0 g of L-cystine in 1.0 g of L-tryptophan'' to: Suspend 4.0 g of L-cystine and 1.0 g of L-tryptophan
R-425	*Olive Oil*	SPECIFIC TESTS Absence of Sesame Oil	Line 2 under *Analysis*: Change ''0.35 (v/v) solution'' to: 0.35% (v/v) solution
R-435	*Polyvinyl Acetate Dispersion*	ASSAY Procedure	Insert after the list of variable definitions: **Acceptance criteria:** The content of polyvinyl acetate is 25.0%–30.0%.
R-505	*Methylene Blue Injection, Veterinary*	ASSAY Procedure	Line 1 under *Acceptance criteria*: Change ''9.5–10.5 mg/mL of the labeled amount of $C_{16}H_{18}ClN_3S \cdot 3H_2O$'' to: 9.5–10.5 mg/mL of $C_{16}H_{18}ClN_3S \cdot 3H_2O$
R-543	*Tiagabine Hydrochloride Oral Suspension*	ASSAY Procedure	Line 3 under *Chromatographic system*: Add **Column:** 3.0-mm × 15-cm; packing L10 Under *System suitability, Suitability requirements:* Change ''**Replicate standard deviation**'' to: **Relative standard deviation**