OPADRY®ENTERIC

Acrylic-Based Coating

Opadry® Enteric Product Information

Opadry Enteric is a family of fully formulated, delayed release coating systems for solid oral dosage forms, which are 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	Polymer	Polymer Dissolution pH
91 series	Polyvinyl Acetate Phthalate (PVAP)	pH 5.0
94 series	Methacrylic Acid Copolymer (Methacrylic acid-methyl methacrylate 1:1 copolymer)	pH 6.0
95 series	Methacrylic Acid Copolymer (Methacrylic acid-methyl methacrylate 1:2 copolymer)	pH 7.0

OPADRY ENTERIC - 91 SERIES

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

Features	Benefits
▪ Fully formulated system ▪ Less susceptible to hydrolysis ▪ High coating solids concentration (15% coating solids using a hydro-alcoholic solvent system; 5-8% coating solids for an organic solvent system) ▪ Pigmented or clear systems are available ▪ Simple to dispense and dispense in solvent systems (45 minutes at low shear) ▪ Enteric protection is achieved with 6-8% coating weight gain on tablets** ▪ Polymer start to dissolve at pH 5.0 above	▪ Time and cost savings ▪ Stable produce (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. and other countries that accept NF compliance. Not acceptable for use in dietary supplement coatings in the U.S.
- 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 multi-particulates.

Packaging

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

Recommended Storage Conditions

- Seal container tightly.
- Keep below 30°C / 80°F; not more than 65% relative humidity. Product packaging contains desiccant.

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.

OPADRY ENTERIC - 94 SERIES

Opadry Enteric- 94series is formulated using the delayed-release polymer

Methacrylic Acid Copolymer, Type A USP/ NF

Methacrylic Acid- Methyl Methacrylate Copolymer (1:1) Ph. Eur

Methacrylic Acid Copolymer L JPE

Features	Benefits
Fully formulated system Non-tacky Hydro-alcoholic solvents are recommended Pigmented or clear systems are available Simple to dispense and disperse in solvent systems (45 minutes at low shear) Enteric protection is achieved with 5-6% coating weight gain on tablets** Polymer start to dissolve at pH 6.0 and above Methacrylic acid copolymers have excellent stability against hydrolysis	Time and cost savings Processing ease Allows rapid coating application Produces elegant glossy coatings while exhibiting excellent enteric protection Provides rapid, reproducible drug release in alkaline dissolution media. Stable product (12 months re-evaluation period*)

Regulatory

- Acceptable for use in pharmaceutical enteric coatings in the U.S. and other countries that accept NF compliance.
- Not acceptable for use in dietary supplement coatings in the U.S.

Applications

- Tablets, soft-gelatin capsules, hard-gelatin capsules and multi-particulates.

Packaging

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

Recommended Storage Conditions

- Seal container tightly.
- Keep below 30°C / 86°F; not more than 65% relative humidity. Product packaging contains desiccant.

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). London: Taylor & Francis Ltd.

2. Lehmann, K. (1997). Polymethacrylate Coating Systems. In: McGinity J (Ed.) *Aqueous Polymeric Coatings for Pharmaceutical Dosage Forms* (p.136) New York: Marcel Dekker Inc.

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

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