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PHARMACY PRODUCTS
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Seven Steps to Success in Capsules

Empty Hard Gelatin Capsules are shipped with a moisture content between 13-15%. It is important that this moisture content is maintained and exposure to high temperatures or cycling between high/low temperatures is avoided.

When capsules are empty (unfilled) they are most susceptible to damage as the capsule walls are unsupported and there is a tremendous volume of air contained inside the capsule that can extract or release moisture from the capsule walls. Once the capsule is filled the walls are supported and the air inside the capsule is essentially eliminated. Thus, the sensitivity of capsules to environmental conditions is reduced.

The major cause of customer with capsules is improper conditions during storage and filling or inadequate final packaging. Spectrum is ready to assist you in handling and packaging capsules. Please contact us.

1. Packaging Of Empty Capsules:

To protect empty hard gelatin capsules from exposure to large variations in the surrounding relative humidity, they are packed in food grade anti-static plastic bags inside heavy-duty corrugated cartons.

2. Transportation of Empty Capsules:

On the rare occasion that you ship empty capsules, care must be taken during transportation to ensure no damage to capsules.

1. Do not leave shipments on a loading dock or in a truck.
2. Ensure your customs is aware that capsules are heat sensitive and that they are handled properly immediately upon arrival.

3. Inspection of Capsules on Receipt:

Inspect your shipment on arrival. The following are examples of heat damage during transportation:

- Capsules are smaller in size (average length less than lower tolerance limit) or vary in size.
- Capsules are stuck together in lumps and do not come apart.
- Capsules are brittle or shatter very easily during handling or filling.
- Capsules are severely distorted in shape.
- Capsule cap is stuck to body and resists separation.

Contact Spectrum immediately if you observe the above. Please note the batch and box number on the outer case and, if available, purchase order number and date of receipt.

4. Warehousing/Storage

If the proper storage conditions are observed, empty hard gelatin capsules may be stored for several years.

Storage conditions are given in the table below:

Condition	Min.	Ideal	Max
Relative Humidity	40%	50%	60%
Temperature	15°C	20°C	25°C
	60°F	68°F	75°F

- Store capsules away from direct sunlight (e.g. windows and skylights) as it can raise the surface temperature of a carton to 150°F.
- Store capsules away from hot water/air radiators, hot water pipes and steam pipes.
- Store capsules on pallets off the ground.
- Store capsules away from potential sources of water condensation e.g. under water pipes.
- Do not store empty capsules in freezers.

4. Warehousing/Storage (continued)

The effect of prolonged storage (over a few days) in areas outside the recommended conditions may cause the damage indicated in the table below:

Damage to Capsule	Probable Cause	Capsule Moisture
Softening and loss of shape.	Storage high RH	Increased
Difficult to separate lump of capsules; visible condensation on surface of bag; some capsules reduced in size.	High temperature or temperature cycling during storage	Decreased
Capsules shatter when pressure applied; all capsules slightly reduced in size.	Storage at low RH	Decreased At

At time of print, The following equipment is available for monitoring temperature and humidity. It is available from from Cole Parmer (Tel. 800 323 4340 or www.coleparmer.com).
• Temperature/Humidity Digital Indicator (Cole Parmer Model EW-37100-05), $60.
• Temperature/Humidity Chart Recorder (Cole-Parmer Model EW-80001-70, $450.

5. Capsule Filling:

Optimum filling conditions are between 20-25oC (68-75oF) and 45-55% Relative Humidity to maintain the 13-15% moisture content of capsules.

Filling Problem	Environmental Cause	Solution
Capsules soft or sticky; denting during locking	High temp or RH or both	Air Condition & De-Humidify
Capsules cling to each other or plastic surfaces due to static electricity	RH below 40%	Humidify
Capsule crack or shatter when pressure applied	RH below 40%	Humidify

To reduce the temperature or RH, use an air conditioner or dehumidifier (residential or commercial). You may need to use a dehumidifier in addition to an air conditioner depending on the amount of moisture removal required to reduce the RH.
To increase RH, we recommend using a humidifier (e.g. a residential room humidifier). See our Winter Bulletin for more information on the effect of low RH and solutions.
Capsules can be used outside these conditions but within the normal storage conditions. Keep only the minimum level of stock open to the atmosphere (one bag) and for a maximum of 1-2 hours.
• Keep empty and filled capsules covered when not being filled to minimize moisture loss.
• Seal or tie bags containing empty capsules during shift breaks or at the end of shifts.
• Store filled capsules in plastic drums with lids until they are packed in final container.

6. Packaging of Filled Capsules

• Always protect capsules from moisture loss or gain by using **at least one layer of plastic packaging** e.g. bag, bottle, blister pack, etc.
• Do not use desiccants or other moisture absorbers as these absorb moisture from the capsule shell leading to brittleness.
• Eliminate unnecessary headspace in the package. However, avoid the use of excess cotton and do not use cotton treated with furfural (interacts with the gelatin shell).
• If you pack in bottles and have reports of capsule breakage, add a sheet of corrugated cardboard between the bottle and the bottom of the outer carton to act as a cushion.

7. Shipping of Filled Capsules

United Parcel Service will conduct an evaluation of your package for a fee. Test results are not used to accept or refuse packages. The package you give UPS will be subjected to vibration and drop tests. Additionally, the outer cardboard container will be evaluated for bursting strength.
Information courtesy of Torpac®, Fairfield, NJ 07004