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.

<table>
<thead>
<tr>
<th>USP32–NF27</th>
<th>Title</th>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1178</td>
<td>Butylated Hydroxytoluene</td>
<td>Related compounds</td>
<td>Line 1 under Potassium ferricyanide solution: Change “50 mg” to: “500 mg” Line 1 under Ferric chloride solution: Change “105 mg” to: “1050 mg”</td>
</tr>
<tr>
<td>1855</td>
<td>Cefprozil</td>
<td>Chemical names</td>
<td>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, [6R-[6a,7b(R*)]]- Change the second chemical name to read: (6R,7R)-7-[(R)-2-Amino-2-(p-hydroxyphenyl)acetamido]-8-oxo-3-propenyl-3-thia-1-azabicycle[4.2.0]oct-2-ene-2-carboxylic acid monohydrate</td>
</tr>
</tbody>
</table>
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 C₄H₁₁N₅·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).

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 C₄H₁₁N₅·HCl is dissolved in 60 minutes.
### USP32–NF27

<table>
<thead>
<tr>
<th>Page</th>
<th>Title</th>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>3372</td>
<td>Prednisolone Sodium Phosphate</td>
<td>Related compounds</td>
<td>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.</td>
</tr>
</tbody>
</table>
| 3374 | Prednisolone Sodium Phosphate Injection | Identification   | Change: “B: It responds to Identification test A under Prednisolone Sodium Phosphate.”

**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.
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.
### 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

#### 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,