## **Product Information**

# OPADRY®**Enteric**

Acrylic-Based Coating System - 91 Series

Opadry<sup>®</sup> Enteric is a family of fully-formulated, delayed release coating systems for solid oral dosage forms, applied by organic or hydro-alcoholic processing techniques.

Specific Opadry Enteric coating formulations have been developed from a choice of enteric polymers, with solubility as a function of the environmental pH in the gastro-intestinal tract. The various Opadry Enteric products available from Colorcon are listed below along with the constituent enteric polymer and pH at which the system starts to dissolve.

Opadry Enteric Type	Polymer	Polymer Dissolution pH
91 series	Polyvinyl Acetate Phthalate	pH 5.0
94 series	Methacrylic Acid	pH 6.0
95 series	Methacrylic Acid	pH 7.0

### **OPADRY ENTERIC - 91 SERIES**

Opadry Enteric - 91 series is a fully formulated delayed release system using Polyvinyl Acetate Phthalate NF (PVAP, Phthalavin).

Features	Benefits
Fully formulated system	Time and cost savings
Less susceptible to hydrolysis than other phthalate	Stable product (12 months re-evaluation period*)
esters such as CAP or HPMCP1	Produces elegant glossy coatings while
Solvents such as Isopropanol: dichloromethane	exhibiting excellent enteric protection
(60:40) and Isopropanol: water (80:20) are	Allows rapid coating application
recommended	Provides rapid, reproducible drug release in
High coating solids concentration (15% coating solids)	alkaline dissolution media.
using a hydro-alcoholic solvent system; 5-8% solids is	
recommended for an organic solvent system)	
Pigmented or clear systems are available	
Simple to dispense and disperse in solvent systems	
(45 minutes at low shear)	
Enteric protection is achieved with 6-8% coating	
weight gain**	
Polymer dissolves at pH 5.0 and above	



#### Regulatory

- Acceptable for use in pharmaceutical enteric coatings in the U.S., Europe and many other countries. Not
  acceptable for use in dietary supplement coatings in the U.S. and Europe.
- Currently no precedence of use for PVAP in Japan exists for pharmaceutical or dietary supplement coatings.

## **Applications**

Tablets, soft-gelatin capsules, hard gelatin capsules and multiparticulates.

#### **Packaging**

25 kg carton with double polyethylene bags and desiccant between bags.

## **Recommended Storage Conditions**

- Seal container tightly
- Keep below 30°C/86°F
- Avoid high humidity

#### Re-evaluation Period (Warranty)

- 12 months from date of manufacture\*
- \* May vary based on pigment selection.
- \*\* To be determined on a case-by-case basis.

#### References

1. Hogan, J. E. (1995). Modified Release Coatings. In: G. Cole (Ed.) *Pharmaceutical Coating Technology* (p. 435). Taylor & Francis Ltd, London, United Kingdom.

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