tablet coating

Tablet coating basics

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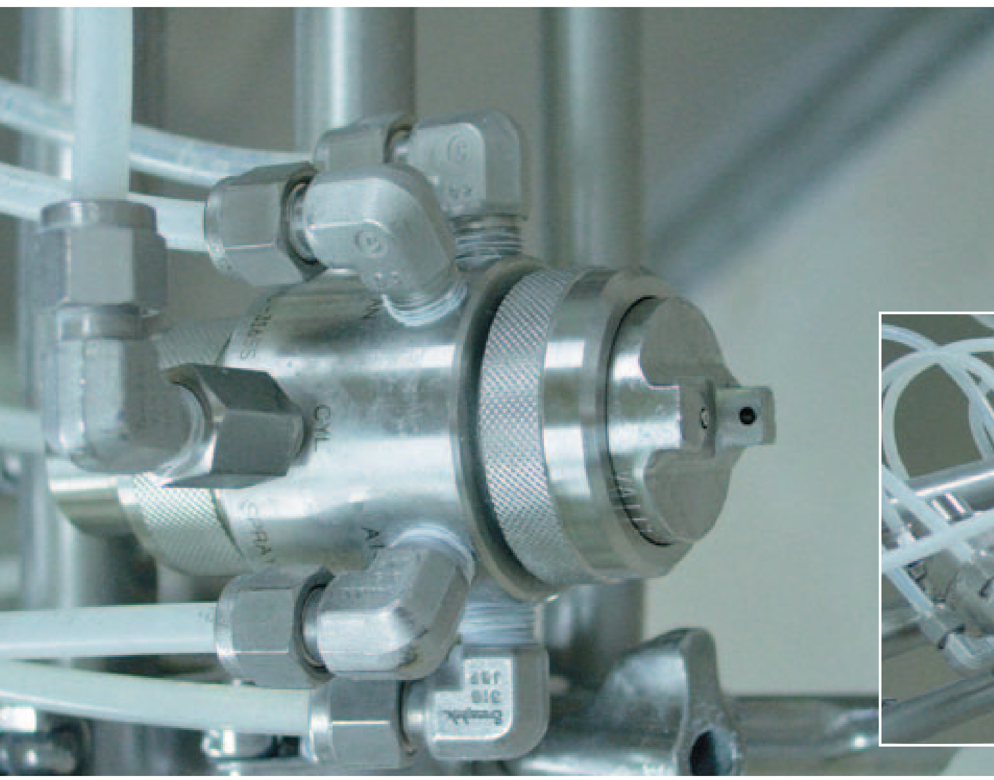


After making a good tablet, you must often coat it. The coating can have several functions. It can strengthen the tablet, control its release, improve its taste, color it, make it easier to handle and package, and protect it from moisture. This article reviews the basics of tablet coating and describes common tablet coating defects.

There are many ways to coat tablets. Sugar coating was one of the earliest methods, and the process is still widely used in the confectionery industry. Wurster coating is another means. It employs a cylindrical chamber in which tablets are suspended by air and a coating solution is introduced into the air stream. Fluid-bed coating is a similar process. Dry coating is the technique of making a tablet within a tablet. But the principle means of applying a coating to pharmaceutical and nutraceutical tablets is called film coating, and it is the focus of this article.

Coating solutions

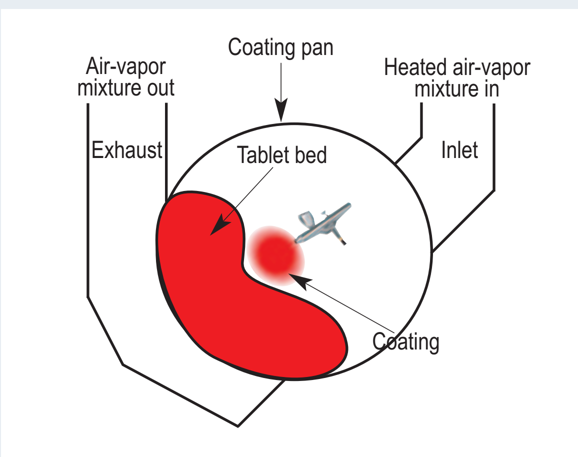
Film coatings are a mixture of solids and liquids. For many years, the liquid component of coatings was a volatile solvent, such as alcohol or other quick-drying substances like methylene chloride. While solvent-based coatings performed well in many respects, they presented problems in handling, operator safety, recovery, and odor. They could even make the finished tablets smell like solvent, which is not a desirable side effect. Solvent-based coatings are still used in some applications, but water-based, or aqueous, coatings have largely replaced them. As a result, coating has become much more challenging, because water-based coatings are much less forgiving. You must apply the coating and remove the water before it can jeopardize the integrity of the tablet.

Coating equipment

A modern tablet coating system combines several components: a coating pan, a spraying system, an air-handling unit, a dust collector, and the controls. The coating pan is actually a perforated drum that rotates within a cabinet. See Figure 1. The cabinet enables you to control airflow, air temperature, air pressure, and the coating application. The spraying system consists of several spray guns mounted on a manifold, a solution pump, a supply tank and mixer, and an air supply. The pump delivers the coating solution to the guns, where it combines with atomizing air to create a fine mist that is directed at the bed of tablets in the coating pan. The air handling unit heats and filters the air used to dry the coating on the tablets. Depending on your circumstances, it may include a humidifier or dehumidifier. The dust collector extracts air from the coating pan and keeps a slightly negative pressure within the cabinet. The controls enable you to orchestrate the operation of all the components to achieve the desired results.

FIGURE 1

A simple diagram of a tablet coating system



Coating in action

Once you load a batch of tablets into the coating pan, you need to preheat the tablets and allow time for dust and tablet flash to exit the pan. Once the temperature of the outlet air reaches 42° to 46°C, usually within 15 minutes, spraying can begin.

The spray guns create a fine mist of coating solution that dries just after it contacts the tablet. As the water evaporates, it leaves the solids behind to form a thin film on the tablet. The key to tablet coating is to get the surface slightly wet and immediately dry. Your objective is to apply the coating in many short, fast exposures, not in long, slow exposures.

I was taught the three D's of tablet coating: dose, distribute, and dry. Dose is the exposure to the solution. Distribute is the fast motion of the tablets rubbing against one another to transfer the solution. Dry is the removal of the liquid component. It might be helpful for you to think of film-coating tablets as spray-painting a bunch of golf balls. You can envision that it's best to spray them lightly and evenly so that successive light coatings lock together. That's how tablet coating works.

Once the base coating is applied, you can increase the rate of solution addition and the pan speed proportionately. Typically, it takes about 20 minutes before you can increase the spray rate and pan speed significantly. Soft tablets and tablets that are very porous may require an initial spray rate that is slower than the average of 100 milliliters per minute per gun. Be sure to monitor spraying to see whether the spray pattern changes. If it does, there is likely a buildup of solids on the gun tips. You can correct this only by cleaning the tips, which means stopping the spray and the pan. The images on page 20 show tablet coating spray nozzles being cleaned.

The film coating solution dries on the tablet surface because there is a constant supply of hot air entering the drum and passing through the drum's perforations into the bed of tablets. Over time, the film builds layer after layer of solids. How long it takes to form the final film varies from dozens of minutes to a few hours. It depends on tablet quality, the coating solution type (solvent-based coatings dry faster), the percentage of solids in the coating, and the rate of coating addition. Other important factors include the air volume, air temperature, and the air pressure within the coating cabinet. After you've finished applying the solution and drying it, the tablets must cool.

For coatings to adhere properly, the tablets must remain at a specific temperature, the solution must be applied at a consistent rate, and the motion of the tablets must be active yet tranquil. Disrupt any of these conditions, and you will often produce a defective tablet. For reproducible results, you have to eliminate or minimize every possible variable. That begins with tablet quality.

Tablet quality

My description of tablet coating presumes you are coating high-quality tablets that are tough enough to tumble as they're coated and dried. If tablet quality is consistent, the coating process is much easier. Consistency is typically not a problem for pharmaceutical manufacturers. It's more of an issue for makers of vitamins, herbals, and other dietary supplements, because they use many natural ingredients that vary in moisture content, bulk density, granule structure, flow characteristics, and compressibility. So naturally—pardon the pun—the quality of their tablets tends to vary. You can't coat a bad or marginal tablet and expect a good tablet when you're done.

First, the tablets must be consistent in porosity and hardness. They must also be free of dust. Furthermore, they must not break apart during the preheat cycle at the start of the coating process or during the first few minutes of exposure to the atomized solution.

Consistent hardness of the tablet surface enables the coating to "lock" into the surface. If the surface is too soft, the impingement of the solution can erode the tablet. Too hard a surface will not allow the solution to impinge and adhere, and the coating will peel away. Both of these coating defects can also occur by over- or under-applying the coating solution or by applying the coating with too much or too little force. A combination of these factors could also be at work. See the sidebar on defects on page 22 and the accompanying photos.

Tablet coating checklist

Since spraying, coating distribution, and drying take place at the same time, tablet coating is a dynamic, complex process that is affected by many variables. In no particular order, here are some of the parameters that you should check when evaluating your coating operation to determine the source of defective coated tablets.

Control. Many problems occur in coating when you can't control every important parameter, such as temperature, pan pressure, spray rates, and atomization pressure.

Coating defects

Here is a list of common defects associated with coated tablets and some likely causes.

This photo shows multiple defects. The initial problem was erosion of the tablet edge due to a soft or friable tablet or because the pan was turning too fast or both. Peeling and breakage also appear here.

Just one broken tablet can distribute particles to all the other tablets and mar their appearance. These tablets likely broke because they had poor hardness.

This photo shows a very porous tablet that prevented the coating from adhering to the surface. These tablets should have been coated longer, and the atomization pressure should have been reduced to decrease the slight orange peel, or textured, surface.

I attribute the peeling in this photo to excessive moisture within the tablet, which prevented the coating from adhering. However, the tablet coating also pulled the granulation out of the tablet, a picking defect. That is usually caused by over-wetting the tablet or by a tablet that is too soft.

Picking and sticking. This is when the coating removes a piece of the tablet from the core. It is caused by over-wetting the tablets, by under-drying, or by poor tablet quality.

Bridging. This occurs when the coating fills in the lettering or logo on the tablet and is typically caused by improper application of the solution, poor design of the tablet embossing, high coating viscosity, high percentage of solids in the solution, or improper atomization pressure.

Capping. This is when the tablet separates in laminar fashion. The problem stems from improper tablet compression, but it may not reveal itself until you start coating. How you operate the coating system, however, can exacerbate the problem. Be careful not to over-dry the tablets in the preheating stage. That can make the tablets brittle and promote capping.

Erosion. This can be the result of soft tablets, an over-wetted tablet surface, inadequate drying, or lack of tablet surface strength.

Twinning. This is the term for two tablets that stick together, and it's a common problem with capsule-shaped tablets. Assuming you don't wish to change the tablet shape, you can solve this problem by balancing the pan speed and spray rate. Try reducing the spray rate or increasing the pan speed. In some cases, it is necessary to modify the design of the tooling by very slightly changing the radius. The change is almost impossible to see, but it prevents the twinning problem.

Peeling and frosting. This is a defect where the coating peels away from the tablet surface in a sheet. Peeling indicates that the coating solution did not lock into the tablet surface. This could be due to a defect in the coating solution, over-wetting, or high moisture content in the tablet core.

Chipping. This is the result of high pan speed, a friable tablet core, or a coating solution that lacks a good plasticizer.

Mottled color. This can happen when the coating solution is improperly prepared, the actual spray rate differs from the target rate, the tablet cores are cold, or the drying rate is out of spec.

Orange peel. This refers to a coating texture that resembles the surface of an orange. It is usually the result of high atomization pressure in combination with spray rates that are too high.

T&C

Tablet quality. As discussed earlier, the tablets must have the proper porosity, surface, hardness, and moisture content. You can't have consistent coating without consistent tablet quality.

Waiting period. Most tablets cannot be coated immediately after they've been compressed. The energy within the tablets is still fairly high. In fact, they are still warm. In addition, tablet hardness changes over 24 to 48 hours. Let the tablets rest at least that long before you coat them.

Batch size. Variation in batch size changes the required pan speed, gun geometry, spray rates, and temperature. The more your batch sizes vary, the more quality issues that will arise in the coating process.

Solution preparation. Again, consistency is the name of the game. Does your company prepare coating solutions the same way, regardless of the batch, the shift, or the operator? Track the solution temperature, mixer speed, and storage time. All are important. Oh, and is the mixing blade correctly installed? Be sure by marking it "top" and "bottom."

Spray gun calibration. You should calibrate or check the calibration of the guns every time you change products. This means checking the gun's overall condition and its filter, nozzle alignment, and needle condition.

Gun geometry. Geometry refers to the gun-to-gun alignment, gun-to-tablet bed alignment, and distance from the gun to the end of the pan. Use a ruler to be sure the distances are consistent. Furthermore, make sure all the guns are pointed in exactly the same direction and are maintaining the same spray pattern. Make certain that the tubing and connections are tight and do not interfere with alignment, which is a common problem.

Gun nozzles. The spray gun nozzles must be kept clean and free of product buildup. Use a flashlight during coating to look into the cabinet and check the nozzles.

Pan loading. While loading the tablets, look for tablets that are broken, capped, chipped, or covered with black specks. Doing so will help you pinpoint the source of any defects that occur. Do the defects appear during loading, during initial pan rotation, or after preheating? A visual inspection is critical when coating tablets that are friable or that chip or break easily.

Cleaning. Make sure you've cleaned and dried each component of the spraying system before re-installing it after a product changeover.

In tablet coating, small changes in almost any parameter can lead to big differences in results. The more consistent you make operations, and the tablet, the less you must rely on the skill of the operator. Coating may be something of an art, but you'll get better results when you apply a little science to it. *T&C*

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