# Uses of Sieves in the Pharmaceutical Industry and the Increased Demand for Containment



**A sieve or screener is an essential part of every pharmaceutical production process, particularly as product quality and integrity are so important. The use of a sieve safeguards against customer compensation or litigation, as it eliminates all oversized contamination. It therefore ensures that ingredients and finished products are quality assured during production and before use or dispatch.**

However, the design of sieving equipment has had to undergo radical changes in recent years to overcome the new demands of companies manufacturing pharmaceuticals. These demands include improved productivity and product quality and, most importantly, improving the health and safety of the operators of sieves and screeners. The latest generation of sieve has made large improvements to safety by containing the powders being processed, thus adhering to occupational exposure limits. In basic terms, a sieve consists of a housing containing a removable wire mesh of a defined aperture size. This assembly is vibrated by an electric motor so particles which are small enough pass through the mesh apertures, and any particles or contamination that are too big remain on the top. Most units used in the pharmaceutical industry tend to be circular in shape and of a high-quality good manufacturing practice (GMP) design (see Figure 1). Stainless steel mesh with a high tolerance on the apertures is also specified to give excellent product quality.


## Types of Sieving

There are two main types of sieving – safety screening and grading. This article will concentrate on sieves used for safety screening, but a quick explanation of grading will also be given. Safety screening of powders, sometimes known as control sieving or security/check screening, is carried out to ensure the correct product quality. The sieve removes any oversized contamination from the powder. This could be something which has accidentally found its way into the process line, such as packaging, a piece of PPE equipment, or extraneous particles, which may be inherent in the material. The removal of this contamination improves the quality of the powder and final product, and therefore ensures the reputation of the pharmaceutical company. Grading or sizing of powders or granules is carried out to separate different ranges of particle sizes. For example, primary and intermediates need to be sieved to remove oversized and undersized particles in

order to ensure a correct particle size distribution ready for granulation and subsequent tablet pressing.

## Where are Sieves Used?

Most pharmaceutical processes are hazard analysis and critical control point (HACCP) controlled. This means that an analysis of the process is carried out in terms of where hazards can occur. Critical control points are identified and some form of prevention is put in place. Sieving equipment will help considerably at any point at which there is a risk of contamination entering the process. These critical control points are found in many different areas of the production process. On the primary side, a good example is where raw ingredients are de-bagged because of the potential for parts of the bag to be accidentally introduced into the process. Another example on the primary side is where mixing or blending takes place, as this is another area for potential contamination. On the secondary side, many pharmaceutical companies consider the finished powder packaging area critical and place a sieve here to prevent contamination and therefore customer complaints.

## Features and Benefits of Check Screening Sieves

Sieves used for check screening are designed to be extremely simple to operate and maintain, with the emphasis on making them easy to strip down and clean effectively. Their compact design means that they can be placed in small or restricted height areas of the production process – possibly where a sieve was not originally deemed necessary but is now essential. The sieve mesh itself is a removable item, so the aperture size of the mesh can be changed according to the powder being processed. Modern units use mesh that is securely bonded with adhesive to a frame, which gives a much higher tension in the mesh than older styles that secured the frame with a clip or screws. Having a consistent and high-tension level gives better throughputs and reduces blinding or blocking of the sieve apertures. Another recent development is the use of an FDA-approved adhesive to bond the sieve mesh to the frame. All other contact parts of the sieve are manufactured from stainless steel and can be polished to very low surface roughness (Ra) values in order to ensure good flow properties and easy cleaning. These components are simple to remove and wash in an autoclave or other cleaning vessel, thus removing any chance of cross-contamination between different batches of material.

## Pneumatic Conveying and the Sieving Process

One of the most popular ways of transporting solids at manufacturing sites is through pneumatic conveying systems. Pneumatic conveying is often selected because it is totally enclosed and dust-tight, ideal for dusty or dirty materials. These systems can also be installed anywhere a pipeline can be fitted within a site.

Sieving manufacturers have had to innovatively develop machines to allow producers to sieve ingredients before, during and after pneumatic conveying. Sieving ingredients before they enter the system ensures a product free of contaminants, which could otherwise lead to rejected products or potentially damage other equipment. Screening material within or after the systems allows for a high level of quality control.

There are two main types of pneumatic conveying – by positive pressure or vacuum. Simply explained, positive pressure systems can achieve longer distances at higher rates as jet blowers push air through the pipes. Vacuum systems, on the other hand, use suction technology to draw air and displace materials, and cannot generally achieve the distances and high levels of pressure systems. Different sieves must be used depending on the type of conveying system employed. For example, in most cases, a certified pressure vessel is required for positive pressure pneumatic conveying. On the other hand, a manufacturer using a vacuum system is not so restricted and can select from a wider range of sieve designs tailored for vacuum pneumatic conveying systems.

## High-quality Mesh – What to Look For

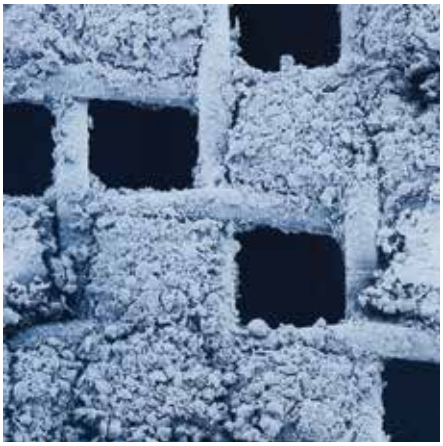
Any company using a sieve needs to carefully consider the quality of mesh being used, regardless of the exact type of sieve model. A poor-quality mesh can easily break, resulting in not only unnecessary downtime but also compromised product quality. Mesh screen material, mesh size and mesh tension must all be looked at. The most common screen material is woven stainless

steel wire mesh, although more exotic metals, such as bronze, can be used if required for a specific application. Stainless steel is a reliable, durable material and is suited for most applications. Synthetic woven meshes are also available, where chemical compatibility is a concern. In general they are made of polyester or nylon.

Historically, and particularly in the USA, mesh count, which is the number of apertures per linear inch, was used to specify the screen opening size of a mesh. However, this method often led to a false measurement. Nowadays, it is more common to use microns to define opening size, i.e. by measuring the number of microns per aperture, which provides a much more precise and accurate measurement. To ensure the optimal operating efficiency of the screen, it is crucial the mesh is properly tensioned; otherwise the screen will not give its best performance.

## Ultrasonic Deblinding System

Most powders can be screened quickly and accurately by a standard sieve, however, some pharmaceutical powders may be sticky or have irregular shaped particles, which can cause mesh-blinding problems (see Figure 2). The method of ultrasonically



exciting the stainless steel mesh wires of a powder-screening machine by high-frequency, low-amplitude vibration to prevent apertures blocking has been used for over 25 years. The ultrasonic frequency is applied to the sieve mesh via an acoustically developed transducer (see Figure 3).

This breaks down the surface tension, effectively making the stainless steel wires friction-free and preventing particles both slightly greater and smaller than the mesh from blinding or blocking it. Screen blinding or blocking is a common problem when sieving difficult powders on screens of 500$\mu$m and below. It occurs if either one or a combination of particles sit on or in an aperture of the mesh and

stay there, or when particles adhere to the mesh wires, preventing other particles from using these openings to pass through. It is particularly common with sticky powders or materials, which contain a large number of particles of a size similar to that of the apertures of the mesh. When blocking occurs, the useful screening area is reduced and therefore capacity will drop. The system works on the power by demand (PBD) principle, which solves the problem of uneven loading. Constant feedback from the separator screen to the PBD controls monitors the throughput of material in the system. When there is a heavy loading on the sieve mesh, PBD increases power, maintaining the amplitude of the ultrasonics to pass materials through quickly and efficiently without blinding. There are several knock-on benefits to eliminating blinding via an ultrasonic deblinding device. The first is that sieving capacities improve, increasing productivity. The second is that because the mesh is kept free from blockage for longer, manual cleaning is more infrequent and therefore the chance of damaging the mesh is reduced. Finally, ultrasonic deblinding systems enable powders to be sieved using meshes with smaller apertures. This enables even finer-quality products to be produced than previously possible, or even to screen powders that could not be sieved before.

## The Effect of the Atex Directive

Recent legislation has had a significant effect on the design of sieving equipment. On March 1st, 1996, the European Community adopted a Directive on equipment and protective systems intended for use in potentially explosive atmospheres (94/9/EC). 'Atmospheres Explosibles' is more commonly referred to as the ATEX Directive, whose primary function is to eliminate the possibility of explosions. It applies to electrical and mechanical equipment intended for use in potentially explosive atmospheres. The Directive affects all industries involving powders, dusts and vapours including food, metal powders, powder paint, pharmaceutical powders and chemicals. From July 2003, all new equipment purchased for installation and use in a potentially explosive atmosphere has had to comply with the requirements of the ATEX Directive. Design changes to sieving units are mainly focused on making sure that the unit is free of any potential sources of ignition. Therefore, it is essential to properly earth all components and remove all other possibilities of a spark or excessive heat generation. However, when an electrical component is continuously in contact with powder and dust during sieving there is a further hazard of an explosion. The ultrasonic probe of the deblinding system described earlier needs to be made safe as it is placed inside the sieve – an area often categorised as Zone 20. Some manufacturers have addressed this by enclosing the transducer and cable to eliminate the possibility of any explosion. The equipment has to go through rigorous testing procedures and be approved by certified bodies. Only then can it be deemed to meet essential health and safety requirements. This, in turn, allows difficult-to-sieve powders to be screened effectively and safely, and gives the user complete peace of mind.

## Improvements in Containment

Employers have been using occupational exposure limits (OELs) for many years to safeguard their employees' health. They are used to assessing the adequacy of the control measures and indicate if a problem ever occurs. This has forced manufacturers of process equipment to design machines which contain dust and fumes much more effectively, so that these OELs can be met. In the case of sieving equipment, this is especially important as the very action of a vibrating sieve causes dust to be generated. Traditionally, sieves have used either over-centre toggle clamps or circular band clamps to secure the component parts together. These are not ideal mechanisms for ensuring dust-tight operation, as they rely on operators to tighten them correctly to ensure an adequate seal. The latest generation of sieve addresses this clamping issue by utilising a validated pneumatic clamping system, giving large improvements in product containment and operator health and safety. The GMP design of the sieve is based on clean lines, which makes sanitation easier and performance greater. Clean-down times are reduced as the sieve is simple to disassemble in seconds without the need for tools. Crevice-free, smooth surfaces make the product contact parts easy to clean and fully washable. The unit is clamped together with an airlock system. This pneumatic lock gives an even and high clamping force across all sealing faces, and therefore guards against powder leakage more effectively than traditional band clamps or over-centre toggle clamps (see Figure 4). To assist with FDA process approval, this pneumatic clamping system can be validated, as it provides a repeatable and measurable seal.

## Conclusion

It is obvious that sieves or screeners continue to have a large part to play in the safe production of pharmaceutical products. However, it is important that companies using this equipment choose carefully, making sure that they comply with the new ATEX legislation and safeguard the health and safety of their operators.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