

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.

Polymer	Polymer Dissolution pH
Polyvinyl Acetate Phthalate (PVAP)	pH 5.0
Hypromellose Phthalate (HPMC-P)	pH 5.5
Methacrylic Acid Copolymer (Methacrylic acid-methyl methacrylate 1:1 copolymer)	pH 6.0

Applications

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

OPADRY ENTERIC - Polyvinyl Acetate Phthalate

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

Features	Benefits
<ul style="list-style-type: none">Fully formulated systemPigmented and clear systems are available	<p>Time and cost savings</p> <p>Ability to differentiate product for improved patient safety and brand recognition</p> <p>Produces elegant glossy coatings while exhibiting excellent enteric protection</p>
<ul style="list-style-type: none">High coating solids concentration (15% coating solids using a hydro-alcoholic solvent system; 5-8% solids is recommended for an organic solvent system)	<p>Allows rapid coating application</p>
<ul style="list-style-type: none">Simple to dispense and disperse in solvent systems (45 minutes at low shear)<ul style="list-style-type: none">Solvents such as Methanol: Water (90:10) and Isopropanol : water (80:20) are recommended	<p>Easy and quick preparation</p>
<ul style="list-style-type: none">Less susceptible to hydrolysis	<p>Stable product (12 month re-evaluation date*)</p>
<ul style="list-style-type: none">Enteric protection is achieved with 6-8% coating weight gain**	<p>Reliable performance; Provides rapid, reproducible drug release in alkaline dissolution media</p>
<ul style="list-style-type: none">Polymer dissolves at pH 5.0 and above	

*May vary based on pigment selection

**Typical results, can be optimized on a case-by-case basis

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.

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*

OPADRY ENTERIC - Hypromellose Phthalate

Opadry Enteric is formulated using the delayed-release polymer Hypromellose Phthalate (HPMC-P).

Features	Benefits
<ul style="list-style-type: none">Fully formulated systemPigmented and clear systems are available	<p>Time and cost savings</p> <p>Ability to differentiate product for improved patient safety and brand recognition</p> <p>Produces elegant glossy coatings while exhibiting excellent enteric protection</p>
<ul style="list-style-type: none">High coating solids concentration (12.5% coating solids using a hydro-alcoholic solvent system)Simple to dispense and disperse in solvent systems (45 minutes at low shear)<ul style="list-style-type: none">Solvents such as Ethanol: water (80:20) are recommended	<p>Allows rapid coating application</p> <p>Easy and quick preparation</p>
<ul style="list-style-type: none">Less susceptible to hydrolysisEnteric protection is achieved with 8-10% coating weight gain**Polymer dissolves at pH 5.5 and above	<p>Stable product (12 month re-evaluation date*)</p> <p>Reliable performance; Provides rapid, reproducible drug release in alkaline dissolution media</p>

*May vary based on pigment selection

**Typical results, can be optimized on a case-by-case basis

Regulatory

- Acceptable for use in pharmaceutical enteric coatings in the U.S., Europe, Japan, China, India and many other countries. Not acceptable for use in dietary supplement coatings in the U.S. and Europe.

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*

OPADRY ENTERIC - Methacrylic Acid Copolymer Type A

Opadry Enteric 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
<ul style="list-style-type: none">Fully formulated systemPigmented and clear systems are available	<p>Time and cost savings</p> <p>Ability to differentiate product for improved patient safety and brand recognition</p> <p>Produces elegant glossy coatings while exhibiting excellent enteric protection</p>
<ul style="list-style-type: none">High coating solids concentration (15% coating solids using a hydro-alcoholic solvent system; 5-8% solids is recommended for an organic solvent system)	<p>Allows rapid coating application</p>
<ul style="list-style-type: none">Simple to dispense and disperse in solvent systems (45 minutes at low shear)<ul style="list-style-type: none">Solvents such as Ethanol : water (85:15) and Isopropanol : water (80:20) are recommended	<p>Easy and quick preparation</p>
<ul style="list-style-type: none">Excellent stability against hydrolysisEnteric protection is achieved with 5-6% coating weight gain**Polymer dissolves at pH 6.0 and above	<p>Stable product (12 month re-evaluation date*)</p> <p>Reliable performance; Provides rapid, reproducible drug release in alkaline dissolution media</p>

*May vary based on pigment selection

**Typical results, can be optimized on a case-by-case basis

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.

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*

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