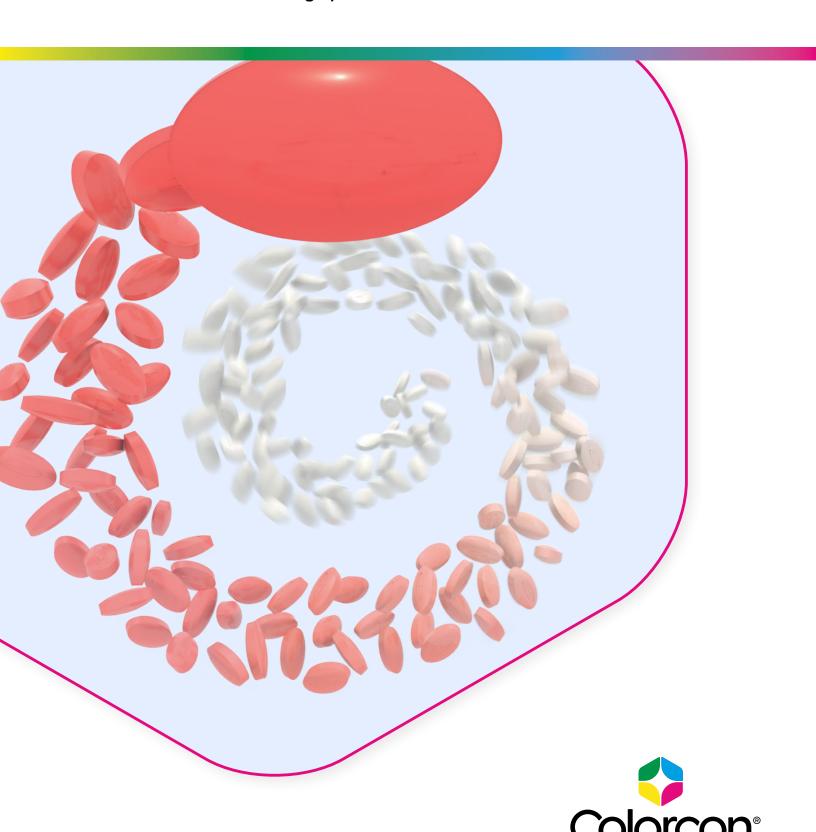
Opadry®QX

Quick and Flexible Coating System



Working Together for a Healthier World



Quick and Flexible Coating System

Process Adaptability for the Perfect Finish

- Productivity Enhancement and Efficiency
- · Wide Processing Latitude
- Excellent Appearance

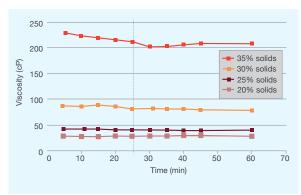
Process Adaptability for the Perfect Finish

Opadry QX®, quick and fleXible film coating, is setting new productivity, efficiency and appearance standards for coated tablets. As an innovative technology breakthrough, Opadry QX greatly reduces solution preparation and coating production times, operates under a broad range of process parameters in any type of coating equipment, and always results in a premium quality finish.

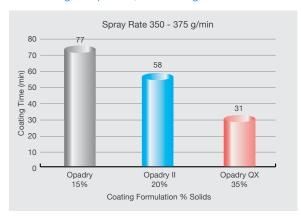
Gain Time with Process Efficiency

Opadry QX is a low viscosity formulation that is mixed with water and ready for use in 25 minutes or less – cutting preparation time in half. Even at high solids levels up to 35% w/w, the viscosity of the formulation remains low, allowing faster spray rates to help achieve greater productivity for each coating run.

Opadry QX is Fully Hydrated in 25 Minutes

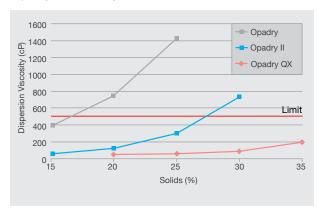


Film Coating Comparison, 48" Coating Pan



Using Opadry QX at the typical 3% weight gain, coating uniformity is achieved faster compared to alternative systems. This improved processing means tablets are exposed for far less time to the tumbling, heat and moisture associated with coating.

Opadry QX Viscosity Below Recommended Level



Overcome Process Challenges

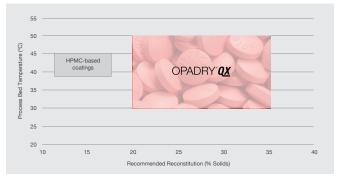
Opadry QX offers unparalleled process and equipment variability without compromising the tablet finish. It successfully outperforms previous coating systems through variable bed temperatures, solids dispersion levels, plus air flow adaptability.

Greater than 40% Reduction in coating time

Broad Tablet Bed Temperatures

Opadry QX can be applied at higher bed temperatures which decreases coating times and reduces the impact of humidity. Yet the fleXibility offered of operating at low bed temperature settings also makes Opadry QX a film coating ideally suited for temperature-sensitive active pharmaceutical ingredients.

Opadry QX Provides Wider Processing Latitude



Solids Levels

The increased solids level achievable with Opadry QX means that films are applied faster, color uniformity reached earlier and all coated tablets have a uniform, defect-free finished appearance.



Quick and Flexible Coating System

Overcome Process Challenges

Air Flow

Opadry QX maintains a premium coated finish, even when used in coating equipment with limited air flow capacity. In a design of experiments (DOE) performed in a 24" fully perforated pan, air flows ranged from 150 to 350 cfm, and the resulted coated tablets were consistently glossy and smooth.

From Batch to Continuous

Opadry QX is proven to perform in all types of coating equipment, from solid through to fully perforated pan coaters. It has also been validated in the latest continuous and semi-continuous equipment representative of several manufacturers.* In each continuous coating trial conducted, Opadry QX matched the full capacity of each machine with improved coating uniformity and a perfect finish in record time.

Regulatory

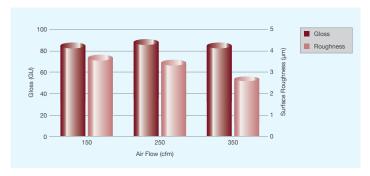
All ingredients in Opadry QX are approved for pharmaceutical use in the major markets.

The Perfect Finish

Coating with Opadry QX results in an exceptional appearance across a wide range of process variables. Demonstrated using a production scale 48" side-vented coating pan, Opadry QX was successfully applied over a range of coating solids concentrations, variable pan speeds and spray rates.

Appearance targets consistently met across a range of process variables

Superior Gloss and Surface Finish



Quick and FleXible

- Defer capital investment as productivity demand increases
- Easily transition drug production between manufacturing sites
- · Save energy through more efficient manufacturing

Variable Process Parameters				Appearance Targets				Total coating
Solids concentration (%)	Product bed temperature °C	Pan speed range (rpm)	Spray rate (g/min)	Coated tablet gloss (GU)	Surface roughness (SA)	Logo definition	Color uniformity St. dev. (ΔE)	time to 3.0% weight gain (min)
20	42 - 46	5.0 - 8.0	400	- > 75	< 5.0	Excellent	<1.0	49
25	42 - 46	5.0 - 8.0	400					39
30	42 - 46	6.5 - 8.0	400					33
35	42 - 46	7.5 - 8.0	375					30

Process constants: 130 kg pan load; 350 mg round standard concave placebo tablets, 1800 cfm process air flow; 3 – Schlick ABC spray guns, 25 ns; atomizing and pattern air pressures.

For technical information and case studies for Opadry QX, visit the Colorcon website www.colorcon.com/opadryQX

Deliver high-performance products — with Colorcon

Choose Colorcon, leader in pharmaceutical solid oral dose solutions, as a formulation partner of choice in every phase of your product development.

Film Coatings

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

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

Contact your Colorcon representative or call:

North America Europe/Middle East/Africa +1-215-699-7733 +44-(0)-1322-293000

Latin America India China

+54-11-5556-7700 +91-832-6727373 +86-21-61982300 **www.colorcon.com**

© BPSI Holdings LLC, 2016. All trademarks, except where noted are property of BPSI Holdings LLC. The information contained herein, to the best of Colorcon's knowledge, is true and accurate. Any recommendations of Colorcon with regard to the products provided by Colorcon 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. Colorcon makes no warranty that the use of the products provided by Colorcon 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. Any regulatory information provided is intended solely as initial general guidance. Each customer is responsible for determining the regulatory acceptability of the finished product in their specific application.

