Preventing Brittleness in Capsules, from Cradle to Consumer

By Steve Lee, Contributing Editor

Often, the first person to notice a cracked and broken capsule is the consumer—obviously the worst-case scenario for any quality manufacturer. If the consumer tastes leaking product, the negative impression left may be long lasting. This begs the questions: Why wasn't this observed during manufacturing process or quality checks? And where did the capsule lose moisture along the way?

When manufacturers hear of brittleness in two-piece capsules, their general inquiries turn to capsule storage conditions or empty capsule manufacturing. While these are both critical players in the stability of capsule shells, many other factors play a role and may cause problems. Manufacturers need to understand how to prevent brittleness from the cradle of the supply chain to the consumer purchase point.

Maintaining optimal moisture in capsule shells is key to preventing brittle capsules. Shell moisture must be maintained above 13 percent in two-piece gelatin capsules to prevent breakage. For some hypromellose ("veggie") capsules, especially those that meet USP dissolution requirements, brittleness can occur when moisture falls below 4 percent. Loss of moisture can combine with other physical factors, such as filling pressures and impact points.

Following are areas along the supply chain where capsules commonly become brittle and crack:

Warehousing & Transportation

Storing capsules in areas that are too hot or cold will affect the moisture level of the capsules. In all storage areas, make sure capsules are kept within the recommended temperature range listed on the capsule cartons. If the humidity in the warehouse area cannot be controlled, make certain temperature ranges are adhered to. The capsule bag liner will provide some protection against low humidity until the capsule bag has been opened; optimum humidity is very important in the capsule filling room. In warehousing, remember rising heat is trapped near the ceiling levels; as such, it is best to keep capsules away from high rack locations. Hot spots are also found near ceiling lights and HVAC vents. Capsule cartons wrapped in excessive plastic and kept in hot or humid locations can cause a greenhouse effect, trapping heat and moisture around capsules. When transporting either empty or filled capsules, treat them as if they were chocolate, being careful to maintain ideal conditions.

Formulations

Some formulations are hygroscopic, meaning they pull moisture from their environment. A gelatin capsule contains more moisture than hypromellose, and tends to lose moisture more quickly. For hygroscopic formulas, a hypromellose capsule is generally a safer bet. Also, for moisture-pulling formulas, consider avoiding the use of colored capsules with high levels of titanium dioxide (the ingredient that makes capsules opaque), as by their nature, opaque capsules are more brittle. In formulating empty capsules, sodium lauryl sulfate (SLS) is commonly used as an emulsifying agent and surfactant. SLS is like the soap that allows grease and water to occupy the same space; hence,

SLS-free capsules are prone to having thin spots, where cracking occurs most frequently in the shoulder area of the capsule. For hygroscopic formulas, hypromellose may best suit the application.

Capsule Filling

Conditions in the filling room are paramount in terms of both humidity and temperature. During cold winter months, heating systems dry out the facility air to the point where it is commonly recorded at 15 to 20 percent relative humidity. Capsules openly exposed to such dry air will lose moisture in a matter of minutes, becoming brittle. During these times, portable industrial humidifiers can be used to maintain relative humidity at an optimal range of 45 to 50 percent. Using re-sealable bag ties for opened capsule cartons will make it easier for operators to protect capsules while in the encapsulation room. On the filling machine, use only the required amount of vacuum necessary to separate empty capsules, especially when using opaque (colored) capsules. Excessive vacuum can cause pin-hole fracturing in the body dome. In capsule closing, use of a Go/No-Go gauge can prevent cracking caused by over-closing a filled capsule.

Packaging

During packaging, several heat and impact sources can contribute to capsule breakage, usually after significant moisture loss has occurred due to storage, formulation or other processing. Common heat sources include blister equipment and heat tunnels. Brittle capsules may crack when they are dumped from bulk containers into capsule counters, or when used with aggressive brush boxes. To avoid capsule cracking in the packaging area, use care in handling. Design material transfer processes that minimize impact and avoid excessive weight load in bulk hoppers. Avoid extended exposure to heat, especially where capsules may sit on hot equipment such as a thermo-former. Also, be aware that capsules packaged with desiccants (which are designed to absorb moisture) can cause brittleness in finished goods inventory and on store shelves.

High-quality capsules will withstand the rigors of many manufacturing and formulation challenges. For those exceptions, implementing the practices described above will ensure the finished capsules arrive at the customer ready to leave the best possible impression.

Steve Lee is the technical service manager with ***CapsCanada® Corp****.*