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## Spray Nozzle Maintenance: A Critical Activity for Assuring Product and Process Reproducibility

You may have noticed that the words “fluidized bed” do not appear in the title of this **Insight**. In reality, spray nozzle performance is critical for ALL process equipment that employs a spray step. This includes high shear granulation, fluidized bed spray granulation/layering/film coating using any of the available configurations as well as tablet coating (in a perforated pan).

Companies that compress tablets have very strict control of their press tooling. A tool room is set aside for inventory control, cleaning, measuring and polishing. The people responsible for conducting this activity are highly trained and specialized, and with good reason. Out of control punch and die tooling leads to an out of control tableted product.

Precisely the same can be said for any spraying process. The critical quality attributes of a product (CQA) are strongly dependent on spray nozzle performance. Indeed, the nozzle itself is the ‘heart’ of the process. It is imperative that a spray nozzle maintenance and testing program is instituted. And it must be as rigorous as a tablet press tooling maintenance program. Not everyone is mechanically inclined and a spray nozzle is a costly, precision device. Following is a list of ‘frequently asked questions’ with respect to spray nozzle maintenance and use:

### 1 How often should the nozzle be completely dismantled for cleaning?

1.1. It is necessary to completely clean a nozzle for a product change, and this includes removing, cleaning and inspecting all o-rings.

### 2 How often should the nozzle o-rings be replaced?

2.1. It is not necessary to replace the o-rings after each batch. They should be replaced only when found to be defective (during the testing of the assembled nozzle).

### 3 How should a spray nozzle be tested and how often?

- 3.1. Every time the nozzle is cleaned and reassembled, it should be installed on its ‘wand’ for testing.
- 3.2. Testing of the nozzle can be conducted with it mounted in the machine and as a step prior to the final drying of the machine tower you will be spraying water). A second alternative is to use a nozzle ‘test station’ – a cart fitted with control air (at 90 psi), atomizing air with a

pressure regulator (with tubing sufficient in diameter to provide the atomizing air volume seen in the process) and liquid delivery for water (usually a spray pump).

3.3. All connections should be made at the wand, including a liquid line, atomizing air line and needle or piston control air.

3.4. The nozzle should be tested *at the spray rate and atomizing air pressure that will be used for the slowest spray rate in the process.*

3.5. A properly functioning nozzle should have a spray pattern that is free from erratic pulsation. If a peristaltic pump is used, there will likely be a rhythmic pulse as the lobes of the pump engage the tubing. This is characteristic of this type of pump and not a defect.

### 4 If I am running a batch, other than by sampling, how can I tell if the nozzle is performing correctly?

4.1. If the pump tubing is jiggling erratically, this is a sign that compressed air is ‘leaking’ into the liquid. This will cause a significant distortion in the spray pattern, and agglomeration (in particle coating or layering) is a virtual certainty.

4.2. If the machine is fitted with a mass flow meter, installed between the pump head and the nozzle wand, the display will be jumpy – a good nozzle should yield variability of only +/- 2-3 g/min about the set point. Erratic pulses exceeded these value are an ominous sign. If seen early in the batch, the process should be interrupted and the nozzle defect corrected.

### 5 If the process IS interrupted, will I need to clean all of the spray nozzles prior to re-starting?

5.1. For a top spray process, no. For a Wurster, in many cases no – if the machine is equipped with atomizing air volume sensors, just prior to pausing the process make a note of this volume (total or for individual nozzles). Discharge the batch and repair the defective nozzle. When finished, conduct a test of the spray nozzles (test mode, if applicable) in the empty machine at the desired atomizing air pressure. If the volume equals the value recorded just before the pause, the nozzle annuluses are clear – reload the batch and continue to completion.