Rupture Test and Bioavailability of Oil-Soluble Vitamins

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Abstract
In lieu of an abstract, here is the article's first paragraph:

Bioavailability of multi-vitamins as dietary supplements has always been a concern. Dissolution studies have been successfully used to predict drug release of bioactive molecules, but with vitamins there are some exceptions. United State Pharmacopoeia (USP) defines the dissolution requirements of multi-vitamin supplements based on the composition and type of dosage form. As oil-soluble vitamins do not meet the criterion of “dissolution”, the performance of dosage forms containing such vitamins is evaluated by disintegration studies primarily. Dissolution studies are not applicable for such dosage forms [1].

Disciplines
Pharmacy and Pharmaceutical Sciences

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Rupture Test and Bioavailability of Oil-Soluble Vitamins

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Bioavailability of multi-vitamins as dietary supplements has always been a concern. Dissolution studies have been successfully used to predict drug release of bioactive molecules, but with vitamins there are some exceptions. United State Pharmacopoeia (USP) defines the dissolution requirements of multi-vitamin supplements based on the composition and type of dosage form. As oil-soluble vitamins do not meet the criterion of “dissolution”, the performance of dosage forms containing such vitamins is evaluated by disintegration studies primarily. Dissolution studies are not applicable for such dosage forms [1].

United States Pharmacopoeia (USP) general chapter <701> describes the disintegration method for evaluation of oral dosage forms, while USP general chapter <2040> is regarding disintegration and dissolution of dietary supplements only. USP chapter <2040> was first published in USP 30-NF 25 in 2007 [2] and since then it has been incorporated in several monographs to evaluate dosage forms used as dietary supplements. USP chapter <2040> introduced “rupture test” as an alternative for evaluation of soft shell capsules. Rupture test involves use of dissolution apparatus 2 (described in USP chapter <711>), water as a medium and the paddles operating at 50 rpm. A soft shell capsule is dropped in the dissolution vessel containing 500 mL of water (sinkers are used if required) and paddles are rotated at 50 rpm. Capsules are observed and the time taken for the capsule shell to rupture is recorded. Capsules pass the test if six of them rupture in not more than (NMT) 15 minutes, if 1 or 2 capsules rupture more than 15 but NMT 30 minutes; test is repeated with additional 12 capsules. Out of these 18 capsules, only 2 are allowed to rupture more than 15 minutes but should rupture within 30 minutes. If all the above requirements are not met, test can be repeated with pepsin (750,000 units or less per 1000 mL) added to the test medium [1]. It should be noted that the test method does not account for the ideal pH (1.5) required for optimal pepsin activity and a revision should be requested in this regard to chapter <2040> rupture test.

There have been attempts to compare rupture test (chapter <2040>) with the disintegration test (chapter <701>). There are significant differences between these two tests which need to be studied. Table 1 highlights the differences between the two test methods.

<table>
<thead>
<tr>
<th>Difference</th>
<th>Chapter &lt;701&gt;</th>
<th>Chapter &lt;2040&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apparatus</td>
<td>Six cell basket rack assembly</td>
<td>Dissolution apparatus 2</td>
</tr>
<tr>
<td>Volume of test medium</td>
<td>1000 mL</td>
<td>500 mL</td>
</tr>
<tr>
<td>Hydrodynamics</td>
<td>Up/down strokes</td>
<td>Rotary paddle</td>
</tr>
<tr>
<td>Duration</td>
<td>NMT 45 minutes</td>
<td>NMT 15 minutes</td>
</tr>
<tr>
<td>End point</td>
<td>No palpable firm core</td>
<td>Rupture of capsule shell</td>
</tr>
</tbody>
</table>

Table 1: Differences between disintegration test (USP chapter <701>) and rupture test (USP chapter <2040>).

Currently, USP is collecting more supporting data from different sources to address the concerns of nutraceutical/pharmaceutical companies regarding the use of chapter <2040>. Further scientific data using rupture test will ensure appropriate revisions for the test method and will assist in evaluation of various soft shell capsules containing oil-soluble vitamins.

References

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