

## Reconstitution – Pigmented or White (231U)

231 U formulas are the pigmented coating part of the Opadry® SGR, rapid sugar film coating system used to add a pigmented (or white) color. The other components (sold separately) include a bulk coating for rounding the tablet core, and a clear coat to produce the high gloss finish. Each component is quick and easy to prepare. Simply pour the Opadry SGR bulk powder into water and mix for 45 minutes with a propeller stirrer as described below.\* It is recommended that the 231U coating suspensions are reconstituted at 20% solids w/w and applied to a minimum weight gain of 4.2 – 5.6 mg/cm<sup>2</sup> (3-4%). Your Colorcon Area Technical Manager (ATM) can assist you to optimize the solid levels for this dispersion according to the atomizing capabilities of your equipment.

### MATERIALS

- OPADRY® SGR film coating system
- Water, deionized or distilled preferred, ambient temperature (maximum 30 °C)

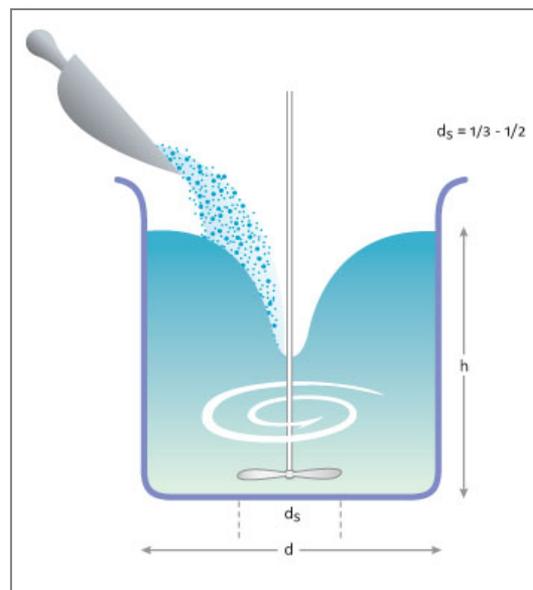
### EQUIPMENT

- Variable-speed mixer capable of producing and maintaining a vortex.
- Propeller stirrer with a diameter equivalent to 1/3 - 1/2 of the diameter of the mixing vessel. (Figure 1)
- Mixing vessel large enough to contain a liquid volume 15% to 25% greater than the total suspension being prepared. The liquid height should be equal to or greater than the vessel diameter.

### \*MIXING PROCEDURE

1. Weigh necessary quantity of water into the mixing vessel.
2. Weigh necessary quantity of OPADRY® SGR film coating system.
3. Place the propeller in the center and as close to the bottom of the vessel as possible. Stir the water to form a vortex without drawing air into the liquid. (Figure 1)
4. Steadily add the OPADRY® SGR powder to the vortex, avoiding powder flotation on the liquid surface. If required, increase the stirrer speed in order to maintain the vortex.
5. After all the OPADRY® SGR powder has been added, reduce the mixer speed to nearly eliminate the vortex.
6. Mix for 25 minutes.

Figure 1



## SUSPENSION HANDLING

The prepared OPADRY® SGR dispersion can be pumped directly from the preparation vessel if desired. We recommend that the Opadry SGR dispersion be gently agitated during the coating process.

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