



OPADRY[®] ENTERIC

FORMULATED FOR ORGANIC SOLVENT COATING



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.

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 and Benefits

Features	Benefits
<ul style="list-style-type: none"> ▪ Fully formulated system ▪ Less susceptible to hydrolysis than other phthalate esters such as CAP or HPMCP¹ ▪ Solvents such as Isopropanol: dichloromethane (60:40) and Isopropanol: water (80:20) are recommended ▪ High coating solids concentration (15% coating solids using a hydroalcoholic 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 	<ul style="list-style-type: none"> ▪ Time and cost savings ▪ Stable product (12 months re-evaluation period*) ▪ Produces elegant glossy coatings while exhibiting excellent enteric protection ▪ Allows rapid coating application ▪ Provides rapid, reproducible drug release in alkaline dissolution media.

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.

World Headquarters

Colorcon

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Locations	Telephone	Facsimile	Locations	Telephone	Facsimile
<i>United States</i>			<i>Asia/Pacific</i>		
Santa Ana, California	714-549-0631	714-549-4921	Singapore	65-6438-0318	65-6438-0178
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
<i>Europe</i>			<i>Latin America</i>		
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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