



PHARMACEUTICAL EQUIPMENT AND SERVICES, L.L.C.

White Paper: Tablet Coating Challenges

What are the main reasons why a manufacturer should coat tablets ?

There are many reasons why a manufacturer should coat tablets. Here are some of the key items:

- Enteric coating to allow the drug to be targeted within the body by dissolving at a particular location.
- Taste masking to hide an unpleasant product.
- Color to give better appearance.
- Flash coating to help the user swallow a smooth product.
- Help product stability encapsulating the product in a protective barrier.
- Help packaging and manufacturing machines **run dust free**.

What are the components of an appropriate tablet coating system?

- Inlet unit producing clean heated air, which can be dehumidified or humidified, in some parts of the world
- An extract system with sufficient capacity and good filtering
- A solution application control system for film or sugar application.



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- The coating pan with good internal mixing.
- A control system to meet customer needs for control and records.

What type of coating solutions are used in today's manufacturing processes ? Why ?

There are lots of options for coating from the in-house basic HPMC formulations to sugar syrups.

The more commercial branded solutions offered by manufacturers each have pros and cons.

The in-house formulations tend to be the low cost option, but consistency and traceability can be an issue. The proprietary solutions are supplied with paperwork making it easier for the end user to keep records.

What are some of the secondary or auxiliary equipment that manufacturers will need to purchase with their tablet coating systems ? Why?

The main supporting equipment for use with a coating machine will be a vessel for mixing and agitation of solution during application to stop suspended solutions from falling out of suspension.

Some solutions need heating or cooling so jacketed vessels can be used.

What are some of the challenges of manufacturers today with tablet coating ? Why ?

One of the main challenges is cost and the ability to coat tablets in either a reduced time, using lower cost materials, or reduce the running cost of the equipment.

How do you overcome the challenges listed above ?



- The solution costs can be reduced by purchasing an efficient machine which has an efficient mixing and spraying system, which does not exit the materials through the exhaust.
- Reduced time can be achieved with effective drying air of good quality and circulation when coating at a high rate of application without over wetting.
- **Running costs can be reduced by reclaiming the heat from the exhaust and using it to pre heat the inlet. Stevens Industries' CSI tablet coaters have implemented this process for several years, although the general industry does not currently.**

What are the effects of inconsistent tablet quality when coating ?

Inconsistent tablet quality can manifest itself in a number of ways.

- Obvious effects are the creation of tablet hardness or friability. This will generate excessive erosion before the coating can build up and be applied properly.
- Subtle issues are inconsistent levels of moisture in a tablet. This moisture will be trapped within a coated tablet and effect numerous desired results, like the tablet's long-term stability.

What are some of the parameters that manufacturers should check when evaluating coating operations to determine the source of defective coated tablets?

This can be a difficult question to answer as it depends on the *type* of manufacturing facility. If the machine only produces one product, then there are two main parameters to evaluate. Firstly, all *readings* should be checked for consistency because any change would indicate a problem with either the equipment or product. Each batch of coated tablets should have a consistent weight gain ratio when holding the amount of tablets and solution constant. Secondly, the performance of the machine should be monitored by ensuring that all factors are consistent: the records, tablet coating, and amount



of solution. If the machine is used more for generic coating and a large number of products are to be coated, then it is recommended to run a batch prior to main production. For example, we have one customer that always coats 2 kg in a lab coater before the main production commences in order to check the coating of the tablet. The result of this coating batch in the LAB machine is representative of the larger production and is an excellent indicator for unknown tablet production. Finally some of the less used indicators nowadays can help with such difficulties such as tablet bed pressure, in the old days due to inconsistencies this could give valuable information nowadays it is less used as the production standards for tablets and solutions along with HVAC improvements and better sprays have removed a lot of issues.

What are 2 suggestions that you would share with manufacturers to make consistent tablets and ease the process of tablet coating ? Why ?

1. Production Speeds: Sometimes it is over looked how changes in production speeds can affect the tablet quality. From machine to machine, the principle of operation is the same, but the effect of position in the die, dwell time and the use of pre-compression can affect the tablet along with shape and the ability to trap air. This becomes important during the first rotations in the pan before you have established a level of coating.
2. Material Preparation: The consistency of the material, which to a large degree, has diminished with direct compression materials. Also, the storage of the materials can effect consistent moisture levels in the tablet. By properly preparing and storing material, coating will be more effective and uniform.



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