

## Weight gain calculation during Pellets coating

An interview with Gabriel Welber – Senior Project Manager, Global R&D Teva

### **Q: Why is there a need for pellets coating, and pellets in general?**

**A:** This technology is used usually for modified release drugs in order to produce complex dissolution profiles. Coating creates an active pharmaceutical ingredient around an inert core, layering it with insoluble substances to form a film. Additional layers determine the dissolution rate of API. This creates a more consistent and replicable dissolution rate that can be conveniently used in tablets and capsules production. Simply put - pellets coating is used for drugs that create a long lasting effect (4-20 hr.) rather than an immediate one.

### **Q: How did you set the spraying profile in the past?**

**A:** Due to the fact that during the pellets coating there are few unwanted processes (e.g. the coating materials tend to stick to the equipment, spray drying etc.) which produce too many variables for the accurate control of the amount of active material ( and other materials) coated on the pellets.

The industry faced a big problem; how to control the required active material to be used during the pellet coating process?

Prior to the pellet counter we relied on quite a bit "trial and error". For example, we took 10 kilograms of active material and started spraying using Wurster - a process that can take up to 20 hours. We also used many complicated calculation, eventually reaching only an approximation of the amount of required API. The exact results came from the analytical test.

### **Q: How do you create the spraying profile now with the PH-JR?**

**A:** Now the process lasts seconds, because we use a constant weighing and counting measuring process to get the weight growth of a single pellet.

As you know, each pellet has several layers so eventually we can create a complete profile for each layer and for the entire process.

### **Q: How would you summarize the added value you got from our machine?**

**A:** Well, the impact can be seen in many fields: we no longer need to rely on "trial and error" so we saved a lot of valuable development and manufacturing time.

The spraying profile itself is now precise, resulting in less API loss, both in the R&D lab and during the large scale manufacturing process.

We also use this as a scale-up tool and can quite easily determine the end point of spraying and coating efficiency on different scales. The machine is also used by QC during manufacturing stage.

