OPADRY® Enteric

Product Information

Formulated for Solvent Coating

Polyvinyl Acetate Phthalate (PVAP):

Preparation & Use Guidelines

Opadry Enteric is a family of fully-formulated, delayed release coating systems for solid oral dosage forms, applied by hydro-alcoholic processing techniques.

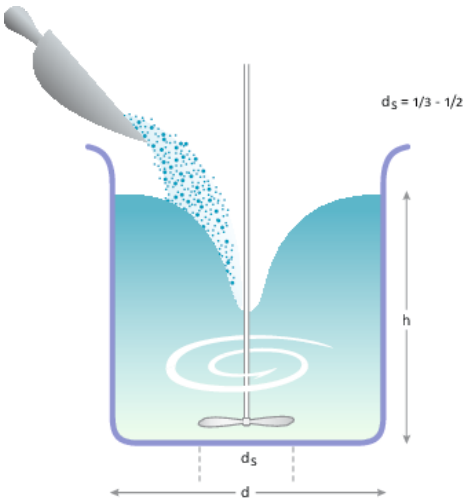
MATERIALS

- Opadry Enteric film coating system
- Hydro-alcoholic solvent system (see note below)

EQUIPMENT

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

Figure 1



SOLVENT SELECTION

The following solvent systems can be used with Opadry Enteric. The criteria which may be useful in selecting a solvent system have been evaluated and are listed below.

Solvent System	Dispersion Viscosity (cp)
Hydro-alcoholic Solvent Systems	
Methanol: water (9:1)	14.2
Isopropanol: water (8:2)	22.0

**Solvent mixtures by weight

Note: The choice of solvents depends on specific country regulations and local policies. Follow all solvent manufacturer recommendations and associated Material Safety Data Sheets for the safe handling practices for your solvent of choice.

MIXING PROCEDURE

- Determine the amount of Opadry Enteric and solvents required; based on the quantity of tablets to be coated, target coating weight, and solvent system used.
- Weigh the solvents into the mixing vessel.
- Using a propeller stirrer, stir the solvent to form a vortex.
- Weigh the Opadry Enteric and add to the center of the liquid vortex in a slow steady stream, avoiding clumping and maintaining a vortex.
- After all the Opadry Enteric has been added, reduce the stirrer speed until the vortex is just eliminated.
- Continue stirring for at least 45 minutes after which time the dispersion will be ready for coating.
- Ensure the dispersion is gently stirred during the coating process.

USE GUIDELINES

- Opadry Enteric can be reconstituted up to 15% solids using a hydro-alcoholic solvent system; while a 5-8% coating solids content is recommended for an organic solvent system.
- The coating system can be pigmented to meet marketing requirements and is also available as a clear enteric coating system.
- Recommended coating weight gains of Opadry Enteric are 6-8% for delayed release performance, depending on the physicochemical properties of the core tablets. The actual weight gain required for a specific application should be determined by conducting laboratory coating trials.
- A sub-coat may be required to separate the active pharmaceutical ingredient from the enteric polymer, or to strengthen the dosage form prior to enteric coating. A recommended sub-coat is Opadry YS-1-7027 White. The sub-coat can be applied using either an aqueous or an organic solvent system.
- A clear (or colored) Opadry top-coat is recommended at 1-2% weight gain to prevent the tablets from sticking to each other upon bulk storage.

CLEAN UP GUIDELINES

For best results, clean equipment shortly after the end of the coating run.

- Opadry Enteric residue remaining on the coating equipment can easily be removed using a mild (greater than pH 6.0) sodium bicarbonate solution. Sodium bicarbonate ($NaHCO_3$) is regarded as an essentially nontoxic and non-irritant material. Additionally, it is GRAS listed and has compendia status within the USP, BP, JP and PHEur.
- Coating pans can be cleaned with a solution of $NaHCO_3$ and deionized water. If equipped, fill the pan reservoir with cleaning solution and allow the pan to rotate through the solution for 30 minutes.
- Spray equipment (guns and hoses) should be disassembled and can be soaked in the cleaning solution for 30 minutes.
- 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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