Shaking Things Up

By Rob O'Connell at Russell Finex

The use of sieving equipment in pharmaceutical manufacturing ensures a safe, quality end product, with production demands and safety legislation shaping the latest generation of equipment

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 eliminates all oversized contamination, safeguarding against customer compensation or litigation. It ensures that ingredients and finished products are quality assured during production and before use or dispatch.

Figure 1: GMP-designed sieve

Source: Russell Finex Ltd

However, the design of sieving equipment has had to undergo radical changes in recent years to overcome new demands of companies that manufacture pharmaceuticals. These demands include improving productivity, product quality and, most importantly, the health and safety of operators of sieves and screeners.

The latest generation of sieve has resulted in significant improvements in safety by containing the powders being processed, thus adhering to occupational exposure limits (OELs). In basic terms, a sieve consists of housing containing a removable wire mesh of a defined aperture size. This assembly is vibrated by an electric motor so that 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.

Keywords

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Types of Sieving

There are two main types of sieving: safety screening and grading. This article will concentrate on sieves used for the former, but a quick explanation of the latter 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 that has accidentally found its way into the process line, such as packaging, a piece of personal protective equipment, or extraneous particles which may be inherent in the material. The removal of this contamination improves the quality of the powder and the final product, ultimately ensuring the reputation of the pharmaceutical company.

Grading or sizing of powders or granules, on the other hand, is carried out to separate different ranges of

particle sizes. For instance, 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 controlled. This means 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 considerably help 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 during the stage in which raw ingredients are de-bagged, because of the potential for parts of the bag to be accidentally introduced into the process. Another area of potential contamination is the point at which mixing or blending takes place. On the secondary side, many pharmaceutical companies consider the finished powder packaging area critical, and place a sieve here to prevent contamination and ensuing customer complaints.

Features and Benefits

Sieves used for safety 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 they can be located 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 compared to older styles that secure 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 a Food and Drug Administration (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

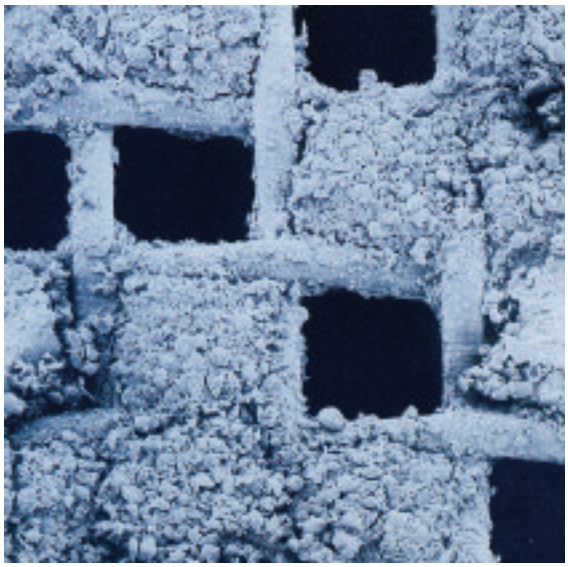

Figure 2: Mesh blinding under a microscope

Source: G Bopp & Co

low surface roughness average (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.

Ultrasonic Deblinding

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 becoming blocked has been used for more than 25 years. The ultrasonic frequency is applied to the sieve mesh

Figure 3: Ultrasonic deblinding system

Source: Russell Finex Ltd

Figure 4: Sieve with revolutionary airlock system
Source: Russell Finex Ltd

via an acoustically developed transducer (see Figure 3 on page 69). 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 500m and below. It occurs if either one or a combination of particles sits on or in an aperture of the mesh and stays 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 ultrasonic deblinding 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, and introduces the ability to screen powders that could not be sieved before.

> The latest generation of sieve addresses clamping issues by utilising a validated pneumatic clamping system, giving large improvements in product containment and operator health and safety

Effect of the ATEX Directive

Recent legislation has had a significant effect on the design of sieving equipment. On 1st March 1996, the European Community adopted the ATEX Directive (94/9/EC). Intended primarily to eliminate the possibility of explosions, this safety directive applies to electrical and mechanical equipment for use in potentially explosive atmospheres. It affects all industries involving powders, dust and vapours, including food, metal powders, powder paint, pharmaceutical powders and chemicals. Since July 2003, all new equipment purchased for installation and use in a potentially explosive atmosphere has had to comply with the requirements.

Design changes to sieving units are focused mainly 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 risk of an explosion.

As a result, the ultrasonic probe of the deblinding system 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 peace of mind.

Improvements in Containment

Employers have been using OELs for many years to safeguard their employees' health, as required by health and safety law. They are used to assess the adequacy of control measures and to indicate if a problem occurs. This has forced manufacturers of process equipment to design machines which generate 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 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

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 they comply with the ATEX legislation and have appropriate control measures in place to safeguard the health and safety of their operators.

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