Tablet Coating Musts

A quick look at what you must know to be successful

By Mike Tousey, Techceuticals

When it comes to coating tablets there are musts that really count and then there are the other things.

The ability to coat tablets well is often considered more of an art than a science. Traditional coating uses a sugar solution that is applied one layer at a time through a process called the three D's; dose, distribute, and dry. Once at the proper temperature the tumbling cores are exposed to an initial dose of solution which is added by the use of a (soup) ladle, pumped, or a controlled spray nozzle. The solution is added in steps and after each addition the cores are continually tumbled to distribute the solution evenly while forced air is blown over the surface of the bed of cores to facilitate the drying process. This process of dose, distribute, and dry is done layer by layer until the required 50-100% weight gain achieves the desired buildup and appearance. Many companies made their own proprietary solution that was kept a closely guarded secret. The art was knowing when the cores were ready for the next layer. If solution was added too soon the cores would stick to each other pulling the coating off other cores. If the previous coating layer was over-dried then the next layer wouldn't adhere properly creating blemishes and rough surfaces, resulting in a defective coating. In the old days coating a tablet was an art, having a lot of touch and feel. Today coatings are demanding because they must do more than a sugar coat and taste mask. Nowadays most tablets are coated with a thin film, referred to as film coating. A typical film is either just a thin clear coating or a more controlled build up of color coating, most commonly a 3% build up of total tablet weight.

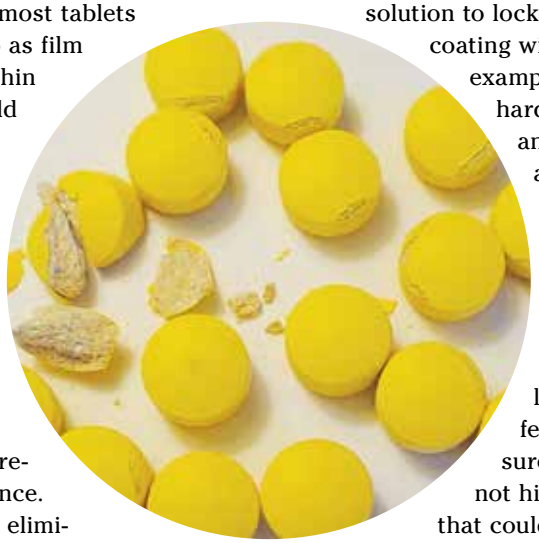
Film coatings provide much more than just being a sweet taste and a protective layer. From a manufacturing standpoint a film coating eliminates dust, makes the tablet tougher, and improves packaging capabilities. From the users standpoint it improves stability, increased tablet hardness, can contain a drug layer, controls the release rates, and improves the appearance.

The process starts with tumbling to eliminate the dust. Dust can create poor adhesion of the initial layer preventing the solution from impinging into the surface of the tablet which would easily peel away regardless of how many layers were added. If the first coat isn't good no amount of subsequent layers will overcome a weak foundation. Once dedusted the known volume of cores (tablets) are loaded into a drum called a coating pan to create a batch of product. The cores are exposed to treated and conditioned air, this air stabilizes the temperature of the cores and the coating chamber to enable accurate adhesion of a sprayed solution. The more we control these conditions the more likely the process will become a predictive one.

Film coating is not at all like sugar coating in that as soon as the solution (dose) hits the tablet in film coating it should dry immediately. The prospect of spreading the solution across the surface like sugar coating would cause damage to the tablet. To make the art of coating more scientific, predictable, and most importantly repeatable here are key elements.

MUSTS

Tablet Hardness: The greatest influence of the success in film coating is the consistency of tablet hardness. The delivery of a sprayed coating solution onto a variable range of tablet surface hardness will net poor results at best. Soft tablets will often result in a dull coating and risk the potential for erosion. Tablets that are too hard don't allow the solution to lock into the surface of the tablet and the coating will often peel off. These are extreme examples, but the subtle variations in tablet hardness can also cause picking, mottling, and reduce the tablet strength. If I were an inventor I would want a tablet surface hardness detector for the best coating results. Traditional hardness testing is not as predictable when it comes to a film coating.



Tablet cores are too soft, tablets breaks apart too easily

STARTUP:

Load: Be careful to load tablets and look for broken, chipped, and other defects as the tablets are being loaded. Be sure to position the pan so the tablets do not hit the mixing baffles or anything else that could dame or chip them. One broken or chipped tablet can ruin the entire batch. Also tablets need to settle after compression for at

least 12 -24 hours or the consistency of coating will not be predictable and may peel or frost.

Dedust: Turn on the exhaust blower and pull the excess dust off the tablets. Jog the pan at a very slow speed and make sure that tablet flash or extrusions are removed with the dust.

Preheat: When it comes to film coating the tablets must be preheated or the coating will not dry immediately. The sweet spot is generally around 43-45°C. Dropping below 42 and going over 48°C is asking for problems (there are always exceptions). Remember that when the spray cycle begins it will have a cooling effect. If temperatures are too high the coating may flash off and not impinge into the surface.

Avoid Black Marks: Sometimes it is helpful to preheat the coating pan before loading tablets that get black marks from the stainless steel. Many calcium based products mark very easily. To avoid the marks there are two methods; preheat the pan or coat the pan with the same solution used to coat the tablets.

Pan RPM: Initially the pan should be jogged to dedust, do not run the pan continuously prior to turning the spray on to avoid erosion. Tablet shape and bed depth have an impact on the flow of the cores within the pan. Generally start up slow at around 4-5 rpm once the initial coating is applied then speed can and should be increased. In general the objective is a tranquil bed of tablet cores, we do not want to see tablets jumping all over the place.

START SPRAYING

Coating Solution: Prepare the coating solution ahead of time to allow the suspension to adequately dissolve. This means the solution should be prepared a minimum of 60 minutes before hand. Make certain the solution is free of lumps and air bubbles. Most solutions require continuous mixing throughout the process. Again the name of the game is reproducibility batch to batch. Establishing a solution hold time is a good idea; and the ideal range is typically 2-24 hours. The wider the range often times the less predictable the results. Spray too soon and the guns clog easily, wait too long and the viscosity changes due to evaporation. The hold time is dependent on the type of solution, water or solvent. The window for solvents based coating solutions needs to be narrower.

Solution Spray Rate: The objective is to spray a thin film across the surface of the tablet bed to get even coverage a little at a time. We want small amounts of coverage multiple times, not the other way around. The spray rate depends on the solution and the core. Generally solution rates are between 40-120 ml/minute per gun. The spray should dry on contact. Too much air pressure will cause spray drying, orange peel, and poor coverage. While not enough air will cause over wetting resulting in sticking, picking, peeling and worse. Again the key is consistency.

Coating solution must be mixed thoroughly

Drying Air: The coating pan has small holes to allow air to dry the coating solution. The air supply and exhaust pressure is balanced to minimize the rubbing of the tablets against the perforated pan surface. If supply air was only blown into the pan the spray would go everywhere. If exhaust air was only pulled out of the pan the air pressure would damage the tablets. The proper way air is balanced is that the incoming air is pushed along with the current of the sprayed solution while at the same time the air is pulled through the tablets like pulling air through a filter. The air flow needs to be fast to carry the moisture away from the tablets. Solvent solutions are not as reliant on air volume as aqueous based solutions.

Build Up: Most film coatings quantities are visual or a thin 3% buildup by weight. Typically tablets are weighed after they are preheated and then the weights are checked throughout the process until the desire weight gain is achieved or the appearance is achieved. Many companies predetermine the quantity of solution to be added and simply spray until it is all gone.

Cool Down: Once the proper coating is on the core the spray is turned off. When the spray is turned off the heat should be turned off. Slow the pan rpm or put into a jog mode until the tablets are cooled and dried. Unload and inspect carefully.

THINGS CAN GO WRONG:

Bearding: Dried solution occurs from the spray drying around the nozzle. This can happen because of a poorly prepared solution, improper spray rates, too much atomization air pressure, and inadequate negative pan pressure.

Broken Solution Lines: If a solution line breaks shut off the spray and the heat supply, keep the pan tumbling to prevent sticking. Make the repairs and continue the process.

Solution adhesion can cause coating defects

Poor Negative Pressure: Make certain the dust collector can handle the entire run. If the exhaust air volume and static pressure change this can cause over wetting and ultimately create many defects.