

## Particle Generation in the Magnetic Mixer

Mixing system: Newmix®- Levtech® Magnetic Mixer

Mixing bag: Custom M-Mix vessel

Mixing type: Liquid-liquid

The Newmix-Levtech Magnetic Mixer is a compact and non-invasive single-use mixing system. The heart of this system is a mixing bag incorporating an innovative bottom-mounted magnetically-driven impeller capable of providing efficient high-torque mixing for all powder-liquid and liquid-liquid mixing applications. The impeller rides on a low-friction, inert bearing assembly designed to ensure low particle shedding while allowing mixing of very high powder loads in large liquid volumes. All product-contacting surfaces are 100% disposable.

## 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 Magnetic Mixer's impeller under liquid-liquid mixing conditions.

In this experiment, Magnetic Mixer impeller, MMIB001A, was used to mix water over an extended period of time, and the particle content of the water was monitored. The impeller was integrated into a custom, small mixing vessel in order to enhance particle sensitivity; results were then normalized to the equivalent of a standard 100L M-Mix bag.



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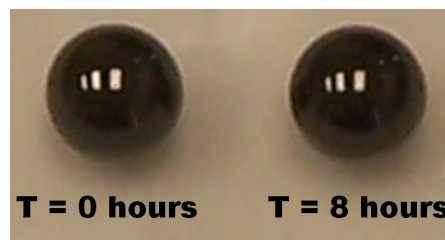
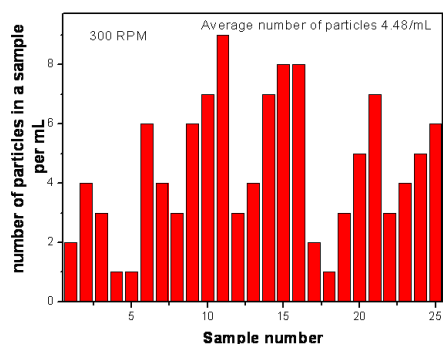
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## Experimental

The vessel was filled with 100mL of Water For Injection (WFI), and the Magnetic Mixer impeller mixing speed set to 300rpm. The mixer was operated for 8 hours, after which 25 aliquots of water were taken, and each analyzed for liquid particle count.



## Results

The accompanying chart shows the particle generation after 8 hours of mixing, normalized to the equivalent of a standard 100L M-Mix bag. The mean number of particles detected was less than 5 particles/mL, which is within USP guidelines for WFI. No particles greater than 10µm in size were observed.

The particles generated were attributed to slow wear of the impeller bearing race. As such, the particles are likely to be of the same USP Class VI material. After mixing for 8 hours, the bearing race was disassembled, and the bearings visually inspected for damage. As can be seen from the accompanying photograph, no significant wear was evident.

## Conclusions

The Newmix-Levtech Magnetic Mixer can be regarded as a low-particle mixing system. Particle generation after 8 hours of continuous mixing does not exceed USP WFI permissible levels.