# Film Coating for Pediatric Oral Solid Dosage Forms

*Whitepaper*

## Getting the Right Coating for Pediatric Tablet Formulations

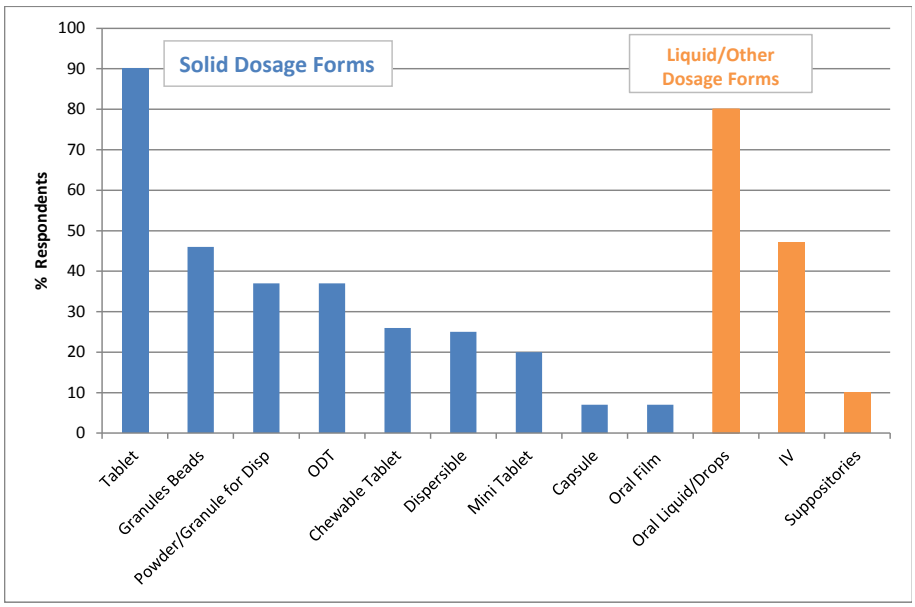
From a recent survey conducted within the pharmaceutical industry[1], by Colorcon, it was confirmed that oral solid dosage forms are a preferred choice for formulation of pediatric medicines (Figure 1).

With careful selection, of an appropriate film coating system, pediatric products may be coated with a suitable color while also providing mechanical integrity, gloss and moisture protection to produce a robust tablet that is effective and easily recognized by consumers and dispensers.

Film coating these dosage forms also brings further advantages, including:

1. masking objectionable tastes or odors[2]
2. improving swallowability[3]
3. helping to positively impact patient preference
4. differentiating the visual appearance of product to mitigate dispensing errors
5. improving packaging efficiency[4]
6. prevention of cross contamination
7. reduced tablet breakage and chipping during manufacture

**Figure1. Platform Technologies Selected by Formulators for Pediatric Medicine Development, Colorcon's Industry Survey of 2012**



## Commonly Used Coatings with Precedence of Use in Pediatric Medicines

Film coatings typically consist of three main components: polymer, plasticiser and pigment. Precedence of use for the polymer and plasticiser is reviewed here, while the more complex assessment for use of pigments and color selection is explained later.

During the development of a pediatric dosage form the formulator needs to assess any risk associated with their formulation to ensure that an age appropriate dosage form is selected.[5] This is to mitigate risk of non-compliance and ensure suitable excipients are selected.[6] One way to assess an excipient is to evaluate its history of use in existing medicines prescribed for pediatric patients to identify if there is "Precedence of Use", applicable for children from 2-18 years old.

Colorcon has extensively reviewed US and EU databases, looking at the medicines currently prescribed for pediatric patients. Review shows that components used in Colorcon coating systems, such as Opadry® and Surelease® have Precedence of Use in pediatric medicines; as well as core excipients Starch 1500®, StarCap 1500®, METHOCEL™, ETHOCEL™ and POLYOX™. Opadry film coatings recommended by Colorcon for use in pediatric medicines are shown in Table 1.

**Table1. Opadry Film Coatings with Precedence of Use in Pediatric Medicines**

| | US and EU Data* | |
|---|---|---|
| | 2-11years | 12-18years |
| Opadry 203A | ✓ | ✓ |
| Opadry II (PVA base) | ✓ | ✓ |
| Opadry and Opadry II (HPMC base) | ✓ | ✓ |

** Reference data available on request for medicines available in both US and the EU markets.*

## Choice of Color

For pharmaceutical products, colors are not governed in the same way as other excipients, with most areas of the world maintaining a list of pigments approved for use in medicinal products as part of regional legislation. However, these lists do not distinguish between adult and pediatric medicines, which means from a regulatory view all approved pigments are permitted for use in pediatric medicines. In reality, it is apparent that pharmaceutical assessors will question licence applications where a young patient is exposed to unnecessary excipients, which could include pigments.

Color has an important role to play in the formulation of dosage forms, including those intended for paediatric use. Color can be used to identify a specific product, distinguish between different dosage strengths and different forms (immediate or extended release) of the same product. Therefore, color can contribute toward minimising medication errors, making a dosage form more appealing to a younger patient, or disguise an unattractive medicine to help improve compliance.

Pharmaceutical assessors expect that applicants perform and document a risk assessment as part of their dossier which discusses the issues relating to differentiation and adherence and to explain the options employed to address them, which will include a justification of the use of color and reason for selection of a specific color.[7]

## Colorcon: From Core to Coating, Your Supplier of Choice

As a market leader in pigmented products and color expertise for the pharmaceutical industry, Colorcon has a wealth of knowledge and years of experience navigating complex global regulations and trends governing the use of colors. With Colorcon as your industry partner you can be assured that the film coating system and excipients you select will be the right choice for your product and the consumer, while satisfying regulatory needs, saving you time and cost.

## References


1. Walsh, J and Hughes, K. Pharmaceutical Industry Approaches to the formulation and development of Pediatric Medicines. EUPFI Poster 2013.
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3. Wilson, C et al. Modern tablet film coating and influence on ease of Swallowing. AAPS 2003
4. Hughes, K et al. Impact of film coating on blister packing efficiency. AAPS 2005
5. Thomson SA, Tuleu C, Wong ICK, Keady S, Pitt K, Sutcliff A* (2009) Assessing the acceptability of mini-tablets for use in children aged 2-6 years old. Pediatrics. 123(2):e235-238.
6. Breitkreutz J, Boos J, Exp. Opin. Drug Del. 4:37-45 (2007)
7. Guideline on pharmaceutical development of medicines for paediatric use EMA/CHMP/QWP/805880/2012 Rev. 1





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