# OPADRY®Enteric

Product Information

Acrylic-Based Coating

## Opadry® Enteric - 91 Series: Preparation & Use Guidelines

Opadry Enteric is a family of fully-formulated, delayed release coating systems for solid oral dosage forms, applied by organic or hydro-alcoholic processing techniques. The 91 Series of Opadry Enteric is a fully formulated delayed release system using Polyvinyl Acetate Phthalate (PVAP, Phthalavin).

### USE GUIDELINES – 91 SERIES

- 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 yet is also available as a clear enteric coating system.
- Recommended coating weight gains of Opadry Enteric are 6-8 % 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 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.

### PREPARATION GUIDELINES – 91 SERIES

**Materials**

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

### SOLVENT SELECTION – 91 SERIES

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

| Solvent System | Enteric Performance | Coated Product Appearance | Dispersion Viscosity (cp) |
|---|---|---|---|
| *ORGANIC SOLVENT SYSTEMS* | | | |
| Isopropanol: dichloromethane (6:4) | Good | High gloss | 3.17 |
| Methanol: dichloromethane (6:4) | Good | No gloss | 2.03 |
| *HYDROALCOHOLIC SOLVENT SYSTEMS* | | | |
| Methanol: water (9:1) | Good | No gloss | 14.2 |
| Isopropanol: water (8:2) | Good | High gloss | 22.0 |

**Solvent mixtures by weight

## EQUIPMENT – 91 SERIES

- 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 – 91 SERIES

- Determine the amount of Opadry Enteric and solvents required, based on the quantity of tablets to be coated, the target coating weight, and the 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.

**Example:**

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

**Hydro-Alcoholic Solvent System (15% coating solids)**

- 600g Opadry Enteric
- 3400g Solvent mixture

**Organic Solvent System (6% coating solids)**

- 600g Opadry Enteric
- 9400g Solvent mixture

### OPADRY ENTERIC CLEAN UP GUIDELINES – 91 SERIES

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 5.5) sodium bicarbonate solution. Sodium bicarbonate ($NaHCO_3$) is regarded as an essentially nontoxic and non-irritant material
- 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.

The responsibility for choice of solvents lies with the end-user to confirm specific country regulations prior to use. Follow all solvent manufacturer recommendations and associated Material Safety Data Sheets for the safe handling practices for your solvent of choice.

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



For more information, contact your Colorcon representative or call:

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You can also visit our website at **www.colorcon.com**



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