Some people swear by wet granulation in high-shear mixers. Others prefer to spray-dry liquid suspensions into granules. But the most straightforward granulation method uses a roller compactor and no liquids. This article summarizes roller compaction and cites its advantages.

Indeed, wet-granulating in a high-shear mixer and tray-drying the mixture in an oven are fraught with problems. Among them: defining the endpoint in the mixer, patchy drying in the oven, and difficulty cleaning the equipment. In fact, it was because of these problems—I’ve been the victim of too many wet-granulation failures—that I first began exploring roller compaction. Some of my failures stemmed from insufficient or variable drying due to changes in atmospheric humidity between seasons. Others stemmed from the difficulty of determining and
validating the granulation endpoint, a task that is especially difficult today given the global nature of the industry. Today, raw materials can come from many different sites, which can lead to slight variations in particle morphology. Those variations, in turn, can alter the process.

But even when a wet granulation process runs properly, the mixer is often covered with a sticky goo, and the oven is very difficult to clean to an acceptable industry standard of no more than 10 parts per million of carry-over. Plus, all that cleaning takes time. If you have many products to densify, consider dry granulation by roller compaction.

And dry it is: Roller compaction uses no water. As a result, there is no possibility of water-induced degradation and no need for drying. That reduces the energy the process requires and eliminates the expense of piping in water. Plus, cleanup is easier, especially since most roller compactors disassemble into easy-to-handle components that you can place into a washing machine. Table 1 lists some advantages and disadvantages of roller compaction compared to wet granulation. Roller compaction also has advantages over tabletting powder blends:

- Uniformity of material (bulk density, particle hardness, porosity, and particle size range)
- Minimal fines and dust
- Better flow properties
- Faster tabletting with less weight variation
- Faster tablet dissolution and better disintegration
- Minimal or no explosion-proofing measures required.

### How it works

Roller compactors use counter-rotating rollers to densify dry powder—usually a blend of powders—into sticks or sheets. In operation, the blended powder is fed from an intermediate bulk container (IBC) into the roller compactor’s hopper. As the material flows from the hopper, a variable-speed screw forces it between the two rollers (Figure 1). One roller is usually fixed, while the other moves, enabling an operator or PLC to maintain the size of the gap between them and to apply the desired force. By maintaining a uniform gap and uniform force, the compacts themselves are uniform.

Upon discharge, the compacts pass through a built-in comminutor or they are collected and subsequently milled. Because the API and excipients are locked into the matrix of the granules, there is little risk of segregation during tabletting or capsule filling. So long as fines are not excessive, the granulation preserves the desired ratio of API-to-excipients.

### Roller design and configuration

The shape of the compacts—be they sheets, sticks, briquettes, or wafers—depends on the surface profile of the rollers (photo, page 26). The rollers themselves are arranged horizontally, vertically, or at an angle (Figure 2). As the powder enters the slip region—so named because of the sliding motion observed between the rollers—it is deaerated before it is forced into the gap between the rollers. This area is known as the nip region, and is typically offset 60 degrees from horizontal. See Figure 3.

The size, speed, and design of the rollers determine how much powder they pull into the gap. Smooth rollers exert a great deal of force but minimize throughput.
Axially grooved rollers pull large amounts of powder through, but if the powder is not cohesive enough, a weak compact may result. Knurled rollers are the best default option. Their grooves pull in the material, while their smooth sections exert great force. The result is an evenly compacted material across the entire surface of the wafer.

Some materials, such as potassium chloride, need high pressure, while others, such as penicillin and amoxicillin, require low pressure to avoid discoloration. (Adding sugar to penicillin prevents it from over-compacting and turning yellow.) In fact, sticky powders and those with a low melting point are difficult to process and may require dilution in a suitable excipient, as discussed below. But the vast majority of dry powders can be economically and consistently dry-granulated. Bonding mechanisms include particle rearrangement, deformation, fragmentation, van der Waals’ forces, valence forces, partial melting and solidification, and interlocking granules. Simply stated, dry granulation is agglomeration by the removal of interstitial air between particles. All compacts, however, undergo elastic recovery (expansion) after discharge. How much they expand is a function of the physical characteristics of the materials, the roller diameters, and the speed at which they turn. Basic trial and error will help you identify the set points.

Processing aids

If a powder isn’t compressible, it can be made to compress by adding binders, such as microcrystalline cellulose (MCC), methyl cellulose, and hydroxypropyl cellulose (HPC). Sometimes, fillers—lactose and/or starches—are added either before or after compaction to aid compression. Glidants—starches, modified starches, and colloidal silicon dioxide—may be added to improve the flow properties of uncompacted blends.

In most cases, disintegrants (starches and modified starches) and super-disintegrants (croscarmelose sodium and crosspovidone) are added twice: before and after compaction. Added before compaction, they speed disintegration and dissolution. Added after compaction, they surround the granules and promote disintegration of the final dosage when wetted.

Lubricants—usually magnesium stearate or another metallic stearate—are also added in two parts. Before compaction, they’re essential to prevent the blend from sticking to the rollers. But be careful not to overdo it. Over-lubrication can lead to soft compacts and retard dissolution, since metallic stearates are hydrophobic. The second portion is added to the final granulation so it doesn’t stick to the punch tips or dies walls of the tablet press. Table 2 lists some effects of overly soft and hard granules.
And yes, despite what you may have heard, it is indeed possible to include colors. You may have to extend the color on a fine excipient (i.e., starch), but I've succeeded in making yellow, pink, orange, blue, and green tablets from dry-granulated formulas. I simply added a pre-milled dye-starch mixture. None of the tablets was mottled or spotty from adding the dry dyes. (I prefer lakes.)

**Selecting a roll compactor**

Experience has led me to prefer certain types of roller compactors over others, but test the different machines for yourself. You'll soon learn which setup is best for your product(s) and processes. Each design has its pros and cons, but look for equipment with these features:

- Rollers that remove rapidly, enabling you to change and clean them quickly;
- A PLC that adjusts the operation to ensure consistent powder flow and compacts of consistent density;
- A variable-speed milling-screening device, preferably with a PLC, that is either integral to the compactor or within close proximity; and
- Seals that keep the powder in the nip area. Evaluate the designs, which differ from manufacturer to manufacturer. They will also differ according to the type of rollers you select: die-and-punch (DP) rollers or flat rollers. With DP rollers, one roller nests within the raised walls of its counterpart. See Figure 3 and the photo on page 28, which shows the seal used on a Freund-Vector roller compactor equipped with DP rollers.

**Conclusion**

In my experience, changing from wet granulation—which entails the possibility of water degradation—was met favorably by regulatory authorities for immediate-release products. In the dietary-supplement industry, anyone with compression problems should investigate roller compaction. It certainly suits herbal products better than wet granulation, which degrades them and unleashes unpleasant odors. 

*Vic Shulman is president of Darvic Consulting, Thornhill, Ontario, Canada. Tel. 905 731 9396. E-mail: darvic@rogers.com. Shulman has been training operators in basic manufacturing principles since 1992. He acquired his knowledge of roller compactors the old-fashioned way: By running and cleaning the equipment.*

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**Table 2**

**Possible implications of overly soft and hard granules**

<table>
<thead>
<tr>
<th>Soft</th>
<th>Hard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soft, friable tablets</td>
<td>Picking and sticking</td>
</tr>
<tr>
<td></td>
<td>at the tablet press</td>
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<tr>
<td>Low tablet weights</td>
<td>High ejection forces</td>
</tr>
<tr>
<td>Excess fines, leading to API segregation and poor flow</td>
<td>Excessive abrasive wear of punches and dies</td>
</tr>
</tbody>
</table>