

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 |
|---|---|
| <ul style="list-style-type: none"> ▪ 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 | <ul style="list-style-type: none"> ▪ 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 | Time and cost savings |
| Non-tacky | Processing ease |
| Hydro-alcoholic solvents are recommended | Allows rapid coating application |
| Pigmented or clear systems are available | Produces elegant glossy coatings while exhibiting excellent enteric protection |
| Simple to dispense and disperse in solvent systems (45 minutes at low shear) | Provides rapid, reproducible drug release in alkaline dissolution media. |
| Enteric protection is achieved with 5-6% coating weight gain on tablets** | Stable product (12 months re-evaluation period*) |
| Polymer start to dissolve at pH 6.0 and above | |
| Methacrylic acid copolymers have excellent stability against hydrolysis | |

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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