RECOMMENDED MIXING EQUIPMENT FOR

Ophthalmic Preparations

APPLICATION SUMMARY:

Ophthalmic solutions, suspensions and emulsions are available in various forms such as eye drops, washes, ointments and injectable drugs. While these sterile preparations vary in terms of active ingredient, viscosity, pH, preservative level and other characteristics, one common requirement is that these products must be free of large particulates to prevent irritation and damage to the eyes. Together with proper formulation and filtration, thorough mixing is very important in meeting this objective.

This bulletin describes several high shear mixing technologies utilized in the production of eye care products and medicines. Mixer selection is based on a number of factors but primarily viscosity profile and shear input.

Ross High Shear Mixers and Multi-Shaft Mixers

Pharmaceutical manufacturers rely on a range of high speed mixers to accomplish dispersion and emulsification. In the processing ophthalmic solutions, for instance, Ross High Shear Mixers are utilized for dissolving salts as well as dispersing viscosity enhancers, antioxidants and other additives. The basic single-stage design features a four-blade rotor turning at tip speeds around 3,000-4,000 ft/min within a close tolerance fixed stator. It imparts mechanical and hydraulic shear by continuously drawing product into the rotor and expelling it radially at high velocity through the openings in the stator. Built-in powder induction mechanisms like the Solids/Liquid Induction Manifold (SLIM) Technology extend the High Shear Mixer’s functionality by enabling more convenient raw material additions, faster dissolution/dispersion and more efficient hydration of thickeners.

More viscous ophthalmic ointments and pastes are more efficiently batched in Multi-Shaft Mixers. These versatile machines are equipped with two or more independently-driven agitators working in tandem to deliver a combination of high shear agitation and laminar bulk flow. One common configuration is the Triple-Shaft Mixer featuring a low-speed anchor, rotor/stator assembly and saw-tooth disperser blade. The agitators can be engaged in any combination and at any speed for any interval during the mixing cycle. Adjustable scrapers attached to the wings of the anchor agitator physically contact the vessel surfaces for tighter temperature control and more enhanced product turnover. The saw-tooth disperser generates a vortex in the liquid surface for quick incorporation of solid ingredients and, along with the anchor, continues to agitate the batch when it becomes too thick to flow through the rotor/stator.
Ross Ultra-High Shear Mixers

Ophthalmic oil-in-water emulsions require sufficient agitation at elevated shear levels to achieve stability. When conventional rotor/stator devices fall short in producing the desired droplet size distribution, the next practical step is to utilize an Ultra-High Shear Mixer. Several designs are available including the Ross X-Series (US Patent No. 5,632,596), a unique inline rotor/stator engineered to run at tip speeds over 11,000 ft/min. It consists of concentric rows of intermeshing teeth; product enters at the center and moves outward through multiple channels. The extremely close tolerance between adjacent surfaces of the X-Series rotor and stator is adjustable for fine-tuning shear levels and flow rates. In many formulations, this Ultra-High Shear Mixer is proven to replace expensive colloid mills and high pressure homogenizers while producing better quality emulsions at much higher throughputs and requiring simpler maintenance.

For more information on Ross Mixers
Visit www.pharmaceuticalmixers.com or click here to download a brochure.