



# OPADRY<sup>®</sup> ENTERIC

FORMULATED FOR ORGANIC SOLVENT COATING

Technical Data Sheet  
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 subcoat 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 subcoat is Opadry YS-1-7027 White. The subcoat 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	Appearance of coated product	Viscosity of coating dispersion (cp)
<b>ORGANIC SOLVENT SYSTEMS</b>			
Isopropanol: dichloromethane ( 6:4)	Good	High gloss	3.17
Methanol: dichloromethane ( 6:4)	Good	No gloss	2.03
<b>HYDROALCOHOLIC SOLVENT SYSTEMS</b>			
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 ( $\text{NaHCO}_3$ ) is regarded as an essentially non-toxic and non-irritant material
- Coating pans can be cleaned with a solution of  $\text{NaHCO}_3$  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 deionised 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.

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Indianapolis, Indiana	317-545-6211	317-545-6218	Nishiyama, Japan	81-5-4465-2711	81-5-4465-2730
Humacao, Puerto Rico	787-852-3815	787-852-0030	Shanghai, China	86-21-5442-2222	86-21-5442-2229
Quebec, Canada	514-337-8341	514-337-9159	Goa, India	91-832-288-3434	91-832-288-3440
			Seoul, Korea	82-2-2057-2713	82-2-2057-2179
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Dartford, Kent, England	44-1322-293000	44-1322-627200	Buenos Aires, Argentina	54-11-4552-1565	54-11-4552-3997
Bougival, France	33-1-3082-1582	33-1-3082-7879	Cotia, Brasil	55-11-4612-4262	55-11-4612-3307
Idstein, Germany	49-6126-9961-0	49-6126-9961-11	Bogota, Colombia	571-418-1202	571-418-1257
Gallarate, Italy	39-0331-776932	39-0331-776831	Santa Fe, Mexico	525-5-3000-5700	525-5-3000-5701
Budapest, Hungary	36-1-200-8000	36-1-200-8010	Caracas, Venezuela	58-212-442-4819	58-212-442-8724
Barcelona, Spain	34-9-3589-3756	34-9-3589-3792			
Istanbul, Turkey	90-216-465-0360	90-216-465-0361			

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