

Solutions for Your TOUGHEST
MIXING Applications in

PHARMACEUTICALS

Introduction

Manufacture of

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Pharmaceutical Tablet

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Coatings

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The Advantages



PHARMACEUTICALS

Manufacture of Pharmaceutical Tablet Coatings

Pharmaceutical tablets are given a coating for a number of reasons:

- To improve the appearance and aid identification.
- To protect the tablet from moisture and other adverse conditions.
- To lubricate the tablet to ease swallowing.
- To disguise unpleasant tastes.
- To create a barrier between the active ingredient and the gastrointestinal tract.
- To control the release of drug into the body.

Coatings generally consist of a sugar or cellulose based binder, plasticizer, film forming agent and colorant. These are supplied in granulated or powder form for dispersion in aqueous or organic solvents at concentration varying from 10 -20% depending on the desired properties and formula.

The Process

A typical method of dispersion is as follows:

- The water/solvent is charged into the mixing vessel, with the mixer positioned off center to create a vortex.
- The dry ingredients are added and drawn into the vortex.
- Mixing continues until the ingredients are fully dissolved.
- The finished coating is applied to the tablets by spraying in coating pans.

In order to achieve the above, a number of processing factors must be considered:

- The mixer must be capable of circulating the entire contents of the vessel to ensure uniformity.
- A wide range of colors are used in tablet coatings, and batch sizes are generally small.
- Equipment must be easily cleaned and ideally adapted to be cleaned in place (CIP).
- The mixer must be capable of processing at ambient temperatures as some ingredients may be heat sensitive.

PHARM

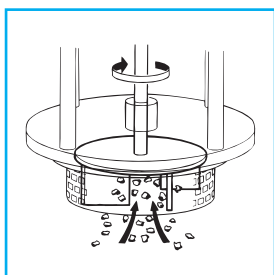
The Problem

Whilst many proprietary coatings are designed to be easily dispersed, a number of problems are frequently encountered when using conventional mixers and agitators:

- Conventional agitators cannot rapidly dissolve materials at ambient temperatures.
- Agitators are not capable of rapidly breaking down agglomerates.
- A low particle size is required in order to avoid clogging of the spraying apparatus.
- If the colorant is not properly dispersed, flecks of color can occur in the tablets.

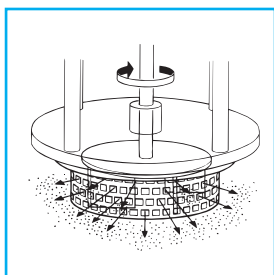
The Solution

A Silverson high shear mixer can overcome all of these manufacturing difficulties. The rotor/stator workhead is capable of dissolving sugar and dispersing cellulose type materials in a fraction of the time taken by conventional agitators, operating as follows:



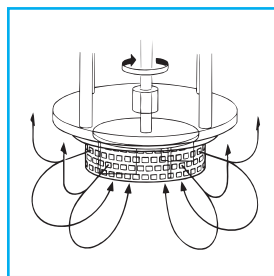
STAGE 1

The vessel is charged with the base liquid. The mixer is started and the coating granules and other ingredients are added. The high speed rotation of the rotor creates a powerful suction which draws the granulated or powdered coating material and liquid into the workhead. They are rapidly mixed and driven towards the periphery of the workhead by centrifugal force



STAGE 2

The granules are milled by the intense action provided by the rotor/stator workhead. Agglomerates are broken down and dispersed. The materials are then forced out through the stator into the body of the mix. Fresh liquid and powdered ingredients are drawn into the workhead.



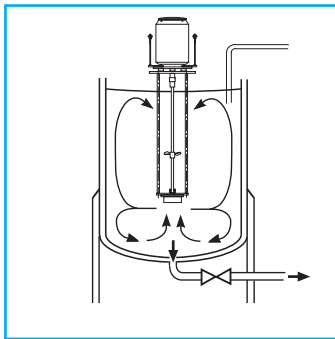
STAGE 3

This develops a circulatory pattern of mixing within the vessel which ensures that all material passes through the workhead many hundreds of times, quickly dissolving the granules into the liquid and progressively reducing the particle size. This is achieved without the need for raised temperatures.

The Advantages

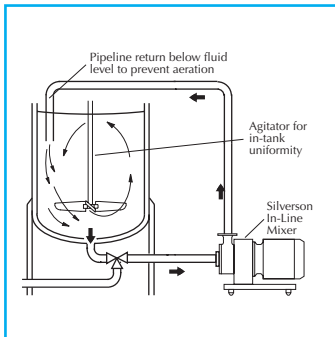
- Consistent product quality and repeatability.
- Agglomerate-free mix.
- Rapid mixing time.
- Maximized yield of raw materials as thickening agents are fully hydrated and other ingredients fully dispersed.

The batch size, formulation, type of ingredients and the viscosity of the end product dictate which machine from the Silverson product line is best suited to individual processing requirements:



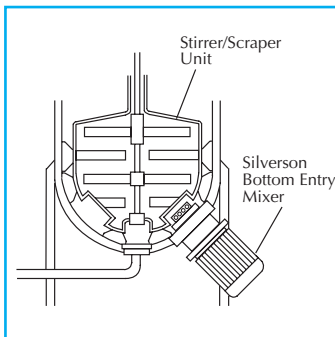
High Shear Batch Mixers.

- Suitable for batch sizes up to 400 gallons.
- Can be used on mobile floor stands.
- Sealed units available for pressure/vacuum operation.
- Small units available for R&D and pilot production.



High Shear In-Line mixers.

- Ideal for larger batches
- Aeration-free
- Easily retro fitted to existing plant
- Self pumping
- Can be used to discharge vessel
- Ultra Hygienic models available



High Shear Bottom Entry mixers.

- Suitable for use on high viscosity products in conjunction with an anchor stirrer/scraper
- Ultra Hygienic models available



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