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*. Errata are considered to be items erroneously published that have not received the approval of the Council of Experts and that do not reflect the official requirement. 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**
310	⟨788⟩ *Particulate Matter in Injections*	*Introduction*	Second paragraph, line 2: Change ''of mobile undissolved particles,'' to: of extraneous mobile undissolved particles,
1178	*Butylated Hydroxytoluene*	*Related compounds*	Line 1 under *Potassium ferricyanide solution*: Change ''50 mg'' to: 500 mg Line 1 under *Ferric chloride solution*: Change ''105 mg'' to: 1050 mg
1855	*Cefprozil*	*Chemical names*	Change the first chemical name to read: 5-Thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid, 7-[[amino(4-hydroxyphenyl)acetyl]amino]-8-oxo-3-(1-propenyl)-, monohydrate, [6*R*-[6α,7β(*R**)]]- Change the second chemical name to read: (6*R*,7*R*)-7-[(*R*)-2-Amino-2-(*p*-hydroxyphenyl)acetamido]-8-oxo-3-propenyl-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylic acid monohydrate

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1948	*Citalopram Hydrobromide*	*Related compounds*	*Table 1* referenced under TEST 1, *Procedure*, appears at the bottom of page 1950.
2906	*Metformin Hydrochloride Tablets*	*Dissolution* ⟨711⟩	Insert Test 3, official in Second IRA of 2007. TEST 3—If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 3.* *Medium:* pH 6.8 phosphate buffer; 1000 mL. *Apparatus 1:* 100 rpm. *Time:* 60 minutes. Determine the amount of $C_4H_{11}N_5 \cdot HCl$ dissolved by employing the following method. *0.05 M Sodium phosphate with 1-pentanesulfonic acid solution*—Dissolve 1.38 g of monobasic sodium phosphate in about 1800 mL of water. Add 3.484 g of 1-pentanesulfonic acid sodium salt, and mix. Adjust with diluted phosphoric acid to a pH of 3.00 ± 0.05. Add water to make 2000 mL, and mix. *Mobile phase*—Prepare a filtered and degassed mixture of *0.05 M Sodium phosphate with 1-pentanesulfonic acid solution* and acetonitrile (19:1). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩). *Standard stock solution*—Transfer about 25 mg, accurately weighed, of USP Metformin Hydrochloride RS to a 100-mL volumetric flask, and add about 50 mL of *Medium*. Sonicate until dissolved, and dilute with *Medium* to volume. *Standard solution*—Transfer 10.0 mL of the *Standard stock solution* to a 50-mL volumetric flask, and dilute with *Medium* to volume. *Test solution*—Withdraw a portion of the solution under test, and pass through a 0.45-μm nylon filter. Dilute with *Medium,* if necessary, to obtain a concentration similar to that of the *Standard solution.* *Chromatographic system*—The liquid chromatograph is equipped with a 230-nm detector and a 4.6-mm × 25-cm column that contains 5-μm packing L1. The flow rate is about 1.0 mL per minute. Chromatograph replicate injections of the *Standard solution,* and record the peak responses as directed for *Procedure:* the tailing factor is not more than 2.0; the column efficiency is not less than 1500 theoretical plates; and the relative standard deviation for replicate injections is not more than 2.0%. *Procedure*—Separately inject equal volumes (about 40 μL) of the *Standard solution* and the *Test solution* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the percentage of metformin released by the formula: $$\frac{r_U \times C_S \times 900 \times 100}{r_S \times D \times LC}$$ in which r_U and r_S are the peak responses obtained from the *Test solution* and the *Standard solution,* respectively; C_S is the concentration, in mg per mL, of metformin in the *Standard solution;* 900 is the volume, in mL, of *Medium;* 100 is the conversion factor to percentage; *D* is the dilution factor of the *Test solution;* and *LC* is the Tablet label claim, in mg. *Tolerances*—Not less than 70% *(Q)* of the labeled amount of $C_4H_{11}N_5 \cdot HCl$ is dissolved in 60 minutes.

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3372	*Prednisolone Sodium Phosphate*	*Related compounds*	Line 1 under *Test solution*: Change ''Accurately weigh a known quantity of USP Prednisolone Sodium Phosphate RS'' to: Accurately weigh a known quantity of prednisolone sodium phosphate
3374	*Prednisolone Sodium Phosphate Injection*	*Identification*	Change: ''**B:** It responds to *Identification* test *A* under *Prednisolone Sodium Phosphate*.'' to: **B:** *Infrared Absorption* ⟨197K⟩— *Test specimen:* Place 5 mL of the *Assay preparation* obtained as directed in the *Assay,* in a glass-stoppered, 100-mL volumetric flask, mix with 5 mL of *Alkaline phosphatase solution* prepared as directed in the *Assay,* and add 50 mL of methylene chloride. Insert the stopper, and allow to stand, with occasional gentle inversion (about once every 15 minutes), for 2 hours. Filter the methylene chloride layer through a dry paper, and evaporate 25 mL of the filtrate to dryness. *Standard specimen*: Prepare as directed in *Infrared Absorption* ⟨197K⟩, using USP Prednisolone RS.

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		Assay	Change ''*pH 9 Buffer with magnesium*—Prepare as directed in the *Assay* under *Prednisolone Sodium Phosphate.*'' to: *pH 9 Buffer with magnesium*—Mix 3.1 g of boric acid and 500 mL of water in a 1-L volumetric flask, add 21 mL of 1 N sodium hydroxide and 10 mL of 0.1 M magnesium chloride, dilute with water to volume, and mix. Change ''*Alkaline phosphatase solution*—Prepare as directed in the *Assay* under *Prednisolone Sodium Phosphate.*'' to: *Alkaline phosphatase solution*—Transfer 250 mg of alkaline phosphate enzyme to a 25-mL volumetric flask, dissolve by adding *pH 9 Buffer with magnesium* to volume, and mix. Prepare this solution fresh daily. Change: ''*Standard preparation*—Prepare as directed in the *Assay* under *Prednisolone Sodium Phosphate.*'' to: *Standard preparation*—Dissolve a suitable, accurately weighed quantity of USP Prednisolone RS in methylene chloride, and dilute quantitatively and stepwise with methylene chloride to obtain a solution having a known concentration of about 16 μg per mL. Pipet 100 mL of the solution into a glass-stoppered, 100-mL cylinder, and add 1.0 mL of *Alkaline phosphatase solution* and 1.0 mL of water. Allow to stand, with occasional gentle inversion, for 2 hours. Change: ''*Procedure*—Proceed as directed for *Procedure* in the *Assay* under *Prednisolone Sodium Phosphate.*'' to: *Procedure*—Pipet 1 mL of the *Assay preparation* into a glass-stoppered, 100-mL cylinder, add 1.0 mL of *Alkaline phosphatase solution* and about 50 mL of methylene chloride, insert the stopper, and allow to stand, with occasional gentle inversion (about once every 15 minutes), for 2 hours. Add methylene chloride to volume, mix, and allow to stand until the methylene chloride layer is clear (about 20 minutes). Concomitantly and without delay, determine the absorbances of the methylene chloride solution obtained from the *Assay preparation* and the *Standard preparation* at 241 nm, with a suitable spectrophotometer, using methylene chloride as the blank.

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3375	*Prednisolone Sodium Phosphate Ophthalmic Solution*	*Identification*	Change: ''**Identification**—It responds to *Identification* test *A* under *Prednisolone Sodium Phosphate* and to *Identification* test *A* under *Prednisolone Sodium Phosphate Injection.*'' to: **Identification**— **A:** *Infrared Absorption* ⟨197K⟩ *Test specimen:* Place 5 mL of the *Assay preparation* obtained as directed in the *Assay,* in a glass-stoppered, 100-mL volumetric flask, mix with 5 mL of *Alkaline phosphatase solution* prepared as directed in the *Assay,* and add 50 mL of methylene chloride. Insert the stopper, and allow to stand, with occasional gentle inversion (about once every 15 minutes), for 2 hours. Filter the methylene chloride layer through a dry paper, and evaporate 25 mL of the filtrate to dryness. *Standard specimen:* Prepare as directed in *Infrared Absorption* ⟨197K⟩, using USP Prednisolone RS. **B:** Dissolve 65 mg of phenylhydrazine hydrochloride in 100 mL of dilute sulfuric acid (3 in 5), add 5 mL of isopropyl alcohol, and mix. Heat 5 mL of this solution with 1 mL of *Assay preparation* (obtained as directed in the *Assay*) at 70° for 2 hours: a yellow color develops.
First Supplement to USP32–NF27			
4031	*Betamethasone Oral Solution*	*Assay*	Line 1 under *Standard stock preparation*: Change ''Dissolve an accurately weighed quantity of USP Betamethasone RS in alcohol,'' to: Dissolve an accurately weighed quantity of USP Betamethasone RS in dehydrated alcohol, Line 1 under *System suitability preparation*: Change ''Dissolve an accurately weighed quantity of betamethasone in alcohol,'' to: Dissolve an accurately weighed quantity of betamethasone in dehydrated alcohol,