### GOALS AND OBJECTIVES

Upon reading and studying this article, the reader will be able to:

1. Describe the current practice of compounding medications for children when commercially available doses are not available.
2. Explain how stability data can be used to extend shelf life of compounded products.
3. List the different types of stability testing that are currently performed.

### INTRODUCTION

Medications that are not available in study formulations are prepared extemporaneously to meet the specific needs of the patient. The stability of these preparations is critical, as they must maintain their therapeutic concentration over time to ensure effectiveness. Stability studies are performed to ensure that the compounded medications remain stable and effective for the duration of storage.

### STUDY DESIGNS

In general, the procedures include the following steps:

1. Determination of the appropriate storage conditions and the formulation for the study (see Table 6).
2. The study design involves several stability-indicating assays for the active ingredient in the formulation. These may include chromatographic or spectrophotometric methods.
3. The initial samples and the container that the preparations are stored in are kept separate to ensure the integrity of the testing samples and the performance of the stability study.
4. The active ingredient in the formulations is determined via a variety of methods, including high-performance liquid chromatography (HPLC), gas chromatography (GC), and others.

### TABLE 6

<table>
<thead>
<tr>
<th>Storage Condition</th>
<th>Stabilization Time (Days)</th>
<th>Stability (%): Valganciclovir</th>
<th>Stability (%): Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Room Temperature</td>
<td>90</td>
<td>98</td>
<td>97</td>
</tr>
<tr>
<td>Refrigerated</td>
<td>90</td>
<td>97</td>
<td>96</td>
</tr>
</tbody>
</table>

### REFERENCES

For a complete list of references, please consult the original article.

### STABILITY OF EXTEMPORANEOUS PREPARED ORAL LIQUID FORMULATIONS – Part V

Stability is a critical factor in ensuring the efficacy and safety of compounded medications. The stability of these preparations is assessed through various methods, including stability-indicating assays, stability studies, and stability-indicating indicators. These methods are used to determine the stability of the compounded medications over time and to ensure that they meet the required safety and efficacy standards. The stability studies are performed to ensure that the compounded medications remain stable and effective for the duration of storage.
Sulfasalazine (C$_7$H$_6$N$_2$O$_8$S, MW 398.39) occurs as a bright yellow or yellowish green, almost odorless crystalline powder (also as a white to off-white crystalline powder). Sulfasalazine powder is compatible with a variety of diluents and binders. It is soluble in common organic solvents. Cozaar tablets contain either 50 or 100 mg of losartan potassium. Losartan potassium is a white to off-white powder that is freely soluble in water. It is sparingly soluble in alcohol. Two preparations of losartan potassium were studied in this research. A beyond-use date of up to 30 days can be used based upon this study.

For the stability study, the suspension containing 5 mg/mL levodopa and 1.25 mg/mL carbidopa was prepared by pulsating 200 mL of Ora-Sweet, mixing well. This concentrate was allowed to stand at room temperature for at least 2 minutes. This concentrate was then added to 100 mL of a 2.5 mg/mL levodopa, 1.25 mg/mL carbidopa oral suspension, and mixed well. The suspension was then added to a 250 mL calibrated bottle. Add additional Ora-Sweet or Ora-Sweet to cover the tablets and mix well. Levodopa and carbidopa were soluble in 10 mL of Ora-Sweet. Theophylline occurs naturally in tea and is a component of tea. Theophylline products that are soluble in water than theophylline. Theophylline occurs naturally in tea and is a component of tea. Theophylline products that are soluble in water than theophylline.
The Betapace brand of sotalol hydrochloride tablets contain starch, talc, and titanium dioxide. Benazepril is supplied as tablets containing 5 mg, 10 mg and 20 mg of benazepril hydrochloride. Losartan potassium (C₄₂H₄₅N₄O₅·H₂O) occurs as a white to off-white crystalline powder that is soluble in 100 mg/mL in water and is also soluble in ethanol. Sotalol hydrochloride (C₂₂H₂₄N₂O₂·HCl) occurs as a white to off-white crystalline powder that is soluble in 100 mg/mL in water and is also soluble in ethanol. Losartan potassium is available as the monohydrate. Theophylline is only slightly soluble in water, soluble in alcohol and propylene glycol. It is stable in the pH range of 4 to 8.

The results showed there was no significant loss during the stability study. From the results of the study, the suspension should be refrigerated and should be stored for up to 4 weeks. The authors concluded that suspensions of 100 mg/mL sotalol hydrochloride are stable in the pH range of 4 to 8.

The stability of theophylline in oral liquid formulations was generally well maintained, as indicated by the TAC values. The theophylline products that are microcrystalline cellulose, lactose, starch, stearic acid, and is a component of tea. Theophylline products that are available as the monohydrate. Theophylline is only slightly soluble in water, soluble in alcohol and propylene glycol. It is stable in the pH range of 4 to 8. Theophylline 5 mg/mL oral solution was prepared by adding 5 mL of the mixture added to the tablet concentrate and shaken for at least 2 minutes. This concentrate was allowed to settle for at least 2 minutes. The initial pH of the refrigerated temperature samples was 4.07 and 4.02 for the OP-OS and OP-OS-SF samples respectively. The initial pH of the room temperature samples was 4.36 and 4.45, respectively. The final pH of the samples was 4.36 and 4.45, respectively. The initial pH of the refrigerated temperature samples was 4.07 and 4.02 for the OP-OS and OP-OS-SF samples respectively. The initial pH of the room temperature samples was 4.36 and 4.45, respectively. The final pH of the samples was 4.36 and 4.45, respectively. The authors concluded that suspensions of 100 mg/mL sotalol hydrochloride are stable in the pH range of 4 to 8.

Sotalol hydrochloride 5 mg/mL oral liquid was prepared as follows. Sotalol hydrochloride tablets were powdered to a fine powder. The powder was added to the concentrated, carbohydrate-free Ora-Plus (60 mL) and mixed to a fine powder. Sufficient Ora-Sweet was added to the suspension to render the mixture free flowing and mixed and mixed to a fine powder. Sufficient Ora-Sweet was added to the suspension to render the mixture free flowing and mixed. The prepared pH had values of 4.30 and 4.29 initially and 4.34 and 4.32 respectively for the refrigerated and room temperature samples.

The stability of theophylline in oral liquid formulations was generally well maintained, as indicated by the TAC values. The theophylline products that are available as the monohydrate. Theophylline is only slightly soluble in water, soluble in alcohol and propylene glycol. It is stable in the pH range of 4 to 8. Theophylline 5 mg/mL oral solution was prepared by adding 5 mL of the mixture added to the tablet concentrate and shaken for at least 2 minutes. This concentrate was allowed to settle for at least 2 minutes. The initial pH of the refrigerated temperature samples was 4.07 and 4.02 for the OP-OS and OP-OS-SF samples respectively. The initial pH of the room temperature samples was 4.36 and 4.45, respectively. The final pH of the samples was 4.36 and 4.45, respectively. The authors concluded that suspensions of 100 mg/mL sotalol hydrochloride are stable in the pH range of 4 to 8.

Sotalol hydrochloride 5 mg/mL oral liquid was prepared as follows. Sotalol hydrochloride tablets were powdered to a fine powder. The powder was added to the concentrated, carbohydrate-free Ora-Plus (60 mL) and mixed to a fine powder. Sufficient Ora-Sweet was added to the suspension to render the mixture free flowing and mixed and mixed to a fine powder. Sufficient Ora-Sweet was added to the suspension to render the mixture free flowing and mixed. The prepared pH had values of 4.30 and 4.29 initially and 4.34 and 4.32 respectively for the refrigerated and room temperature samples.

The stability of sotalol in OPA/PLSOSA at pH 4 and 25°C.

<table>
<thead>
<tr>
<th>Time</th>
<th>Refrigerated Temperature</th>
<th>Room Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 mg/mL</td>
<td>5.1</td>
<td>5.1</td>
</tr>
<tr>
<td>1 mg/mL</td>
<td>5.4</td>
<td>5.3</td>
</tr>
<tr>
<td>2 mg/mL</td>
<td>5.2</td>
<td>5.1</td>
</tr>
<tr>
<td>3 mg/mL</td>
<td>5.1</td>
<td>5.0</td>
</tr>
<tr>
<td>4 mg/mL</td>
<td>5.0</td>
<td>4.9</td>
</tr>
<tr>
<td>5 mg/mL</td>
<td>4.9</td>
<td>4.8</td>
</tr>
<tr>
<td>6 mg/mL</td>
<td>4.8</td>
<td>4.7</td>
</tr>
<tr>
<td>7 mg/mL</td>
<td>4.7</td>
<td>4.6</td>
</tr>
<tr>
<td>8 mg/mL</td>
<td>4.5</td>
<td>4.4</td>
</tr>
<tr>
<td>9 mg/mL</td>
<td>4.4</td>
<td>4.3</td>
</tr>
<tr>
<td>10 mg/mL</td>
<td>4.3</td>
<td>4.2</td>
</tr>
</tbody>
</table>

Sotalol hydrochloride 5 mg/mL oral liquid was prepared as follows. Sotalol hydrochloride tablets were powdered to a fine powder. The powder was added to the concentrated, carbohydrate-free Ora-Plus (60 mL) and mixed to a fine powder. Sufficient Ora-Sweet was added to the suspension to render the mixture free flowing and mixed and mixed to a fine powder. Sufficient Ora-Sweet was added to the suspension to render the mixture free flowing and mixed. The prepared pH had values of 4.30 and 4.29 initially and 4.34 and 4.32 respectively for the refrigerated and room temperature samples.

The stability results showed a mean sotalol concentration of 96.29% in the refrigerated samples, and a mean sotalol concentration of 93.00% in the room temperature samples, indicating that sotalol hydrochloride tablets are stable in an acidic vehicle.

The stability results showed a mean sotalol concentration of 96.29% in the refrigerated samples, and a mean sotalol concentration of 93.00% in the room temperature samples, indicating that sotalol hydrochloride tablets are stable in an acidic vehicle.

The stability results showed a mean sotalol concentration of 96.29% in the refrigerated samples, and a mean sotalol concentration of 93.00% in the room temperature samples, indicating that sotalol hydrochloride tablets are stable in an acidic vehicle.

The stability results showed a mean sotalol concentration of 96.29% in the refrigerated samples, and a mean sotalol concentration of 93.00% in the room temperature samples, indicating that sotalol hydrochloride tablets are stable in an acidic vehicle.

The stability results showed a mean sotalol concentration of 96.29% in the refrigerated samples, and a mean sotalol concentration of 93.00% in the room temperature samples, indicating that sotalol hydrochloride tablets are stable in an acidic vehicle.

The stability results showed a mean sotalol concentration of 96.29% in the refrigerated samples, and a mean sotalol concentration of 93.00% in the room temperature samples, indicating that sotalol hydrochloride tablets are stable in an acidic vehicle.

The stability results showed a mean sotalol concentration of 96.29% in the refrigerated samples, and a mean sotalol concentration of 93.00% in the room temperature samples, indicating that sotalol hydrochloride tablets are stable in an acidic vehicle.

The stability results showed a mean sotalol concentration of 96.29% in the refrigerated samples, and a mean sotalol concentration of 93.00% in the room temperature samples, indicating that sotalol hydrochloride tablets are stable in an acidic vehicle.

The stability results showed a mean sotalol concentration of 96.29% in the refrigerated samples, and a mean sotalol concentration of 93.00% in the room temperature samples, indicating that sotalol hydrochloride tablets are stable in an acidic vehicle.

The stability results showed a mean sotalol concentration of 96.29% in the refrigerated samples, and a mean sotalol concentration of 93.00% in the room temperature samples, indicating that sotalol hydrochloride tablets are stable in an acidic vehicle.

The stability results showed a mean sotalol concentration of 96.29% in the refrigerated samples, and a mean sotalol concentration of 93.00% in the room temperature samples, indicating that sotalol hydrochloride tablets are stable in an acidic vehicle.
To provide information from the peer-reviewed literature on stability studies of extemporaneously prepared oral liquid formulations—Part V

Valganciclovir

Valganciclovir hydrochloride (C₂₀H₂₇ClN₅O₄·HCl, MW 451.90) occurs as a white, odorless, crystalline powder. It is freely soluble in water and freely soluble in alcohol. Valganciclovir is stable as a liquid in glass or plastic containers. The drug is effective in the treatment of primary and recurrent oral and genital herpes, and for the prevention ofHSV in organ transplant recipients. The drug is available in a form of 500 mg tablets. Extemporaneously prepared solutions of valganciclovir were evaluated for stability over a period of time.

To evaluate the shelf life of valganciclovir extemporaneously compounded oral suspensions, 10 mg/mL valganciclovir suspensions were prepared by the pharmacist as follows: 10 mg valganciclovir tablets were crushed, the powder was then transferred into a 60 mL calibrated amber plastic container, and the container was stored at room temperature. The study design evaluated the stability of valganciclovir suspensions over a period of time at room temperature and refrigerated conditions.

The results showed that the valganciclovir suspensions were stable for up to 90 days. The initial and final pH values were within the range of 4.30 to 4.34. The study also showed that the valganciclovir suspensions were stable for up to 90 days.

### TABLE 7

<table>
<thead>
<tr>
<th>Temperature</th>
<th>Initial pH</th>
<th>Final pH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Room Temperature</td>
<td>4.30</td>
<td>4.34</td>
</tr>
<tr>
<td>Refrigerated</td>
<td>4.30</td>
<td>4.34</td>
</tr>
</tbody>
</table>

### References

1. Pai V, Nahata MC. Need for extemporaneous compounded oral liquid formulations: pediatric administration. Ora-Plus and Ora-Plus Ora-Plus Ora-Plus Ora-Plus SF are the primary vehicles used in these preparations. The initial and final pH values were within the range of 3.5 to 4.5.

The experiments were performed by crushing 10 mg of valganciclovir tablets and added to 30 mL of Ora-Plus. The suspension was prepared by mixing well. The study results showed that the valganciclovir suspensions were stable for up to 90 days. The initial and final pH values were within the range of 4.30 to 4.34.

The study results showed that all formulations were stable for up to 90 days. The initial and final pH values at both temperatures ranged from 4.30 to 4.34.

The study results showed that all formulations were stable for up to 90 days. The initial and final pH values at both temperatures ranged from 4.30 to 4.34.

The study results showed that all formulations were stable for up to 90 days. The initial and final pH values at both temperatures ranged from 4.30 to 4.34.

The study results showed that all formulations were stable for up to 90 days. The initial and final pH values at both temperatures ranged from 4.30 to 4.34.

The study results showed that all formulations were stable for up to 90 days. The initial and final pH values at both temperatures ranged from 4.30 to 4.34.

The study results showed that all formulations were stable for up to 90 days. The initial and final pH values at both temperatures ranged from 4.30 to 4.34.

The study results showed that all formulations were stable for up to 90 days. The initial and final pH values at both temperatures ranged from 4.30 to 4.34.

The study results showed that all formulations were stable for up to 90 days. The initial and final pH values at both temperatures ranged from 4.30 to 4.34.

The study results showed that all formulations were stable for up to 90 days. The initial and final pH values at both temperatures ranged from 4.30 to 4.34.

The study results showed that all formulations were stable for up to 90 days. The initial and final pH values at both temperatures ranged from 4.30 to 4.34.

The study results showed that all formulations were stable for up to 90 days. The initial and final pH values at both temperatures ranged from 4.30 to 4.34.

The study results showed that all formulations were stable for up to 90 days. The initial and final pH values at both temperatures ranged from 4.30 to 4.34.

The study results showed that all formulations were stable for up to 90 days. The initial and final pH values at both temperatures ranged from 4.30 to 4.34.

The study results showed that all formulations were stable for up to 90 days. The initial and final pH values at both temperatures ranged from 4.30 to 4.34.

The study results showed that all formulations were stable for up to 90 days. The initial and final pH values at both temperatures ranged from 4.30 to 4.34.

The study results showed that all formulations were stable for up to 90 days. The initial and final pH values at both temperatures ranged from 4.30 to 4.34.

The study results showed that all formulations were stable for up to 90 days. The initial and final pH values at both temperatures ranged from 4.30 to 4.34.

The study results showed that all formulations were stable for up to 90 days. The initial and final pH values at both temperatures ranged from 4.30 to 4.34.

The study results showed that all formulations were stable for up to 90 days. The initial and final pH values at both temperatures ranged from 4.30 to 4.34.

The study results showed that all formulations were stable for up to 90 days. The initial and final pH values at both temperatures ranged from 4.30 to 4.34.

The study results showed that all formulations were stable for up to 90 days. The initial and final pH values at both temperatures ranged from 4.30 to 4.34.

The study results showed that all formulations were stable for up to 90 days. The initial and final pH values at both temperatures ranged from 4.30 to 4.34.

The study results showed that all formulations were stable for up to 90 days. The initial and final pH values at both temperatures ranged from 4.30 to 4.34.

The study results showed that all formulations were stable for up to 90 days. The initial and final pH values at both temperatures ranged from 4.30 to 4.34.

The study results showed that all formulations were stable for up to 90 days. The initial and final pH values at both temperatures ranged from 4.30 to 4.34.

The study results showed that all formulations were stable for up to 90 days. The initial and final pH values at both temperatures ranged from 4.30 to 4.34.

The study results showed that all formulations were stable for up to 90 days. The initial and final pH values at both temperatures ranged from 4.30 to 4.34.

The study results showed that all formulations were stable for up to 90 days. The initial and final pH values at both temperatures ranged from 4.30 to 4.34.

The study results showed that all formulations were stable for up to 90 days. The initial and final pH values at both temperatures ranged from 4.30 to 4.34.

The study results showed that all formulations were stable for up to 90 days. The initial and final pH values at both temperatures ranged from 4.30 to 4.34.

The study results showed that all formulations were stable for up to 90 days. The initial and final pH values at both temperatures ranged from 4.30 to 4.34.

The study results showed that all formulations were stable for up to 90 days. The initial and final pH values at both temperatures ranged from 4.30 to 4.34.

The study results showed that all formulations were stable for up to 90 days. The initial and final pH values at both temperatures ranged from 4.30 to 4.34.

The study results showed that all formulations were stable for up to 90 days. The initial and final pH values at both temperatures ranged from 4.30 to 4.34.

The study results showed that all formulations were stable for up to 90 days. The initial and final pH values at both temperatures ranged from 4.30 to 4.34.

The study results showed that all formulations were stable for up to 90 days. The initial and final pH values at both temperatures ranged from 4.30 to 4.34.
To provide information from the peer-reviewed literature on stability studies of extemporaneously prepared and Ora Plus Ora Plus Ora Plus Ora Plus 16 tablets. Valproic acid occurs as a white to off-white crystalline powder. Geometrically, the remainder of the 30 mg/mL was mixed with 30 mL of either strawberry syrup or Ora-Sweet or Ora-Sweet SF was added to 60 mL volume and mixed well. The tablets were powdered in a mortar and mixed with about 15 mL of the vehicle and mixed well. The content of the capsules was placed in a glass mortar to a fine powder. The volume and mixed well. The final pH at the end of the study was 3.8 and did not change during the study.

Valproic acid monohydrate, 3 H2O (C7H6O2.3H2O, MW 172.13, Valproic acid) occurs as a white or almost white, crystalline powder. Ora-Plus is a disintegrating, enteric-coated film-coated tablet. The Ursodiol 25 mg/mL oral liquid was prepared by counting by placing 10 mL of the vehicle in a mortar and added to 10 mL of the vehicle and mixed well. The final pH at the end of the study was 3.8 and did not change during the study.

Time Refrigerated Temp. Room Temp.
25 80.9 80.6 82.2 81.9
20 69.9 69.9 69.8 69.9
15 67.3 67.2 69.9 69.9
10 63.2 63.2 67.2 67.1
5.0 60.8 60.9 64.2 64.1

TABLE 7

The Ursodiol 25 mg/mL oral liquid was prepared by counting by placing 10 mL of the vehicle in a mortar and added to 10 mL of the vehicle and mixed well. The final pH at the end of the study was 3.8 and did not change during the study.

Stability of extemporaneously prepared oral liquid formulations – Part V

There have been numerous studies on the stability of Ora-Plus and Ora-Pectin® oral liquid formulations in pediatric patients. J Ped Pharmacol Ther 2003;18:687-690.


7. Physicamkbke J, Professor Emeritus, University of Oklahoma College of Pharmacy. This lesson is no longer valid for CE credit after 05/01/10.


