

Solutions for Your TOUGHEST
MIXING Applications in

PHARMACEUTICALS

Introduction

Production of Cough

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Mixtures and

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Pharmaceutical Syrups

The Solution

The Advantages



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Production of Cough Mixtures and Pharmaceutical Syrups

Traditional cough mixtures are formulated around a syrup at 60-75% concentration which is made from sucrose, maltodextrin, glucose, invert syrup etc. The remainder is made up of thickening agents, stabilizers and active ingredients.

The Process

Manufacturers of cough mixtures generally produce their own syrups as this offers greater control of product quality. The manufacturing process must achieve several functions:

- Dissolving of the sugars to form a syrup
- Hydration of powdered ingredients
- Blending ingredients of widely different viscosity
- Suspension or dissolving of active ingredients
- The end product must be smooth, agglomerate-free and homogeneous.
- Equipment should conform to GMP standards

The Problem

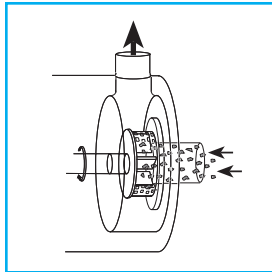
Using conventional mixers and agitators for this process leads to several potential problems:

- Conventional agitators cannot dissolve high concentrations of sugars at ambient temperature.
- Heating of the mixture will be required to aid solution. This is energy inefficient.
- The cooling process after this further adds to costs and process time.
- Crystallization of the syrup can occur during heating/cooling.
- Active ingredients can be damaged by heat.
- Thickening ingredients will form agglomerates which conventional equipment cannot disperse.

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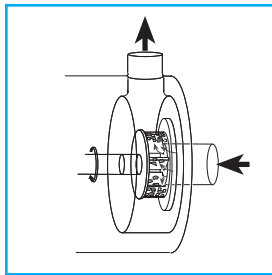
The Solution

These problems can be overcome by using a Silverson High Shear mixer. The 3 stage mixing cycle illustrated below allows the sugars and active ingredients to be dissolved at ambient temperatures:



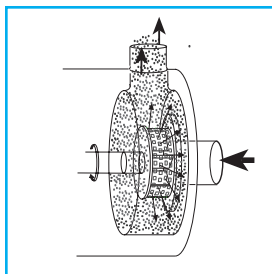
STAGE 1

The vessel is charged with liquid and the mixer is started. The powdered ingredients are added without prior heating of the liquid. The high speed rotation of the rotor blades creates a powerful suction which draws liquid and solid ingredients into the workhead and rapidly mixes them.



STAGE 2

The sugar granules are reduced in the gap between the rotors and stator wall. Increasing areas of powdered and solid ingredients are exposed to the surrounding liquid and dissolved. The active ingredients are similarly reduced to a low particle size and fully coated by the surrounding liquid. This creates a very fine and stable suspension.



STAGE 3

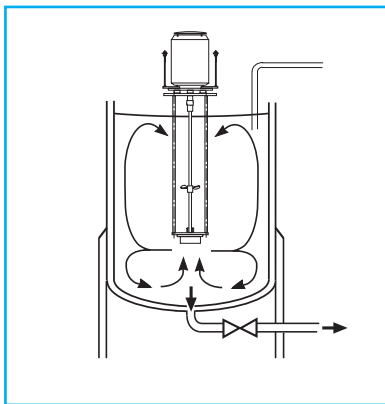
As the product is forced out through the stator, fresh powdered and liquid ingredients are drawn into the workhead and processed as before. A circulatory mixing pattern is set up within the vessel, ensuring all material is passed through the workhead many hundreds of times. A stable suspension of active ingredients is rapidly achieved.

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The Advantages

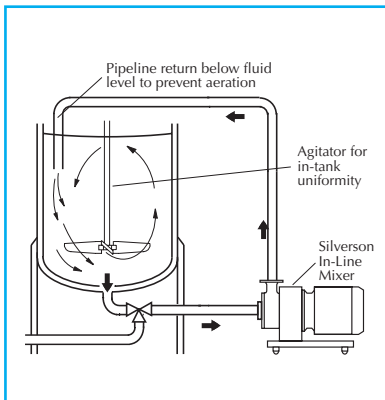
- A Silverson high shear mixer can produce 66% sucrose syrup at ambient temperature.
- The heat of dissolution is imparted in the form of shear
- Consistent product quality and repeatability is obtained.
- An agglomerate free mixture is produced

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 requirements:



High Shear Batch Mixers.

- Suitable for batch sizes up to 800 gallons.
- Smaller units 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



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Issue No. 3PA2

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