

Opadry[®] Enteric – 94 Series: Preparation & Use Guidelines

Opadry Enteric, acrylic-based coating system, is a fully-formulated, delayed release coating system for solid oral dosage forms. The 94 series of Opadry Enteric Systems are formulated using methacrylic acid copolymer Type A (Methacrylic acid- methyl methacrylate 1:1 copolymer), which provides consistent gastro resistance and reproducible drug release.

PREPARATION GUIDELINES

Solvent Selection

- Recommended solvent system is alcohol₁/water mixture. Recommended alcoholic content in the solvent mixture is 80-95% by weight.

₁ = Ethanol or isopropanol

Materials

- Opadry Enteric film coating system
- Hydro-alcoholic solvent system

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.

Equipment requirements

- Variable-speed mixer capable of producing and maintaining a vortex
- Mixing vessel suitable to contain a liquid volume 15-25% greater than the total suspension being prepared

Mixing Procedure

- Opadry Enteric can be reconstituted up to 10% solids using a hydro-alcoholic solvent system. Solids level may vary depending on the solvent system used.
- Determine the amount of Opadry Enteric and solvents required, based on the quantity of tablets to be coated and the target coating weight gain.
- 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.

Example

To coat a batch of 10 kg tablets to a 6% weight gain

HYDRO-ALCOHOLIC SOLVENT SYSTEM

(10% coating solids)

- 600 g Opadry Enteric
- 5400 g Solvent (mixture)

USE GUIDELINES

- Recommended coating weight gains of Opadry Enteric may be in a range of 6-9% for suitable delayed release performance, depending on the physicochemical properties of the core tablets. The actual weight gain required for a specific application will need to be determined by conducting laboratory coating trials.
- A seal-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 seal-coat is Opadry 03K19229 Clear. It can be applied using either an aqueous, hydro-alcoholic or an organic solvent system.
- A clear (or pigmented) Opadry top-coat at 1-2% weight gain may be applied to impart added gloss, color or to aid in printing.

Opadry Enteric 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 be easily removed using a mild (greater than pH 6.0) sodium bicarbonate (NaHCO₃) solution (10% w/v). Sodium Bicarbonate is regarded as an essentially non-toxic 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.

Please contact your Colorcon Technical Representative if you require any further information.

For more information, contact your Colorcon representative or call:

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