



Sample Needed Math Project Scenario

Award # 2100062

PROBLEM STATEMENT

A technician needs to take samples, make measurements, determine if manufactured metered-dose inhalers fall within specified tolerances, and recognize patterns in data to anticipate production problems.

SCENARIO DESCRIPTION–SPECIFIC EXAMPLE

Manufacturing metered-dose inhalers requires assembly of several parts (see Figure 1) including the canister that contains the medication, and the pump valve that dispenses it. Production processes crimp the valve onto the canister, pull a vacuum on it, and inject the precise amount of medication. Whether production is in R&D or in the mass production phase, in-process checks (product sampling) must be done to ensure that parameters are within acceptable tolerances. Pulling samples at regular intervals and measuring parameters will ensure quality products. Most manufacturing companies follow a GMP (Good Manufacturing Practice) model to ensure that products meet high standards.



Figure 1. Metered-Dose Inhaler

During manufacture, the valves are crimped onto the canister. Samples are measured for crimp height (mm), crimp diameter (mm), and net fill weight (g) (see Figure 2).

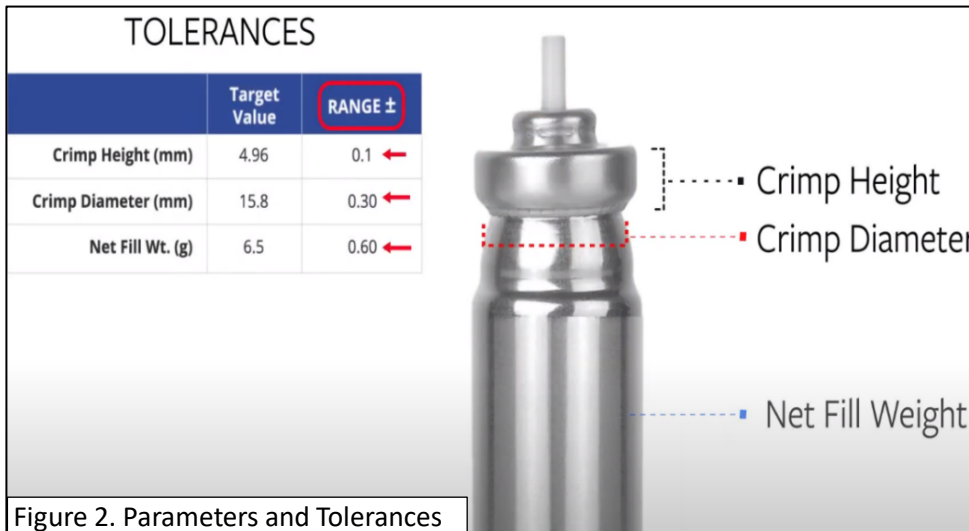


Figure 2. Parameters and Tolerances

crimp diameter (mm), and net fill weight (g) (see Figure 2). During production, the suspension (active medicine and additives) is recirculated to fill the canisters with the proper drug concentration. To ensure product integrity, in-process checks are conducted on the suspension parameters Temperature ($^{\circ}\text{C}$), stir rate (rpm), and recirculation rate (L/min) are measured and recorded. All measured and recorded

have a target and a tolerance. Data from samples are analyzed for “staying in tolerance” and for any occurring trends and issues so that machinery would be adjusted to maintain high quality standards.

ISSUES TO BE ADDRESSED

When manufacturing inhalers, machinery will occasionally produce some that are either not crimped together properly and could dispense incorrectly, or the amount of medicine injected into the canister could be too little or too much in volume. Technicians pull sample canisters off the manufacturing line and take measurements to determine if the canisters are being manufactured according to design. Each measurement must be within a specified tolerance (range). Technicians need to determine when a measurement is out of the given tolerance range. Also, technicians need to recognize patterns that exist in the data being recorded on the measurements to predict when the measurements will probably go out of tolerance.

WHERE DOES MATHEMATICS COME IN?

Tolerances, creating and reading line graphs (MS Excel), mean and standard deviation, sampling to determine any trends.

These could be added:

Questions for teachers to address, potential solutions to questions and issues raised

Teacher resources and notes; pedagogical hints

Additional supporting materials that could come from educators or industrialists