

# Solving the challenge of particle coating

In the past two decades, functional coating of small particles such as granules, pellets and mini-tablets has become an integral part of pharmaceutical development and production. However, the coating process introduced challenges concerning IPC and weight gain. Researchers typically work with theoretically calculated weight gain as well as “trial and error” experiments, supported by PSD measurements.

The traditional solution to this challenge derived from the tablet coating process, where tablets are usually counted in batches of 100 tablets, with repeated weighing during the process. The calculated average weight of one tablet shows when the target weight gain is reached.

But when particles had to be counted, the same procedure was impossible to follow due to the need to count thousands of particles.

The innovative solution to this problem came from DATA’s Pellet Counter, which allows users to count large amounts of particles.

## DATA COUNT PH-JR

### FEATURES

- Accuracy: 99.5% - 99.9% (depending on size and shape)
- Size range: 0.2mm - 3mm
- Can count an unlimited number of objects
- Can count pellets, granules and mini tablets
- Machine weight: 5Kg
- Bowl feeder maximum weight: 50 gr
- Electricity: 110v or 220v
- Environmental conditions: Indoor use only
- CE certification



### PELLETS/BEADS COATING PROCESS

#### IPC in-process control test

Sampling

Drying

#### Counting

Back to line

Re-Sampling

Weighing

Checking the metrical growth

Calculating the single pellet/bead weight

#### Counting - release test

Defining the efficiency of the spraying process

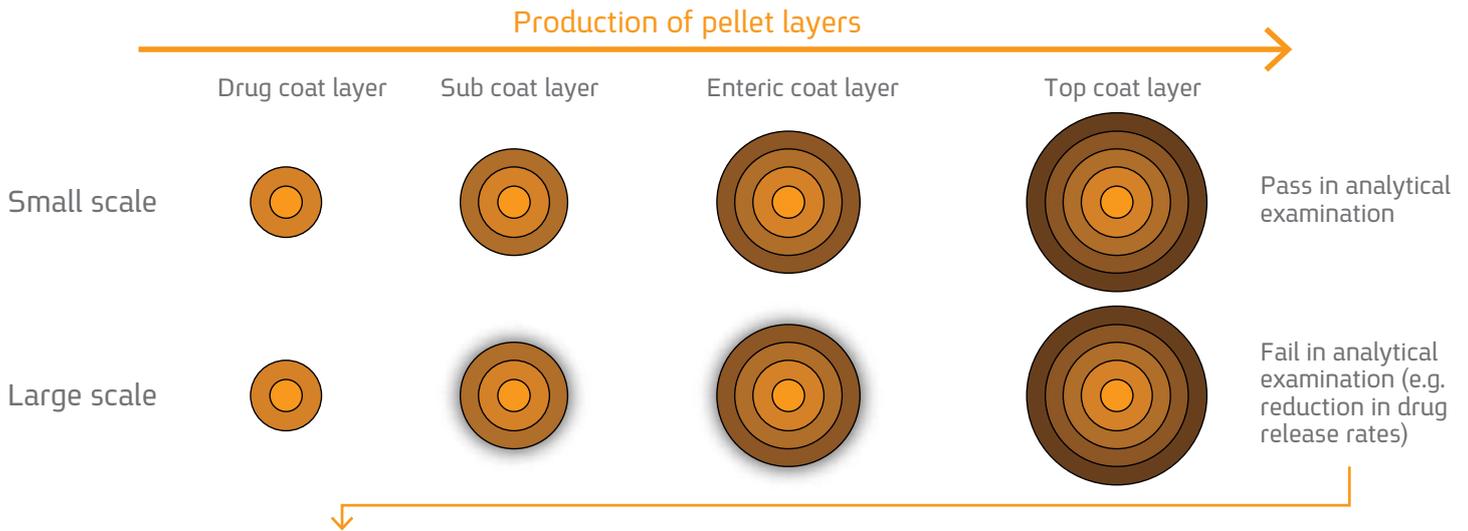
### WHAT CLIENTS SAY:

“Teva has purchased the PH-JR counting machine for R&D purpose, we are using it for the last 4 years for counting beads (pellets) which are relatively small objects used in pharmaceutical industry. It is highly recommended for counting small particles in the same weight & size, which are undergoing the coating process”

Gabriel Welber, Senior Project Manager, Global Generic R&D, Teva



## THE CHALLENGE



### Effecting factors

- Product temp
- Flow rate
- Curing time

### Outcome

Divergence in coalescence of polymer particles.

- Pellets are ground during process
- Lower solids from dispersion are attached to pellet

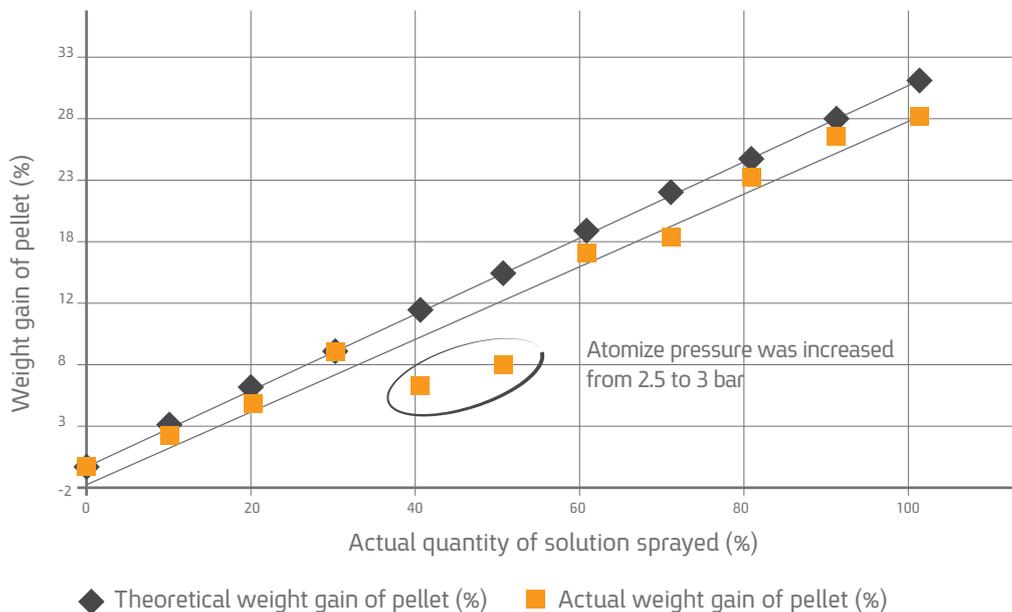
Variance in surface area.

Pellets are enlarged during the coating process. Consistent pharmaceutical processes and manufacturing units are needed to ensure homogenous pellet sizes.

## IN-PROCESS CONTROL

DATA's Pellet Counter provides an excellent means of controlling the coating process and determining the weight gain, i.e. the weight at the end of the coating stage, by a simple weighing and counting of a few thousand particles.

Changes in operation parameters (e.g. atomizing pressure, inlet temp and flow rate) can be adjusted by theoretical vs. actual weight gain of particles during the coating process.

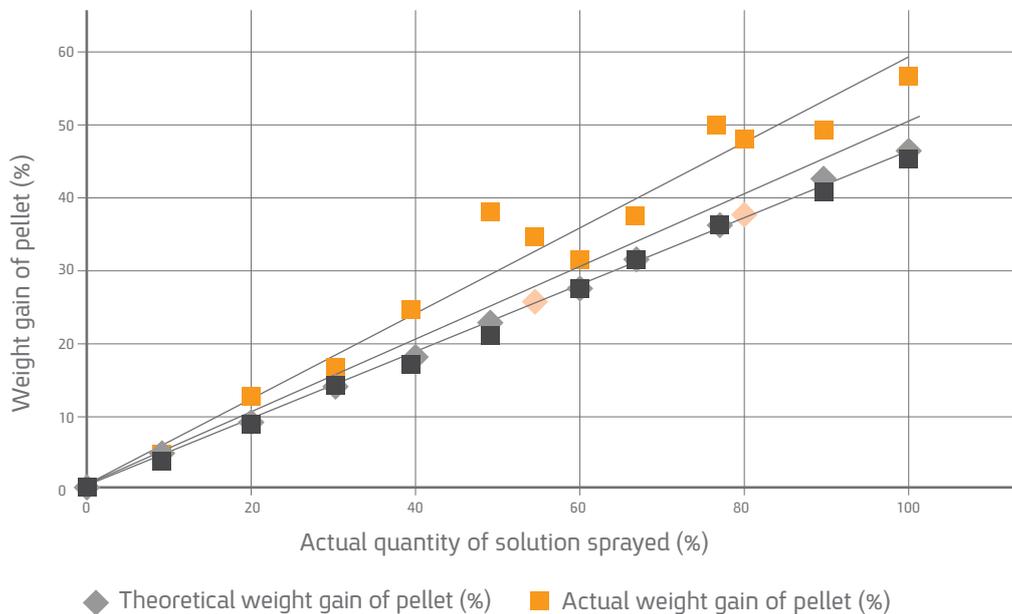


## HOMOGENEITY IN SMALL VS. LARGE SCALE

During scale-up, spraying conditions and temperature regime can be adjusted to correspond to the increasing production volume.

By using the pellet counter it is now possible to:

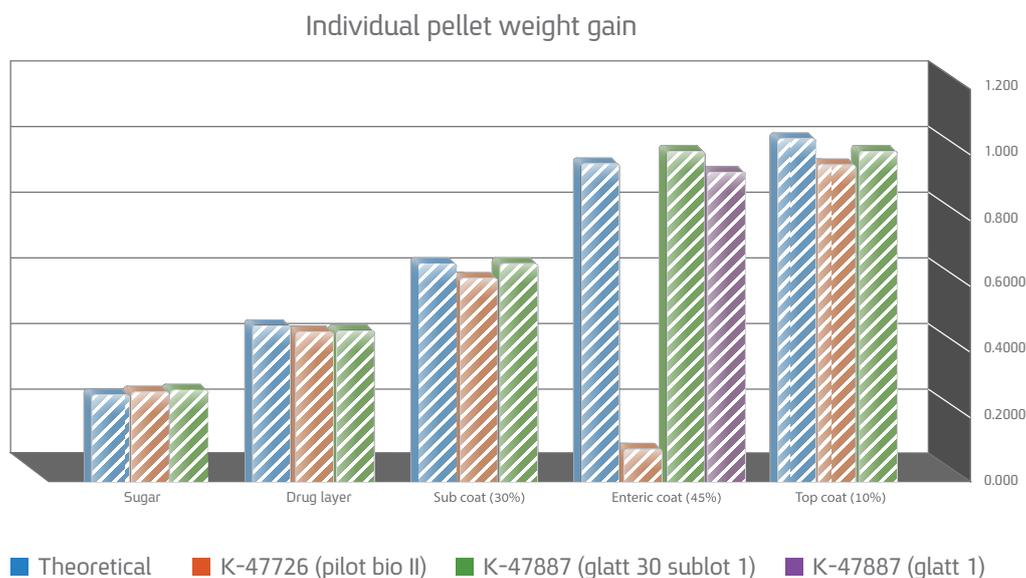
- Identify variations between small scales and scaled-up batches
- Ensure homogeneity in pellet size production at the end of every stage



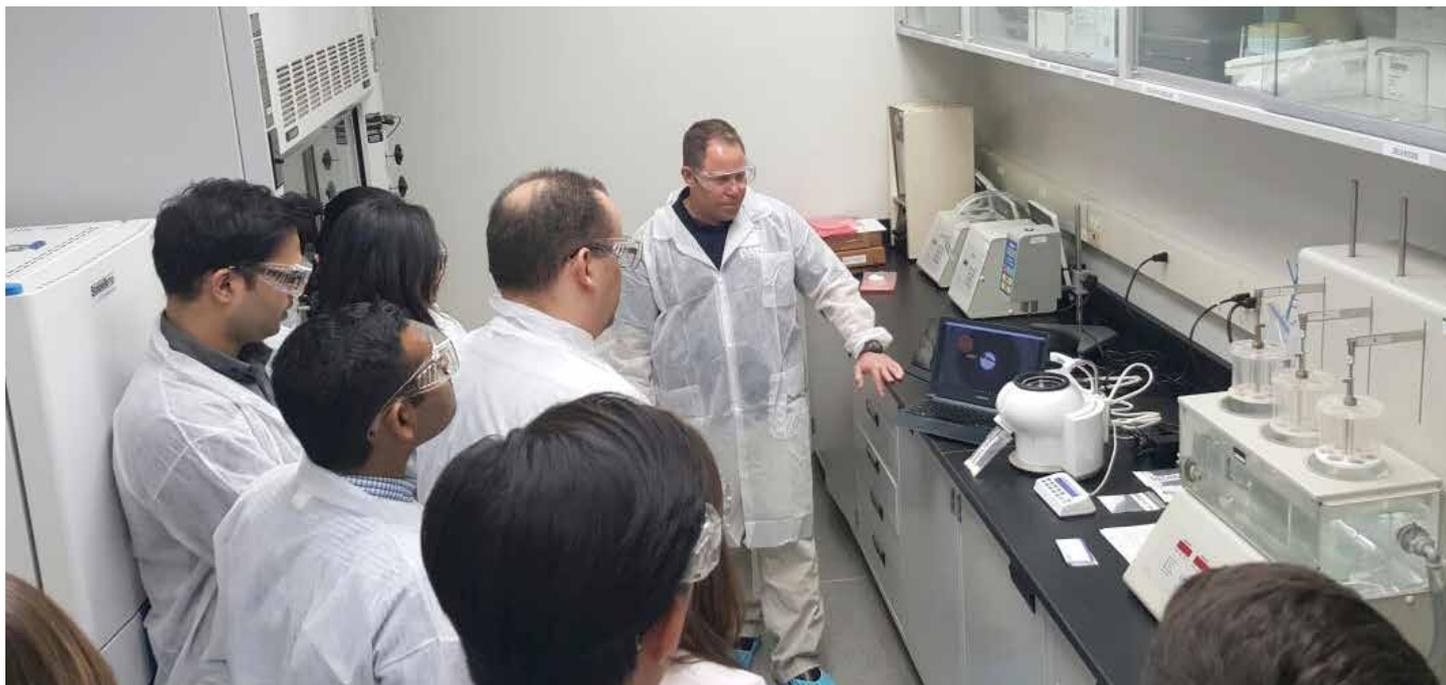
## ENSURE HOMOGENEITY IN PARTICLE SIZE PRODUCTION AT THE END OF EVERY STAGE

In multilayer coating, DATA's Pellet Counter measures each coating stage, enabling step-by-step weight gain control.

As depicted in the graph below, the initial sugar weight, as well as the weight gain after each subsequent coating stage, can be measured.



# When Speed & Accuracy Count



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