

Solutions for Your TOUGHEST
MIXING Applications in

PHARMACEUTICALS

Introduction

Manufacture of Ophthalmic

The Process

and Contact Lens Solutions

The Problem

The Solution

The Advantages



PHARMACEUTICALS

Manufacture of Ophthalmic and Contact Lens Solutions

Contact lens solutions include different products which perform a range of functions including cleaning, disinfecting, lubrication and rinsing. Ophthalmic solutions include safety eyewash and prescription preparations as well as “over the counter” medicinal products.

These solutions tend to have a similar base formulation: a saline solution (typically 5%) with a range of added ingredients according to the desired function. These include thickening agents, surfactants and active ingredients.

The Process

The process equipment must be capable of meeting the following requirements:

- The mixer must provide vigorous in-tank movement to incorporate light powders which tend to float, and to prevent salt granules from sinking to the bottom of the vessel.
- Some ingredients, (e.g. thickening agents and active ingredients) only make up a very small proportion of the formulation, but must be correctly dispersed and/or hydrated to obtain functionality.
- Many thickening agents are affected by salts, making it difficult to obtain functionality. This may be overcome by hydrating these ingredients before the salts are added, or by preparing them separately as a premix.
- The finished product is sterilized, typically by ultrafiltration. The solids must be fully solubilized and/or hydrated to ensure they are not removed during this process.

The Problem

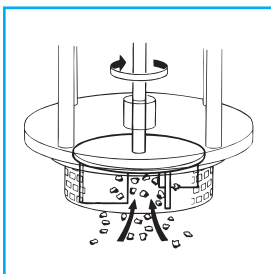
Preparing saline solutions is a fairly simple task which can be adequately carried out using a conventional agitator. However, several problems can be encountered:

- The process must be carried out in the most hygienic manner possible. Problems can arise with conventional systems as they tend to allow a build-up of partially hydrated powder on vessel walls and mixer shafts etc. raising potential hygiene issues.
- Stabilizers tend to form agglomerates which cannot be broken down by agitation.
- Long mixing times are required to fully hydrate and dissolve the solids. This can cause an undesired temperature rise, increasing the risk of bacterial contamination.

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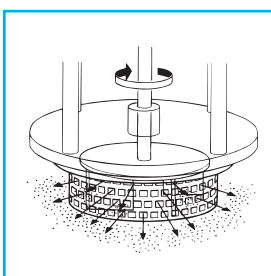
The Solution

These problems can be overcome and process times can be dramatically cut by using a Silverson High Shear Mixer. Operation is as follows:



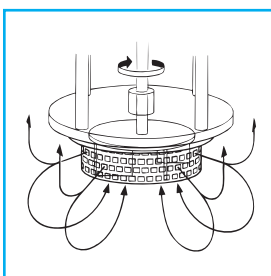
Stage 1

The vessel is charged with water. The mixer is started and the powders are added. The high speed rotation of the rotor creates a powerful suction which draws the liquid and solids upwards from the base of the vessel into the workhead.



Stage 2

Centrifugal force then drives the materials to the periphery of the workhead where they are subjected to a milling action in the gap between the rotor and stator, rapidly reducing granule size. The product is then forced out through the stator at great velocity as fresh material is drawn in.



Stage 3

Each pass through the workhead progressively reduces granule size and exposes an increasing surface area to the water, accelerating the solubilization of the salts, and ensuring that viscosity modifiers and active ingredients are fully dispersed and/or hydrated.

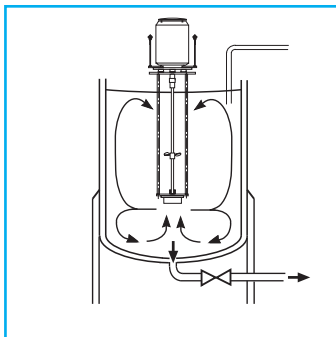
The Advantages

This offers a number of advantages:

- Reduced CIP requirements.
- Processing time is rapidly reduced.
- Rapid incorporation and wetting out of powders.
- Greatly improved product consistency and stability.
- Easy validation.

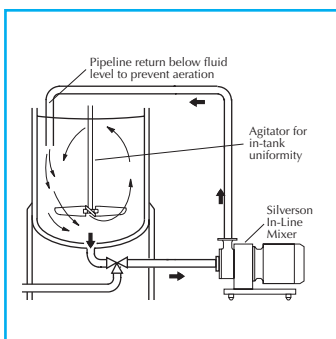
The batch size, formulation, and type of ingredients dictate which machine from the Silverson product line is most suitable, as shown overleaf:

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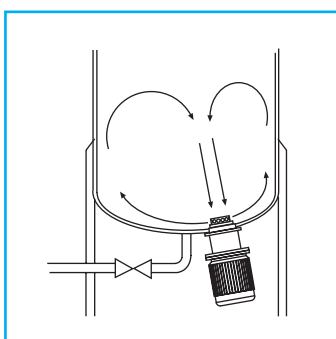
High Shear Batch Mixers.

- Suitable for batch sizes up to 400 gallons.
- Can be vessel mounted or used on mobile floor stands.
- Sealed units available for pressure/vacuum operation.
- Small units available for R&D and pilot production.
- Ultra Hygienic models available
- Can be supplied with FDA documentation



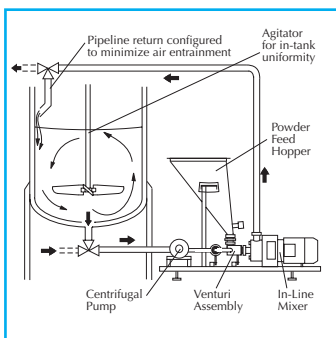
High Shear In-Line mixers.

- Ideal for larger batches
- Aeration-free
- Easily retro fitted to existing plant
- Self pumping
- Suitable for Cleaning In Place (CIP)
- Ultra Hygienic models available, suitable for Sterilization In Place (SIP)
- Can be supplied with FDA documentation



High Shear Bottom Entry mixers.

- Suitable for Cleaning In Place (CIP)
- Ultra Hygienic models available, suitable for Sterilization In Place (SIP)
- Can be supplied with FDA documentation



Flashblend.

- Ideal for larger batches
- Capable of rapidly incorporating large volumes of powder
- Minimized aeration
- Suitable for Cleaning In Place (CIP)
- Minimum operator input required
- Easily automated
- Ultra Hygienic models available, suitable for Sterilization In Place (SIP)
- Can be supplied with FDA documentation



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