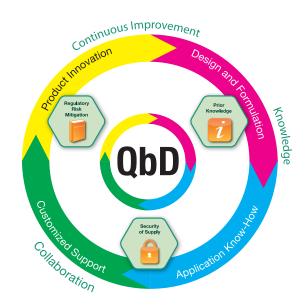
Quality by Design (QbD) Position for Opadry® Film Coating

Our 50+ years of experience in the design, development, and manufacture of fully formulated coating systems provide us with industry-leading insight into Quality by Design (QbD) for Opadry® immediate release film coatings. We help you optimize your process and minimize any risks, leading to predictable outcomes and greater manufacturing efficiency.



Colorcon Uniquely Offers:



Prior Knowledge

Besides color matching expertise, our experience is based on tens of thousands of production batches manufactured per year, along with thousands of samples, and the highest number of NDA and ANDA filings that cite products coated using our fully formulated film coating systems. This knowledge can help you identify the robust film coating process that will ensure consistent drug product performance and improve your manufacturing efficiencies. Colorcon film coating process application recommendations are based on extensive application and Design of Experiment (DoE) data.



Regulatory Risk Mitigation

Colorcon's global regulatory team has extensive experience supporting successful drug applications. Our experts collaborate with customers and governing bodies to mitigate regulatory hurdles and minimize delay in application approvals. We can provide broad support for your QbD filings including unparalleled Inactive Ingredient Database (IID) support and regulatory compliance information for each film coating formulation.



Security of Supply

Our six manufacturing sites located around the globe are cross-validated to ensure interchangeability of coating formulations backed by extensive data. Our strong raw material and supplier qualification program, full business continuity plan (BCP) and ability to interchange raw materials from multiple suppliers ensure holistic risk management.

Begin with the End in Mind

With Colorcon as Your Formulation Partner™ you can design products with improved quality and patient compliance assured. In addition to our QbD assistance, our technical teams can work to enhance performance for challenging substrates, prevent or minimize drug compatibility challenges, optimize tablet appearance using computer aided design (CAD) software, and more.

Call, or visit us online @ www.colorcon.com/products/qbd



Opadry® Fully Formulated Film Coating Systems are consistent, predictable, reliable and controlled.

Using Opadry® fully formulated film coating systems from Colorcon is "low risk" for QbD Applications.

