

## What's New In High Shear Mixers

New advances in rotor/stator mixing technologies can help improve your manufacturing process, optimize operating costs, and boost production.

by Christine Banaszek

**T**he challenge of producing high-quality emulsions, solutions, and dispersions can sometimes be a moving target due to changing market demands, consumer behavior, and product requirements. More than ever, pharmaceutical companies are reevaluating their mixing processes, looking for ways to lower cost, boost production capacity, improve product quality, or simplify cleaning and maintenance while still maintaining processing flexibility.

In particular, the use of high shear rotor/stator mixers has become more and more popular over the years. Compared to other agitation devices such as propellers, turbines, and saw-tooth dispersers, the versatile rotor/stator mixer offers better performance in terms of size reduction, homogenization and emulsification of a wide variety of formulations.

### High Shear Mixers: Basic Design And Theory Of Operation

Rotor/stator mixers, also called high shear mixers, are typically comprised of a four-blade rotor turning at high-speeds within a stationary stator. As the blades rotate, materials are continuously drawn into one end of the mixing head and expelled at high velocity through the openings of the stator. The resulting hydraulic shear promotes fast mixing, breaks down solid agglomerates and reduces the size of suspended droplets. Rotor tip speeds between 3,000 and 4,000 ft/min are typical.

Available in both batch and inline (continuous) configurations, high shear mixers are commonly used in the preparation of fine emulsions and suspensions such as medicated lotions, balms, ointments, gels, creams, and eye drops. High shear mixers are also utilized for dissolving or dispersing solid ingredients into a liquid vehicle when other style mixers with lower tip speeds would otherwise produce very long cycle times or inadequate dispersion quality. Sample applications include coatings, vaccines, pharmaceutical inks, disinfectants, adhesives for drug delivery, etc.

In recent years, two major innovations in high shear mixer technology have shown the greatest potential of helping pharmaceutical companies achieve their processing goals: powder injection systems and ultra-high shear mixers.

Rotor/stator devices with powder injection capabilities enable high-speed mixing of hard-to-disperse solids with minimal agglomeration and dusting. Meanwhile, ultra-high shear mixers feature specially designed rotor/stator combinations set at tighter clearances and which can operate at tip speeds more than three times that of conventional rotor/stator mixers. Size reduction of particles or droplets is achieved under extremely short cycle times and to greater extent.



Example of a four-blade rotor and slotted stator of a high shear mixer.

### Powder Dispersion Into Liquid

Different powders behave differently when added into liquid. Some require more coaxing than others in order to dissolve, hydrate, or disperse completely. Solids that are easier to handle require only mild agitation such as provided by low-speed propeller, turbine, or paddle agitators. More challenging powders benefit from higher-speed devices like open-disc saw-tooth blades which generate a vortex into which the powders are added for faster wet-out. But when dealing with solids that tend to quickly agglomerate upon contact with

liquid, relying on high-speed mixing alone does not necessarily maximize efficiency, especially in a full-scale production setting. For example, even when using a high-speed saw-tooth disperser or rotor/stator mixer, many operators are still compelled to very carefully add powders such as fumed silica, CMC, xanthan gum, alginates, starch, pectin, talc, carbomers, guar gum, carrageenan, tragacanth, clays, pigments, carbomers, etc. Despite a strong vortex, some of these powders will resist wet-out and can float on the liquid surface for hours. Yet, if powders are added too slowly, an uncontrolled viscosity build-up can occur mid-processing which might prevent the rest of the solids from being fully dissolved or dispersed.

On the other hand, charging too fast can aggravate dusting and cause some powders to clump up. When agglomerates solvate they can form a tough outer layer, leaving the interior particles dry, a phenomenon sometimes called “fish eyes.” The formation of fish eyes causes solution defects such as grainy texture and reduced viscosity. The high shear conditions usually needed to break up these agglomerates may overshear the already hydrated or dispersed particles leading to a permanent loss in viscosity. To compensate for this effect, many operators will resort to adding more solids than is really needed and subsequently filter agglomerates out of the mixture.

This practice not only drives up raw material costs but also wastes power, lowers productivity, and slows down over-all production.

Utilizing vacuum to inject powders subsurface is one solution to this issue. In conventional batch systems, an external vacuum pump is used to establish vacuum in the vessel. Solids are typically introduced through a port near the bottom by virtue of the low pressure within the pot. The point of entry is in close proximity to a high-speed mixer so that powders can be dispersed and wetted out before they reach the liquid surface. This method requires a skilled operator to carefully monitor the vacuum level and make frequent adjustments based on the rate of powder injection. Too strong a vacuum can cause powders to shoot out of the liquid and dust, float, or form lumps. On the other hand, a weak vacuum will not motivate the solids to enter the batch. In reality, it is a very difficult balancing act which can lead to variable cycle times and dispersion quality.

New rotor/stator designs combine high-speed and high shear mixing with the vacuum concept.



Example of an inline (continuous) powder injection system. The liquid stream (blue) enters the mixer and immediately encounters the powder addition (yellow). The resulting dispersion (green) is expelled from the stator openings at high velocity.

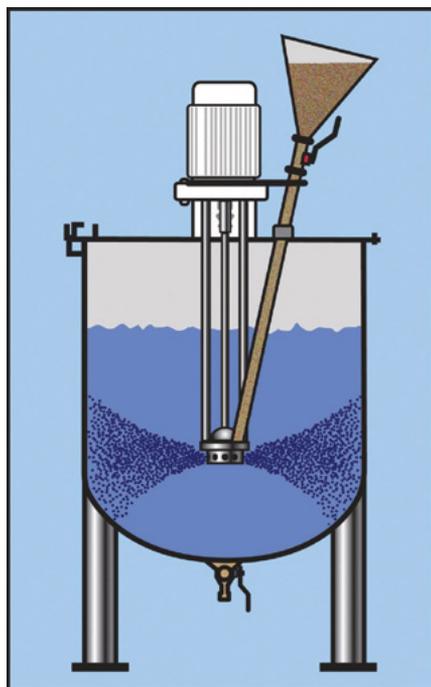
But instead of relying on an external vacuum pump, these powder injection systems utilize a specially engineered rotor/stator assembly that generates its own powerful vacuum to draw solids subsurface. This type of device allows the operator to introduce powders at a fast but controlled rate for highly repeatable and superior dispersion results. Powders encounter the liquid phase not only subsurface but also where shear conditions are the most intense. This mechanism prevents the formation of agglomerates or fish eyes in the first place and ensures maximum yield of the solid components. Revealing their full functionality through efficient mixing lowers

raw material costs and eliminates downstream filtering or rework operations.

Powder injection systems are available in both batch and inline rotor/stator mixers. Powders may be loaded into a hopper or drawn from their original container using a “hose and wand” attachment. The latter is recommended for very lightweight powders to eliminate dusting in the mixing area.

When considering an inline powder injection unit, check whether the mixer requires a pump and eductor as this system will be more complicated to operate. Powder injection systems that operate based on the venturi principle rely on a pump and eductor, in addition to the rotor/stator mixer, to create a vacuum for drawing solids into the liquid stream. This setup is prone to clogging and with three separate devices in series, balancing their performance requires a lot of operator experience and attention. Cleanup and maintenance can also be intensive.

Newer and more compact inline powder injection systems address these limitations by utilizing a unique rotor/stator set that executes the functions of both the pump and the eductor. These systems feature



Example of a powder injection assembly in a batch rotor/stator mixer.

a ported rotor that generates an intense vacuum to draw powders right into the high shear zone of the mix chamber, where they are dispersed instantly with the liquid stream. An auxiliary pump and eductor are not required, allowing the inline system to be completely portable for servicing multiple mix vessels. Operation is simpler and cleaning can be done in place.

### Particle And Droplet Size Reduction

In an inline mixer, the greatest extent of particle or droplet size reduction occurs within the first few passes. This phenomenon is true for almost any dispersion or emulsion. Past this stage of sharp decrease in particle or droplet size, the distribution hovers at an equilibrium despite subsequent recirculation. The same trend applies to batch mixing using a rotor/stator although the actual number of product turnovers is not as easy to define. It is always useful to know the approximate point at which particle size is already in equilibrium in order to avoid overprocessing.

If the equilibrium particle or droplet size achieved

in a conventional rotor/stator is larger than desired, manufacturers often move to higher energy devices such as high-pressure homogenizers and colloid mills. High-cost, labor-intensive cleaning and maintenance as well as low throughput are the main drawbacks commonly associated with these machines. It is therefore a welcome development that new rotor/stator designs now present a number of viable, more cost-effective alternatives to high-pressure homogenizers and colloid mills.

Called “ultra-high shear mixers”, these new devices deliver more vigorous mixing and greater throughput compared to conventional rotor/stator mixers and even colloid mills. When utilized as a premixer installed prior to a high-pressure homogenizer, an ultra-high shear mixer can reduce the number of homogenizer passes required to reach the final droplet size. In some single pass requirements, the ultra-high shear mixer can eliminate the homogenizer entirely.

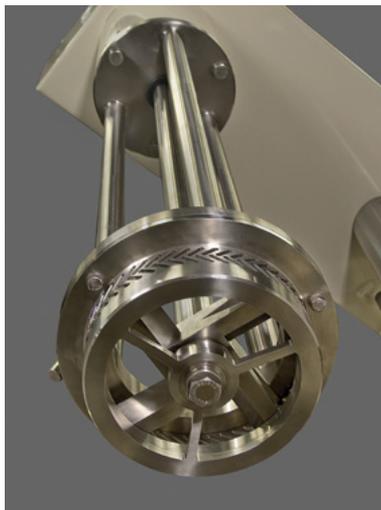
### Batch Ultra-High Shear Mixers

Some batch rotor/stator mixers are now designed to run at

higher tip speeds and produce more turbulent flow within the mix vessel. One such model is the Ross PreMax, a top-entering ultra-high shear mixer. The rotor is specially contoured for high pumping capacity and shear intensity. Product is drawn from above and below the mix chamber then expelled



Example of a batch style ultra-high shear mixer (left). Close-up of rotor/stator (right).



radially through the stator slots at high velocity. This generates upper and lower vortexes allowing for extremely efficient powder additions and rapid turnover rates. Very fine droplet sizes are achieved while solids are wetted out faster. This model is typically used as a stand-alone unit and does not require supplemental agitation for products up to 50,000 cP. For higher viscosity products, it can be used in combination with an anchor agitator in a multi-shaft mixer arrangement. It can also be supplied with a modified rotor designed for subsurface powder injection.

Users switching from a regular rotor/stator to a batch ultra-high shear mixer experience a significant impact on production time. In side-by-side tests, the ultra-high shear mixer has been shown to produce low-viscosity and high-viscosity emulsions up to six times faster than a conventional high shear mixer.

### Inline Ultra-High Shear Mixers

Even more aggressive ultra-high shear mixers are available in inline (continuous) configurations. Running at tip speeds over 11,000 ft/min, these mixers are capable of far greater flowrates compared to a similarly sized high-pressure homogenizer or colloid mill. They are also easier to clean and disinfect in place. Based on user experiences, the shorter cleaning time equates not only to a faster change-over procedure but also to longer intervals between cleaning cycles (longer production runs).

In a typical setup, a simple batch mixer is used to combine the raw materials and the resulting rough premix is then passed through the inline ultra-high shear mixer. Many applications require one or two passes only but more challenging formulations benefit from additional recirculation. Due to the intense energy that the mixer imparts to the

product, temperature must be monitored.

Proven applications include dispersion of nano-sized particles, submicron emulsification, polymer disintegration, activation of microfibrinous cellulose, etc.

### Multi-Step Mixing Processes

In cases where ultra-high shear mixing does not necessarily eliminate homogenization, its utility as a 'premixer' is still sig-

nificant. By producing a fine premix in the ultra-high shear mixer, manufacturers reduce the number of passes through their high-pressure homogenizer and lower the risk of clogging. This multistage approach offers substantial benefits in terms of improved throughput and maximized utilization of the high-pressure homogenizer.

Another typical processing set-up involves piping an inline ultra-high shear mixer to a batch multi-shaft mixer. In the mix vessel, an anchor agitator, high-speed disperser and regular rotor/stator is used to combine all raw materials and prepare a homogenous mixture. Toward the end of the mix cycle, product is fed into the inline ultra-high shear mixer and recirculated a few times to achieve the target size distribution.

### Selecting The Right Rotor/Stator Mixer For Your Process

Evaluating a mixer for a new product line or upgrading an existing process is best done through actual simulation trials utilizing your own raw materials. Like most specialty mixers, rotor/stator devices produce results that are very formulation-dependent. Partner with an experienced equipment manufacturer that offers testing services as well as a variety of scalable mixers, including the latest in rotor/stator designs. ■



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