

OPADRY[®] Enteric

Product Information

Acrylic-Based Coating System – 91 Series

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	Benefits
<ul style="list-style-type: none">Fully formulated systemLess susceptible to hydrolysis than other phthalate esters such as CAP or HPMCP1Solvents such as Isopropanol: dichloromethane (60:40) and Isopropanol: water (80:20) are recommendedHigh coating solids concentration (15% coating solids using a hydro-alcoholic solvent system; 5-8% solids is recommended for an organic solvent system)Pigmented or clear systems are availableSimple 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 savingsStable product (12 months re-evaluation period*)Produces elegant glossy coatings while exhibiting excellent enteric protectionAllows rapid coating applicationProvides 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.

The information contained herein, to the best of Colorcon, Inc.'s knowledge is true and accurate. Any recommendations or suggestions of Colorcon, Inc. with regard to the products provided by Colorcon, Inc. are made without warranty, either implied or expressed, because of the variations in methods, conditions and equipment which may be used in commercially processing the products, and no such warranties are made for the suitability of the products for any applications that you may have disclosed. Colorcon, Inc. shall not be liable for loss of profit or for incidental, special or consequential loss or damages.

Colorcon, Inc. makes no warranty, either expressed or implied, that the use of the products provided by Colorcon, Inc., will not infringe any trademark, trade name, copyright, patent or other rights held by any third person or entity when used in the customer's application.

For more information, contact your Colorcon representative or call:

North America
+1-215-699-7733

Europe/Middle East/Africa
+44-(0)-1322-293000

Asia Pacific
+65-6438-0318

Latin America
+54-11-5556-7700

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



© BPSI Holdings LLC, 2013.

The information contained in this document is proprietary to Colorcon and may not be used or disseminated inappropriately.

All trademarks, except where noted, are property of BPSI Holdings, LLC.

PI_opadry_ent_91series_ver3_12_/2013