Migrating from an Oscillating Granulator to a Conical Mill

Author: Hanningfield Process Systems Ltd.

History

Oscillating granulators developed in the mid 1920's was widely adopted by almost all pharmaceutical companies that produced oral solid dose tablets. Oscillators were employed for wet de-lumping of mixed ingredient prior to drying. However, more often, oscillating granulators were used for the sizing of dried pharmaceutical compounds prior to tableting. These devices developed primarily for the pharmaceutical industry produced particles or so-called granules in the range of 10mesh to 30mesh (2mm down to 0.6mm) while producing minimal objectionable fine dust. Oscillators were eventually utilized for the size reduction of slugs and compacts created by roll compactors for dry granulation pharmaceutical formulas.

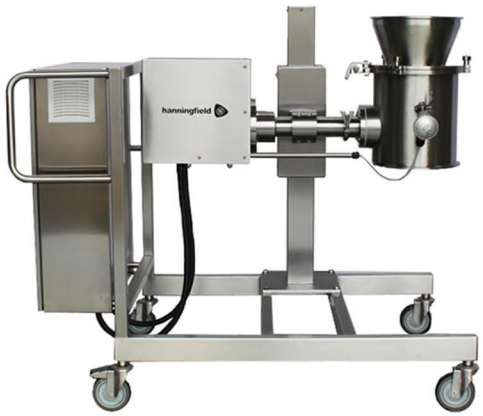
Function

With reference to the diagram to the right, coarse particles, lumps as well as compacted feed material is loaded in the oscillating granulator feed hopper. An oscillating bar rotor assembly forces the particles against a wire mesh screen supported by a backing retainer. Size reduction occurs by the attrition of particles against the wire mesh screen. Operating parameters are the screen size and frequency or speed of the oscillations.

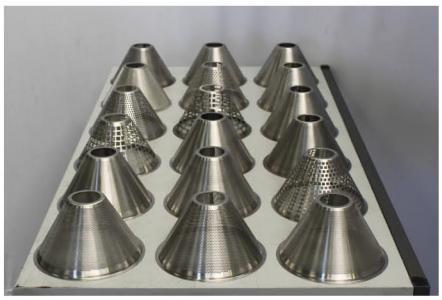
Early oscillators and even some oscillating granulators currently produced rely on an interference rubbing of the oscillating bars against the sizing screen. Oscillator technology has since advanced to the point where provisions are made for external adjustment of the bar to screen clearance, useful for some applications. Additionally, some modern oscillators have a continuous rotation mode. However, for many applications, an interference of the screen against the oscillating motion of the granulator bar produces the tightest particle size distribution and most efficient operation.

Evolution

When the conical screen mill or often referred to as a cone mill emerged on the scene on the late 1970's, oscillating granulators and competing blade and screen mills were rapidly being displaced by this new technology. Ironically, the cone mill was not developed specifically for the pharmaceutical industry but has become the mill of choice for both wet and dry granulations as well as other size reduction tasks. Still to this day, the trend continues due to the advantages and benefits of the conical screen mill technology. The Hanningfield Uni-Mill builds on the original conical screen mill concepts with state-of-the-art features. The Uni-Mill continues to evolve along with the requirements of the pharmaceutical and other sanitary industries.



Benefits



Unlike the oscillating graulator,the Uni-Mill always maintains a close but specific clearance between the impeller and screen. This avoids abrasion of the screen which not only causes undue wear but can lead to metal contamination issues.

The conical 360 degree screen used in the Uni-Mill has more total screen area compared with a similar size oscillator. This leads to higher throughput.

The useful speed range of the Uni-Mill is much greater than the oscillator. Specific capacity is higher as the impeller speed increases. The wide variable speed range is ideal for manipulating and tailoring the milled powder to a specific particle size distribution. This means more material produced in the desired particle bands.

The stress mechanism of the Uni-Mill is different from the oscillating granulator. The impeller gently pushes the process material through the screen versus relying on compression and attrition. This enables better particle size control as well as more efficient operation while potentially avoiding screen blinding on cohesive, wet and other materials with special characteristics.

In the context of safety, friction is avoided thus making the Uni-Mill ideal for materials with low minimum ignition energy (MIT) and low minimum ignition temperature. Beyond this, Uni-Mills can be manufactured with bearing and screen temperature sensors in compliance with ATEX and other safety standards and requirements. Under-driven model Uni-Mills as shown in the above image have a cylindrical housing that lends itself to nitrogen inerting and easily can be manufactured for pressure shock resistance (PSR) ratings.

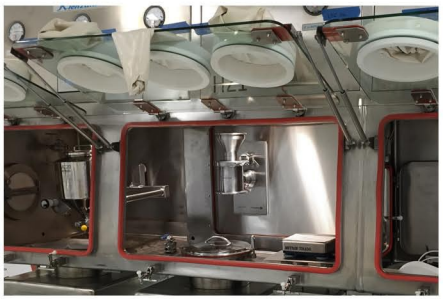
Uni-Mills have a very wide range of tooling options compared to very limited tooling options offered by the occilating granulator. Screens are manufactured from soild metal sheet versus woven wire. Various easy to install impellers and screens also referred to as “tooling” allow the Uni-Mill to perform a wide variety of size reduction and de-aglomerating tasks in a wide range of particle sizes. Screens are available in perforation sizes ranging from 150 microns to up to 30 mm. This allows the Uni-Mill to perform admirally for tasks such as: wet and dry de-agglomerating, fine to coarse size reduction, reclaimation of tablets and other brittle materials, conditioning and size reduction of cohesive, fatty, viscous and semi-solid materials.

Process Integration

Back in the day when the occilator was developed, most processes were unit operations. Little thought was giving to the integration of various unit operations such as mixing, granulation, drying, size reduction, tableting and material handling. In today's competitive environment, safety, efficiency, waste reduction, ergonomics, compliance and labor all must be considered. The monetized benefit of each process component as well as the entire process chain must represent a clear and short return on investment. To this end, Uni-Mills are designed to be integrated with other process components as well as both gravity and pneumatic conveying systems such as the Uni-Vac. Continuous processing and meeting safety concerns with an oscillating granulator is impractical and often impossible.

The above image illustrates a tightly integrated oral solid dose wet granulation line. From right to left, wet granulated material is discharged continuously from the granulator bowl into the Uni-Mill. Using the suction fan for the fluid bed dryer, the wet de-agglomerated mass is pneumatically conveyed into the fluid bed dryer bowl. After the drying cycle is completed, a Uni-Vac system is employed to convey the dry compound through a second dry grinding Uni-Mill for final sizing. Sized powder is collected in the Uni-Vac's filter/receiver and discharged into an intermediate bulk container (IBC). The entire operation is contained.

High Potency – High Efficacy Process Integration



Today's APIs active pharmaceutical ingredients often require high containment. Dust containment levels often classified in Operator Exposure Bands (OEB) can be as low as nanograms per cubic meter of air. To protect operators from exposure, processing in an isolator is often required. It is desirable to separate the utility and process drive components of a size reduction machine from the actual process module.

In the case of the oscillator this would be extremely challenging to design and manufacture. On the other hand, the underdriven Uni-Mill is a natural fit requiring only minor modification to allow isolator integration with total separation of process and utility/drive components.

Summary

In today's changing pharmaceutical manufacturing environment, the choice of a Uni-Mill is clear with its many advantages and attributes. Although oscillating granulators have had their place in the size reduction role and still may excel in limited circumstances, it has been outpaced by the Uni-Mill conical screen mill. The advantages are so compelling, that the costs of revalidating legacy oral solid dose drugs are minor in comparison to the monetize benefits afforded by the Uni-Mill. There are almost no new drugs developed utilizing oscillating granulator technology. The remaining use of oscillating granulators are mainly in low cost manufacturing of low potency generic and over the counter drugs. The one exception is the integration of the oscillating granulator with some dry granulation roll compactors.