



Ingredients & Brittleness

Identifying Ingredients That May Cause Brittleness in Gelatin Capsules.

A) Test Objective

We recommend conducting stability tests as specified in US/EU Pharmacopoeia for all new formulations you plan to fill in capsules. We are providing this test method for identifying individual ingredients that may cause brittleness and not as a substitute for stability studies before putting your product on the market.

B) Context

Gelatin capsules may start showing signs of brittleness when the moisture content of the capsules shell falls below 12%. Typically, brittleness is observed as the capsule cracks when it is pressed between thumb and forefinger or it is found cracked when the plastic^a storage container that it is packed in, is opened. Gelatin capsules are shipped with a moisture content for 14-16%.

If you are finding brittleness with your formulation in gelatin capsules that are packed in a plastic storage container, this procedure may help you identify if one or more of the ingredients you are filling in the capsules may be the cause.

C) Test Method

Fill the following in ten capsules of the same color shade as the capsule you plan to use for your commercial product.

- a) formula you plan to fill
 - b) each individual ingredient
 - c) an inert excipient e.g., lactose monohydrate, microcrystalline cellulose, talc, starch
- If you have ten ingredients this will mean you will be filling a total of 12 x 10 capsules ^b.

You can use a smaller capsule than the one you plan to use for your commercial product.

Place each lot of ten capsules in its own opaque plastic bottle with an airtight lid. Do not add anything else in the plastic bottle. For example, do not add a desiccant pack. Place all the bottles in an area between 15-25 °C (60-80 °F) and 40-60% RH for one month.

After one month open each bottle and press each capsule between your thumb and forefinger.

# of Capsules Cracking	Comment
0	Not likely to be a cause of brittleness
1-2	May be a cause of brittleness
3 or more	Likely to be a cause of brittleness.

There should be no brittleness observed in the capsules filled with excipient. If there is any brittleness, study should be repeated.

Remember that this test is with the individual ingredient at 100% concentration. It is to identify ingredients that may be causing brittleness.

Please let us know the ingredients, the results and the capsule size and color. We will review the result with formulation experts we know on a confidential basis.

D) Additional Notes

This information is provided without any warranty and is not to be interpreted as warranting the use of our gelatin capsules.

^a Always protect capsules from moisture loss or gain by using at least one layer of plastic packaging e.g. bag greater than 0.075 mm (75 microns) in thickness.

^b To reduce the number of samples to be tested you can make a blend of more than one ingredient. Please remember that if a capsule with a blend of ingredients shows brittleness, then you will have to conduct another test with each ingredient individually to identify the specific ingredient that may be causing brittleness.

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