Testing commercially available folic acid capsules

Several reports in the literature have explained the health risks of insufficient folic acid in our diet. Supplementation with folic acid products is necessary for many people. The purpose of this study was to determine whether commercially available nonprescription folic acid capsules meet USP standards and whether the products differ.

We compared three formulations of folic acid capsules on the basis of weight variation, dissolution, disintegration, and content uniformity. Three bottles of each folic acid formulation were purchased from a local supermarket in North Carolina. According to the labels, each capsule contained 800 µg of folic acid.

Twenty capsules were randomly selected from each of the nine bottles to determine weight variation; each capsule was weighed individually.

Six capsules were randomly chosen from each of the nine bottles, and the time for each group of capsules to disintegrate completely was recorded.

For the tests of content uniformity and dissolution, we used the USP high-performance liquid chromatographic (HPLC) method for analyzing folic acid, with minor modifications. Samples were compared with a standard solution of folic acid (25 mg of folic acid dissolved in a sufficient volume of 1 N sodium hydroxide to make 250 mL of solution). Ten capsules were selected from each bottle to determine content uniformity. The dissolution test involved a six-spindle dissolution tester, 500 mL of 1 N sodium hydroxide, a USP grade mannitol, HPLC-grade monobasic potassium phosphate, potassium hydroxide, and 85% phosphoric acid. Fisher Scientific, Fair Lawn, NJ, lots A552-4, P286-1, 864497, and A242-4, respectively.

Folic Acid Powder, USP, Professional Compounding Centers of America, Inc., Houston, TX, lot 51180.

Vanderkamp 600, Van-Kel Industries Inc., Cary, NC.


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<table>
<thead>
<tr>
<th>Brand and Bottle</th>
<th>Time to Complete Disintegration (min/sec)</th>
<th>Mean ± S.D. Folic Acid Content per Capsule (µg)</th>
<th>Mean ± S.D. Dissolution of Folic Acid in 1 hr (µg)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Brand A</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>1.55</td>
<td>835.2 ± 160.8</td>
<td>743.3 ± 29.8</td>
</tr>
<tr>
<td>2</td>
<td>1.45</td>
<td>801.7 ± 54.0</td>
<td>733.0 ± 26.9</td>
</tr>
<tr>
<td>3</td>
<td>1.40</td>
<td>717.5 ± 71.5</td>
<td>612.7 ± 21.2</td>
</tr>
<tr>
<td><strong>Brand B</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>2.50</td>
<td>721.0 ± 61.7</td>
<td>593.3 ± 43.1</td>
</tr>
<tr>
<td>2</td>
<td>3.20</td>
<td>729.8 ± 81.0</td>
<td>701.0 ± 7.9</td>
</tr>
<tr>
<td>3</td>
<td>3.05</td>
<td>705.7 ± 72.6</td>
<td>711.0 ± 20.3</td>
</tr>
<tr>
<td><strong>Brand C</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>3.05</td>
<td>809.5 ± 35.9</td>
<td>316.0 ± 415.7</td>
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<tr>
<td>2</td>
<td>3.15</td>
<td>682.6 ± 97.1</td>
<td>179.9 ± 249.0</td>
</tr>
<tr>
<td>3</td>
<td>3.20</td>
<td>719.9 ± 151.6</td>
<td>567.3 ± 301.2</td>
</tr>
</tbody>
</table>

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hours after application of nicotine patches.4

We contacted the manufacturers of clonidine, fentanyl, nitroglycerin, and nicotine transdermal patches to determine the necessity of protecting their patches during a shower. All stated that their patches can be worn uncovered in the shower. None of the manufacturers has performed a study evaluating the effect of covering a transdermal patch with an occlusive dressing.5

Boehringer Ingelheim. Personal communication [name not recorded]. 1997 Nov 26.


5. Mettler AJ. 100 balance. Mettler-Toledo AG, Greifensee, Switzerland.

Zorbax C8 column, 10 µm, 4.6 mm × 25 cm, DuPont Instruments, Wilmington, DE; sodium perchlorate, Sigma, St. Louis, MO; lot 7/715795; HPLC-grade methanol, HPLC-grade monobasic potassium phosphate, potassium hydroxide, and 85% phosphoric acid. Fisher Scientific, Fair Lawn, NJ, lots A552-4, P286-1, 864497, and A242-4, respectively.

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