

# Quadro Ytron®

## DUST-FREE MANUFACTURING OF RADIOGRAPHIC CONTRAST MEDIA

### BACKGROUND/REQUIREMENT

A U.S. based contract manufacturer of pharmaceutical products was investigating the scale-up of a powder wetting and mixing application. The product they manufacture is an injectable, radiographic contrast media used for X-ray diagnosis of circulatory problems around the heart and brain. The existing 350L batch production involves the manual addition of solids from drums via an open manway, in an agitated vessel. The solids are added slowly, to limit the amount of dusting and to prevent build-up on the vessel bottom, which slows down the dissolution of the solid material into the WFI water.

In scale-up to the larger 1500L batch size, the manufacturer wanted to address the slow addition of powder and dust contamination, without creating problems in the mix tank. It was anticipated that it would take approximately 12 hours via the current method of operation, to produce a 1500L batch.

### QUADRO'S APPROACH

To solve the manufacturer's problem, a Quadro Ytron® ZC1Q was recommended in recirculation with the mix tank. The ZC1Q is a ZC1 Mini-Skid System with an integrated Quadro Vac® and centrifugal feed pump. The ZC1Q was set up in recirculation with the 1500L batch tank and the existing turbine agitator. The integrated Quadro Ytron® ZC/Quadro Vac® System is comprised of a high-capacity powder hopper and filter separation cap mounted to the powder inlet of the Quadro Ytron® Mixer. A replaceable conical filter cap assembly is inserted into the top of the hopper by means of a quick-release clamp.

Powder transfer rates to the hopper are controlled by an integrated vacuum pump with a hopper-mounted powder level sensor controlling a vacuum relief valve. The vacuum pump generates enough air flow to transfer powder into the hopper. Once the powder is introduced into the Quadro Ytron® Dispenser prior to hydration, it is sheared into the liquid via close tolerance rotor-stator tooling, immediately dispersing the powder into a blended solution. A PD pump is then employed in order to transfer the mixed solution to its receiving vessel.

### SUMMARY

- The powders are conveyed from the drums by wanding and are readily dispersed into the WFI water without emitting dust into the processing area, thereby decreasing the amount of clean-up required, as well as product losses.
- Forty drums of powder are emptied during a 2 hour time-frame, with no additional mixing required in the vessel.
- The Customer reported a successful implementation with an efficient vacuum conveyed powder transfer via the Quadro Vac® and good CIP capability of the ZC Powder Dispenser.



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