This article describes common problems encountered during capsule filling and provides troubleshooting tips for solving them.

Two-piece hard-shell capsules are an attractive and versatile solid oral dosage delivery system that can be used with powder, granule, minitablet, liquid, and semi-solid formulations. Modern hard capsules are designed to work with fully automated capsule filling machines at fill rates of 200,000 or more capsules per hour. Achieving maximum speed, efficiency, and throughput during capsule filling requires care and planning, from the receipt of the empty capsules to final packaging.
Many technicians, operators, and process engineers know their capsule filling equipment inside and out, but problems occasionally arise that may require outside assistance. This article describes some common capsule filling problems, along with the corresponding corrective actions. While not all-inclusive, the issues covered here are the most prevalent problems our technical services teams are asked to address in the field. For this article, I'll assume that the formulation is compatible with the capsule, the capsule size is correct for the fill amount, the dosing-disk thickness is correct, and the formulation forms a suitable slug, depending on the capsule-filler type.

**Capsule shipping, handling, and storage**

Be sure to follow the capsule supplier’s recommended shipping, handling, and storage conditions. Capsules may deform if exposed to high temperatures during shipping. Additionally, be sure to follow the supplier’s guidelines when resealing cartons opened for inspection and sampling. Resealing the liner keeps the moisture barrier intact and prolongs the capsules’ integrity. Once the capsule packaging is opened, limiting the amount of time the empty capsules spend in the open environment prior to filling is essential. Suppliers should provide recommended processing room conditions for the capsules they supply.

It is important to note that the recommended storage and handling conditions may differ between capsule suppliers and between capsules made from gelatin and those made from hydroxypropyl methylcellulose (HPMC). Gelatin capsules stored in low-humidity environments may lose moisture and become brittle. HPMC capsules, which have a lower moisture content than gelatin capsules, can absorb moisture if not held at the proper conditions during processing. Temperature excursions during transport, storage, and handling can lead to problems with both capsule separation and closing.

**Loose pieces**

A two-piece hard-shell capsule consists of a cap section and a body section, as shown in Figure 1. When the...
capsule is fully closed after filling, a lock ring on each section engages to prevent the capsule from opening prior to patient use. Suppliers ship empty capsules in a pre-locked configuration, which joins the capsule cap and body but does not close the capsule to the point of engaging the lock ring. Prior to filling, separated caps and bodies are commonly referred to as loose pieces. Loose pieces may occur when using a pneumatic conveying system to transfer the capsules from the carton to the capsule filler.

If you’re finding loose pieces in the capsule filler’s hopper, the first troubleshooting step is to note the condition of the capsules in the original carton. If the capsules in the carton are intact, then the pneumatic conveying system is likely the cause. To minimize capsule separation during transfer, ensure that the system is operating at an appropriate air pressure or vacuum and that the conveying run is free of sharp turns.

**Failure to separate**

From the hopper, the empty capsules are fed into capsule filler and rectified to orient the caps and bodies correctly. Then, the caps and bodies are separated by vacuum into the corresponding cap and body segment bores, as shown in Figure 2. If the vacuum is insufficient or the segments are dirty, the caps and bodies may fail to separate. Depending on the equipment design, reduced vacuum at the point of separation may be the result of dirty or clogged filters, leaks in the vacuum lines, or worn bushings. Dirty segments from sticky formulations may cause the capsules to bind in the segment bores.

**Dents, dimples, and punched ends**

Dents, dimples, or punched ends on the capsule caps and bodies tend to be caused by overfilling the capsules. Overfilling occurs when the fill height exceeds the cut edge of the capsule body. You can correct this issue by raising the tamping pin height, selecting the correct dosing disk, lowering the formulation level in the bowl, or slowing the machine speed. If the fill is correct, then the operator should confirm that the segments are correctly aligned and clean. Misaligned or dirty segments may cause the cap and body to bind in the closing station, which can result in the closing pins exerting too much pressure on the capsule ends and damaging the capsules. Closing pins that are misaligned with the segment bores may cause crescent moon-shaped dents on the ends of the capsules.

**Splits, telescoping, and tucks**

Splits can be caused by capsule defects such as a small cap edge, which is a minor edge deformity on the cut line of the cap, that splits during closing; the cap wall thickness being too thin; or the capsules being brittle. Splits can also occur if the capsule is overfilled with formulation prior to closing; if the capsule is overclosed due to an incorrect closing pin height setting; or if powder or granules from the fill become lodged between the cap and body during closing, which creates excess pressure on the capsule wall.

Telescoping can occur when the capsule body is improperly seated or misaligned during closing, causing one of the edges to slice or cut through the other capsule half. Telescoping can be caused by rough or unevenly cut capsule edges; coarse, fibrous, or abrasive formulations; overfilling; or worn segments/biores.

Tucks (also known as folded edges) can occur when the capsule cap and body edges collide during closing, causing one or both edges to fold inward.

**Separation after filling**

Filled capsules coming apart in the capsule polisher typically results from the capsules not being closed properly or the locking mechanism not being fully engaged. Capsule suppliers provide specifications for a capsule’s closed-joined length to assist with verifying the capsule’s proper lock position. Some suppliers offer go/no-go gauges to provide operators with a quick way to visually verify whether the capsules are in a pre-locked or locked position.

**Supplier resources and expertise**

Capsule suppliers have a vested interest in ensuring their capsules run well on different makes and models of capsule filling equipment and with a variety of different fill materials. A capsule supplier should be able to provide detailed technical documents addressing critical capsule attributes, such as dimensions, target weight, and
capacity, along with recommendations for storage and handling to help achieve the best performance during filling operations.

Some capsule and filling machine suppliers have in-house technical services groups to assist with troubleshooting, process optimization, proactive training, and on-site support during capsule filling trials. Be sure to take advantage of these resources to increase throughput, reduce capsule rejects, and ultimately increase the profitability of your next capsule run.

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**Photo 4:** A go/no-go gauge allows operators to quickly verify whether a capsule is in a pre-locked or locked position.