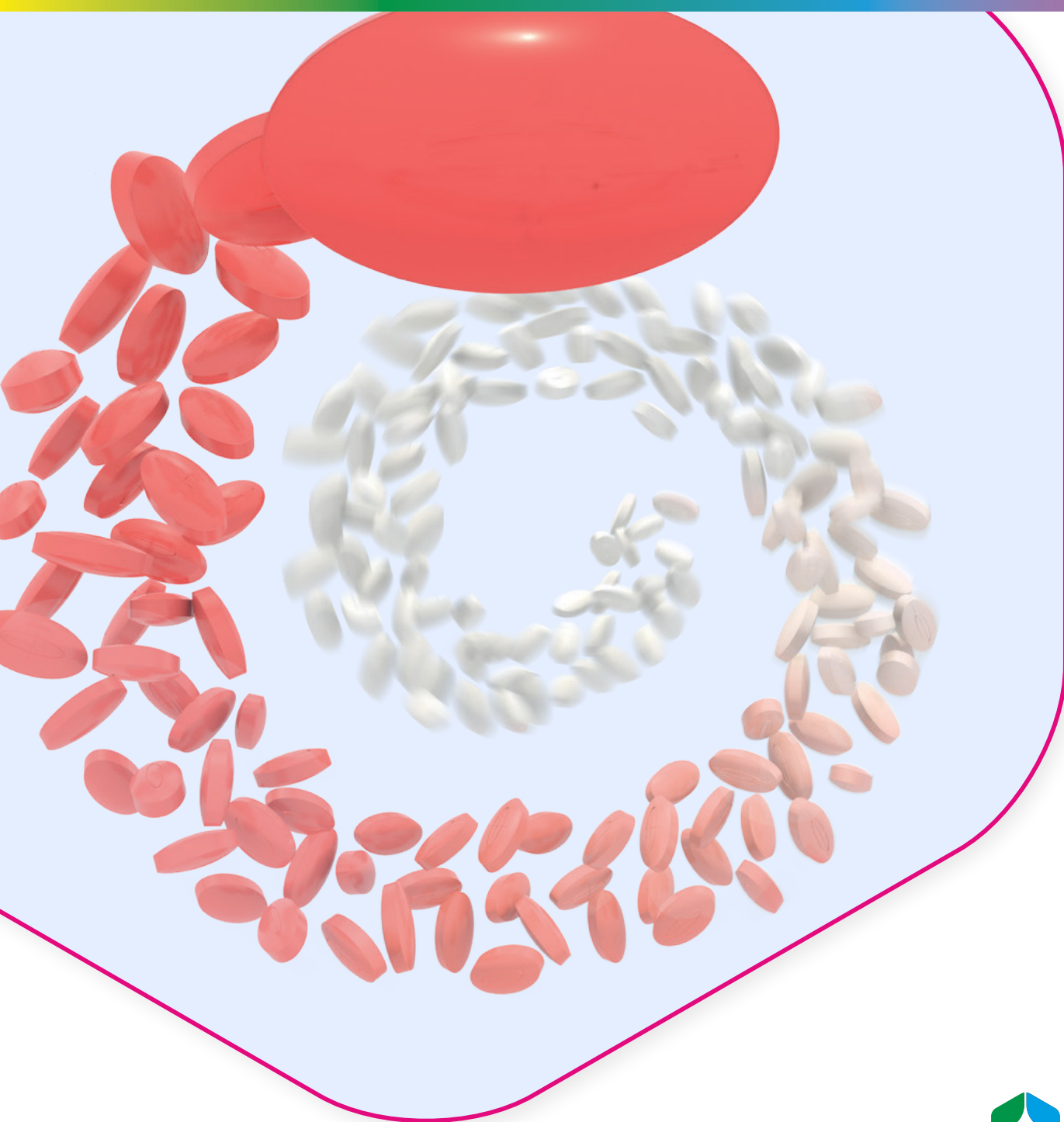


# Opadry® QX

Quick and Flexible Coating System



**Colorcon®**

Working Together for a Healthier World

# Opadry® QX

Quick and Flexible Coating System

## Process Adaptability for the Perfect Finish

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

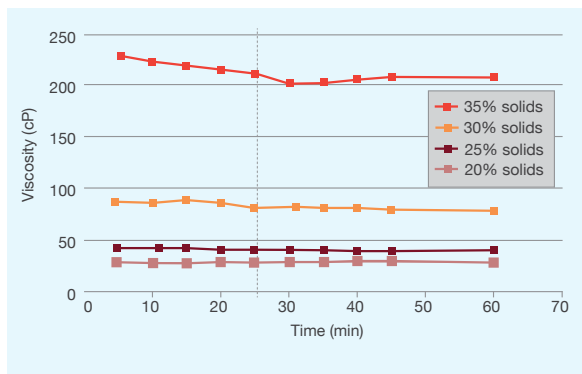
## Process Adaptability for the Perfect Finish

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.

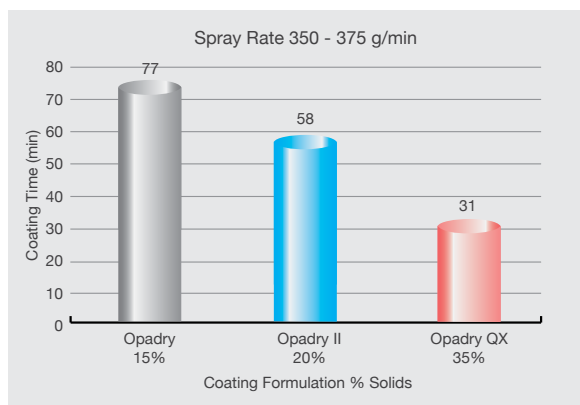
## Gain Time with Process Efficiency

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.

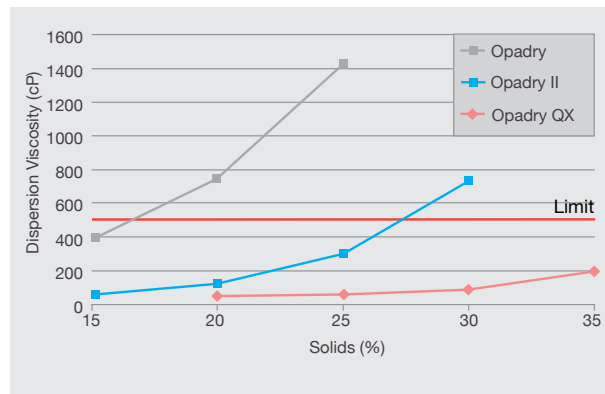
Opadry QX is Fully Hydrated in 25 Minutes



Film Coating Comparison, 48" Coating Pan

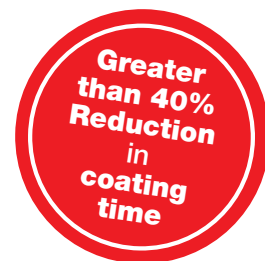


## Opadry QX Viscosity Below Recommended Level



## Overcome Process Challenges

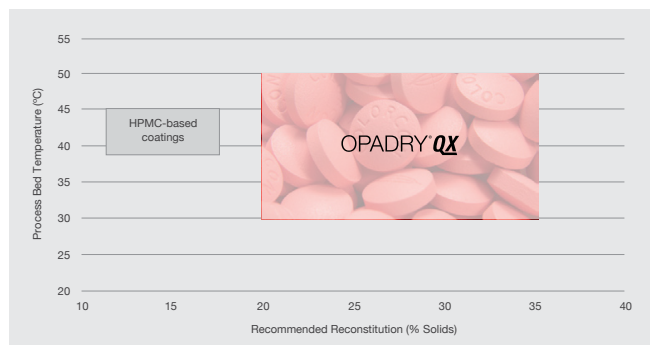
Opadry QX offers unparalleled process and equipment variability without compromising the tablet finish. It successfully outperforms previous coating systems through variable bed temperatures, solids dispersion levels, plus air flow adaptability.



## 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.

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

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.

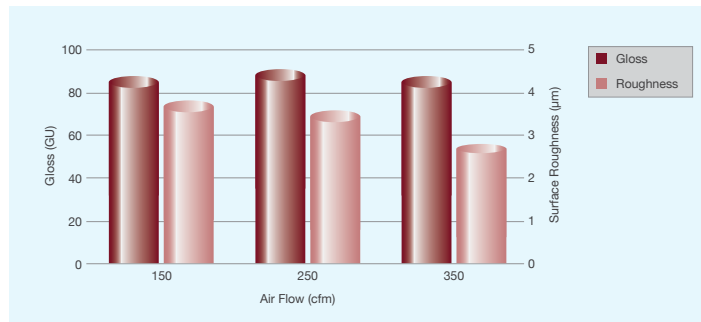
### The Perfect Finish

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 speed and spray rates.



### 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 time to 3.0% weight gain (min)
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)	
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 psi atomizing and pattern air pressures.

Opadry® QX is available without talc. Contact us for more information.

## 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, pearlescence 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

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