

# Particle Sizing: Heat Sensitive API



Pharmaceutical industries have many challenges regarding particle sizing of heat- or moisture-sensitive products. Milling of such material often leads to product degradation or reduced material effectiveness.

Constantly evolving products and manufacturing methods are creating new challenges for the pharmaceutical industry. Thermally unstable Active Pharmaceutical Ingredients (APIs) and bioproducts can degrade during conventional particle sizing. Hence, the need for equipment that facilitates milling without heat dissipation.

## Challenges

Particle size control is the main objective for sizing application. There lies a challenge in reducing overheating of products while milling. Maintaining the strict temperature parameters for heat sensitive materials is difficult too.

Conventional approaches involve using an Oscillator or Multimill for milling applications but each one has several disadvantages. The process parameters need to be monitored

and controlled to achieve the required output; issues related to scalability also exist.

## How Gansons Equipment Helped

Gansons-Hanningfield's Uni-Mill® have a unique screen and impeller design meant to yield reproducible and scalable results. They also generate low dust, heat and noise during operation. The impeller rotates in close tolerance with the screen maintaining a predefined uniform gap. This tightly controlled gap helps avoid the material to be crushed between the screen and the impeller.

Screen selection is also an important parameter while processing similar materials.

## Results

Gansons-Hanningfields' Uni-Mill® achieved the required particle size easily and the process ran smoothly without any stoppage or changeover.

Previously, processing 100kg of material took 3-4 hours and required two Multimills. When a batch of 1kg was milled in Gansons-Hanningfield Uni-Mill® (M-05 U), the entire process was completed in 10 minutes. A trial with batch size of 5kg was checked for

reproducibility and the result was found to be satisfactory.

Gansons-Hanningfield Uni-Mill® models are scalable from laboratory to production models as the tip speed remains the same for all applications. The operation did not involve any special need for cooling or required stoppage.

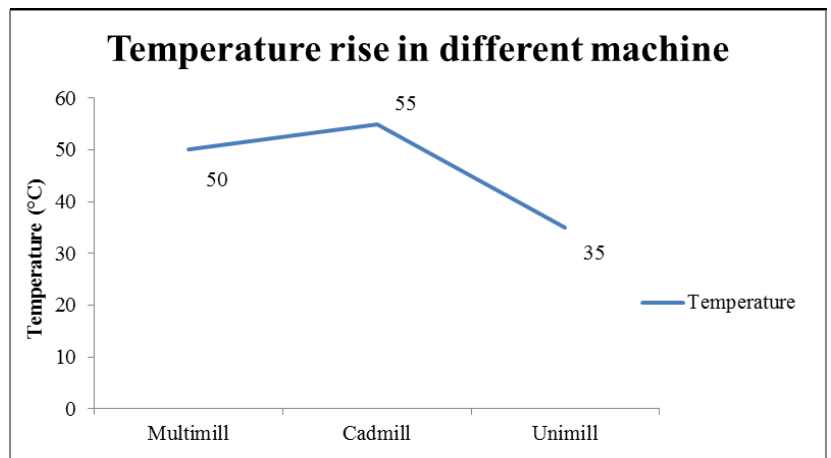


Figure 1: Comparative Temperature Rise

| Table 1: Comparative Data |                                       |                |
|---------------------------|---------------------------------------|----------------|
| Machine                   | Problem                               | Screen used    |
| Multimill                 | Screen blinding, dust generation      | 0.5 mm, 1.0 mm |
| Cad mill                  | Screen blinding, material degradation | 0.5 mm, 1.0 mm |
| Uni-Mill®                 | No blinding of screen                 | 0.6 mm/0.8 mm  |

Please contact us for more information:

Global: [sales@gansons.com](mailto:sales@gansons.com)

Europe: [engineeringUK@gansons.com](mailto:engineeringUK@gansons.com)