



Application Note

USD 3030

Particle Generation in the Pall® Magnetic Mixer

Mixing system: Pall Magnetic Mixer

Mixing biocontainer: Custom Mixer vessel

Application mixing type: Liquid-liquid

The Pall Magnetic Mixer is a compact single-use mixing system. The heart of this system is a mixing biocontainer incorporating an innovative bottom-mounted magnetically-driven impeller capable of providing efficient high-torque mixing for 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 high powder loads in large liquid volumes.

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, a Magnetic Mixer 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 100 L M-Mix biocontainer.



Experimental

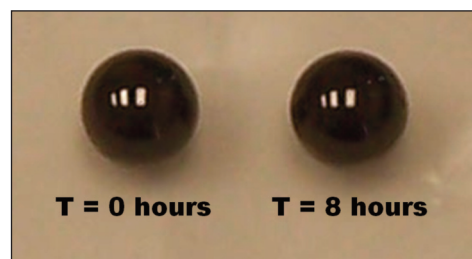
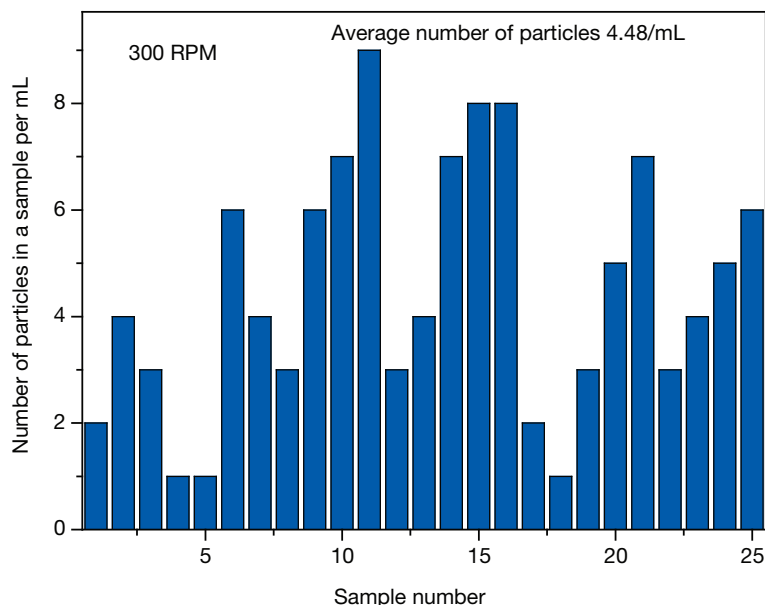
The vessel was filled with 100 mL of Water For Injection (WFI), and the Magnetic Mixer impeller mixing speed set to 300 rpm. The mixer was operated for 8 hours, after which 25 aliquots of water were taken, and each analyzed for liquid particle count.

Results

Figure 1 shows the particle generation after 8 hours of mixing, normalized to the equivalent of a standard 100 L M-Mix biocontainer. The mean number of particles detected was less than 5 particles/mL, which is within USP guidelines for WFI. No particles greater than 10 µm in size were observed.

The particles generated were attributed to slow wear of the impeller bearing race. 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.

Figure 1



Conclusions

The Pall 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.



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