

Preparation and Use Guidelines

Sureteric® is a complete aqueous film coating formulation developed to meet the delayed release coating needs of solid oral dosage forms in the pharmaceutical industry. Sureteric is designed for easy preparation, processing and clean up. General use and preparation guidelines are provided in this information sheet

To ensure enteric protection a three-step coating process is recommended.

1. Subcoat: Opadry® or Opadry II

- Provides a uniform coating surface, reducing the effect of possible substrate imperfections.
- 1 to 2% weight gain of Opadry/Opadry II (formulas Y-1-7000, YS-1-7003, 03K19229 or Y-30-18037) have provided adequate results.

2. Delayed Release Coating: Sureteric

- Sureteric is reconstituted to a 15% solids suspension.
- 8 to 10% weight gain is recommended for enteric protection.

3. Topcoat: Opadry/Opadry II

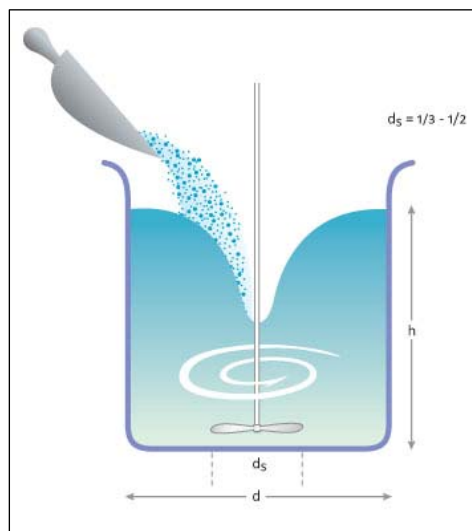
- Opadry/Opadry II formulations provide a protective clear gloss or custom color coating.
- 0.5 to 1.0% weight gain for a clear coat.
- 2 to 3.5% weight gain for a custom color coat.

MATERIALS

- Sureteric formulated powder.
- Cold purified water, maximum temperature 30°C.
- Antifoam emulsion - Dow Corning 30% Simethicone USP (7-9245) or equivalent used at 0.33% of Sureteric solids.

EQUIPMENT

- Variable speed mixer capable of producing and maintaining a vigorous vortex.
- High efficiency propeller stirrer with diameter equivalent to 25-30% of the diameter of the mixing vessel.
- Mixing vessel to contain a liquid volume 20% greater than the total suspension being prepared. (This is to accommodate the initial foam generated with the addition of the Sureteric powder.) 250 micron (60 mesh) sieve.



MIXING PROCEDURE

1. Determine the amount of Sureteric, antifoam emulsion (0.33% of Sureteric solids) and water required based on the quantity of tablets to be coated and the target coating weight.

Example *

To coat 10 kg of tablets at a 10% weight gain

1000.0g Sureteric

5685.6 g water

3.3g antifoam emulsion

2. Weigh the water into the mixing vessel.
3. Using the propeller stirrer, stir the water to form a vigorous vortex.
4. Weigh the antifoam and add to the water.
5. Weigh the Sureteric and add to the vortex in a slow steady stream while maintaining a vigorous vortex. An increase in volume of the suspension and some foaming will occur initially, but will subside rapidly.
6. Reduce mixer speed to low and continue to mix for 30-45 minutes. The suspension must be continuously mixed at low speed throughout the coating process.
7. Pass the suspension through a 250 micron sieve prior to use or use an in-line filter during the coating process.
8. The suspension should be used the same day it is prepared. Colorcon's microbial data shows suspension stability of up to 72 hours.

SURETERIC CLEAN UP GUIDELINES

- For best results, Sureteric should be cleaned off equipment shortly after the end of the coating run. If the product is allowed to dry, the residual film can be difficult to remove.
- If cleaned properly, Sureteric residue is easily removed using a mild sodium bicarbonate solution. Sodium Bicarbonate (NaHCO_3) is regarded essentially as a non-toxic and non irritating material. It is GRAS listed and has compendial status within the USP, BP, JP, and PhEur.

Cleaning Exposed Surfaces

- Prepare a solution of 10% sodium bicarbonate and water.
- Spray this solution onto the surfaces to be cleaned. Heavier residue areas can be treated directly with the sodium bicarbonate powder.
- Wait 3-5 minutes for the solution to settle on the sprayed surfaces.
- Rinse the sprayed surfaces with deionized water until clean.

Coating Pans

- Coating pans can be cleaned with the same 10% solution of sodium bicarbonate and water.
- Fill the reservoir with the pre-mixed solution and allow the pan to rotate through the solution for 30 minutes.

Spray Equipment

- Spray equipment (guns and hoses) should be disassembled and cleaned.
- When cleaning spray guns, it is important to make sure the passages are free of residual coating material that can block the orifice and restrict flow.
- A thin soft brush or swab can be passed through the tip of the gun to ensure all the coating material is removed. Avoid using hard substances because these can damage the gun parts.

All equipment should be rinsed with deionized water after cleaning.

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