

OPADRY[®] ENTERIC

FORMULATED FOR SOLVENT COATING



A complete line of delayed release coating systems, based on phthalate or acrylic polymer technology.

Enteric film coatings are commonly used to protect acid labile drugs from the acidic environment of the stomach and/or to protect the stomach from irritant drugs.

Enteric protection may also be employed as a product enhancement or a life cycle extension strategy by improving patient acceptability, dosage compliance and clinical effectiveness. Nonaqueous enteric coating systems are utilized due to the moisture sensitivity of many active molecules.

Opadry® Enteric is a fully formulated dry powder coating system for rapid reconstitution, providing an efficient means of applying delayed release coatings.

Phthalate and Acrylic Polymers Provide Confidence in Use

- Polyvinyl acetate phthalate (PVAP), hypromellose phthalate (HPMC-P), and methacrylic acid copolymer (L 100) have a long history of use (>40 years) in pharmaceutical systems
- Established use with a wide range of active ingredients and excipients
- Resistant to hydrolysis, affords long term product stability
- USP/NF compliance confers acceptability in majority of countries

Complete, Color Matched, Dry Powder Coating System

- Efficient inventory management, quality control, weighing and dispensing
- Available in colored, white, and clear options
- Batch-to-batch color guarantee, no color adjustment required
- Easy to prepare single component mixture, without the need for high shear mixing

Nonaqueous or Hydro-Alcoholic Solvent Systems

- Can be used with highly moisture-sensitive materials
- Fast coating times are possible
- Hydro-alcoholic option enables safer suspension handling and easy solvent vapor recovery
- Can be rapidly applied using many types of coating equipment, including conventional pans
- Enteric protection achieved at low weight gain (typically 5-8%) on suitable substrates

Polymer Properties

- High film strength and adhesion minimizes common coating defects such as cracking, peeling and logo bridging
- Combination of high film strength and low solution viscosity provides tough, glossy and attractive finished product appearance
- Reliable enteric protection with solubilization above trigger pH (PVAP = pH 5; HPMC-P = pH 5.5; L100 = pH 6)
- Can be applied to many types of oral solid dosage forms including tablets, capsules and multiparticulates

Save Time in Modified Release Formulation Development by Consulting Colorcon

- Consultation on product formulation, process optimization, and cost savings identification
- Regulatory support for film coating materials and excipients

Full supporting product and applications literature is available through the Colorcon website.

Contact your Colorcon representative or call:

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You can also visit our website at

www.colorcon.com

Deliver high-performance products — with Colorcon

Choose Colorcon, leader in pharmaceutical solid oral dose solutions, as a formulation partner in every phase of your product development. Our solution capabilities originate from two main areas of expertise:

Formulation Technologies:

- Full range of functional excipients
- Technologies for development and production of delayed/enteric release and extended/controlled release tablets and multiparticulates
- HyperStart® service and extensive applications data to provide starting formulations to save you development time and money
- Extensive formulation know-how and technical support to achieve the exact drug release profile desired

Film Coatings:

- Optimized formulations specifically for your application and regulatory needs including customized colors and color matching
- Innovative products for mechanical integrity, gloss, pearlescence, and environmental protection
- Brand enhancement concepts, consulting and services to build a strong brand image and stand out from the competition

From formulation and tablet design through product differentiation and branding, Colorcon gives you everything you need to deliver high-performance products.



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