

Mixing system: Newmix®- Levtech® Jet-Drive™ system

Mixing bag: 5L custom A-Mix™ bag

Mixing type: Liquid-liquid

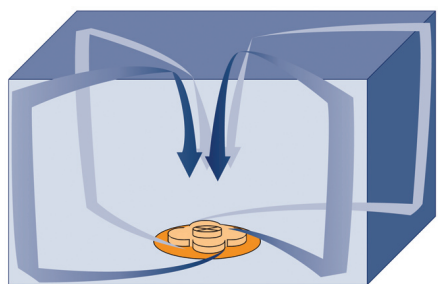
The Newmix-Levtech Jet-Drive system is one of the lightest and most compact disposable mixing systems. It consists of a cubical shaped disposable bag with a magnetically impelled turbine, secured to the bottom of the bag, working as a centrifugal pump.

The established 3D recirculation loop eliminates dead zones and ensures efficient and fast mixing.

Introduction

When mixing pharmaceutical materials, it is desirable to maintain the highest possible standards of cleanliness. All mixing technologies have the potential to add some particulate contamination, particularly at locations where friction is generated, such as the impeller. This study was performed to quantify the particle generation attributable to the Jet-Drive impeller under liquid-liquid mixing conditions.

In this experiment, a Jet-Drive impeller was used to mix water over an extended period of time, and the particle content of the water was monitored. A custom, small mixing bag was used in order to enhance particle sensitivity; results were then normalized to the equivalent of a standard 200L A-Mix bag.



A-Mix bag 3-D recirculation loop

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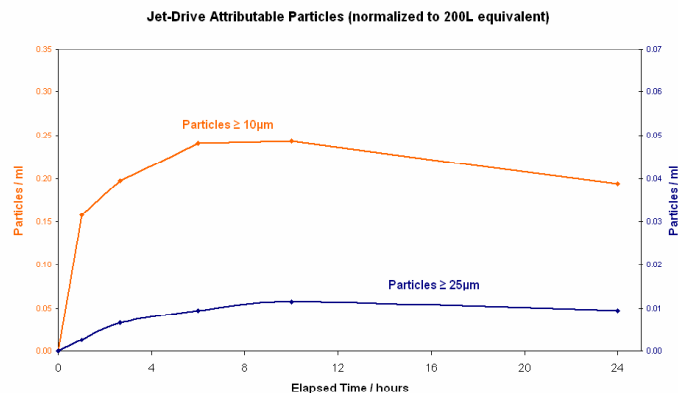
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Application note XA105E 0807rev2

Experimental

A 5L custom A-Mix bag was filled with 3L of Water For Injection (WFI), and the Jet-Drive impeller mixing speed set to 1000rpm. The mixer was operated for 24 hours, with periodic sampling of the mixed liquid. Samples were analyzed for liquid particle count at $\geq 10\mu\text{m}$ and $\geq 25\mu\text{m}$ particle sizes.



Results

The accompanying chart shows the particle generation over 24 hours, at both $\geq 10\mu\text{m}$ and $\geq 25\mu\text{m}$ particle sizes. Particles built up over the first 8 hours, then stabilized at 0.20 and 0.01 particles/ml respectively. These values are only about 1% of the maximum permitted particle level specified by the USP for WFI.

The particles observed were attributed to break-in of the impeller components, and are not expected to increase over longer mixing runs.

Conclusions

The Newmix-Levtech Jet-Drive system can be regarded as a low-particle mixing system. Particle generation after 24 hours of continuous mixing does not exceed USP WFI permissible levels.