

Effective Taste Mask Solution

Technical Data Sheet

Challenge

When developing a pharmaceutical dosage form, it's important to consider factors like appearance, taste, and aroma, as they can influence consumer preference and compliance, especially with high-dose, bad-tasting drugs.

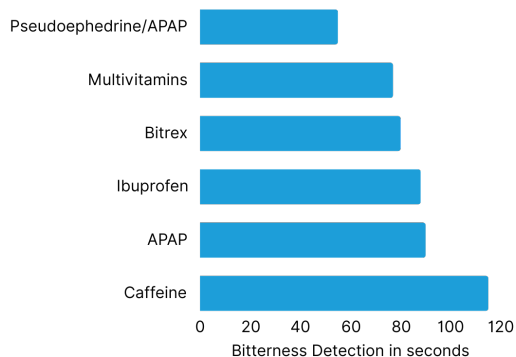
Traditionally, water-soluble film coatings have been used to improve the look of solid oral dosage forms. However, masking unpleasant tastes in tablets has been challenging both technically and commercially. Current methods often use high levels of non-water-soluble coatings, which can be costly and may affect how the drug dissolves or is absorbed by the body. To address this issue, Colorcon developed a product called Opadry® TM.

Product Performance

Opadry TM has demonstrated taste masking efficacy on a variety of actives common in marketed products. The Opadry TM coating system prevents the patient's detection of many displeasing active ingredients for 60 seconds or more in tablets coated to an equal weight gain.

Figure 1 displays the model drug formulations that have been evaluated and the time required for a patient to detect the bitter taste of the active when coated with Opadry.

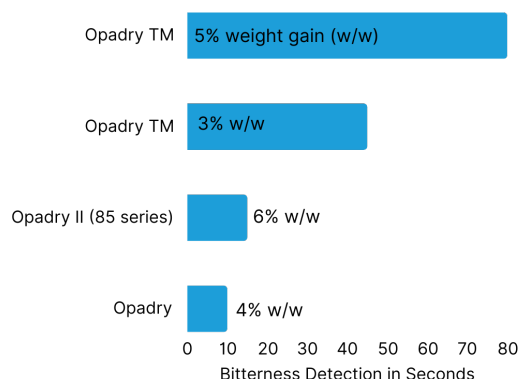
Figure 1. Taste Masking Performance of Opadry TM on Various Pharmaceutical and Nutritional Tablets.



Efficacy at Low Coating Levels

Five sensory panelists were trained to place a tablet on their tongue for 45 seconds to test taste masking. They were given placebo tablets with Bitrex™, coated with various Colorcon products. The coating weight gains were based on previous attempts to mask the taste while maintaining immediate release. Panelists recorded the time to detect bitterness. Results showed Opadry performed best, masking the taste for over 40 seconds at 3% weight gain and over 60 seconds at 5% weight gain.

Figure 2. Comparison of Opadry TM to Commercial Film Coating Systems.



Produce an Immediate Release Profile

Opadry TM provides excellent taste masking properties at standard film coating levels between 3-5% weight gain. Most importantly displeasing tastes are concealed without interfering with the rate of drug release from the tablet formulation.

Studies conducted on model drugs in tablet form have shown that Opadry TM provides an immediate release dissolution profile. Further, this dissolution profile is maintained, and taste masking performance remains consistent, when the tablets are stored under standard International Conference on Harmonization (ICH) stability conditions as shown in Figures 4 and 5.

Figure 4. Dissolution Stability Profile for Opadry™ Coated Caffeine Tablets.

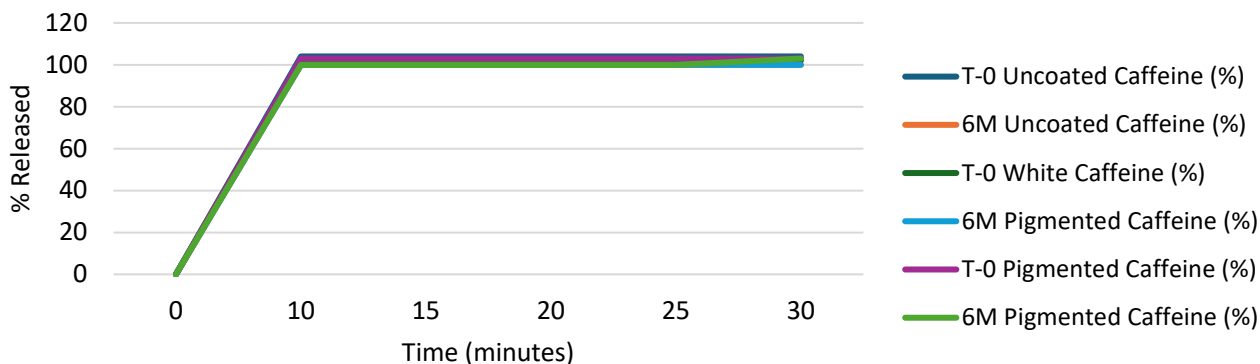
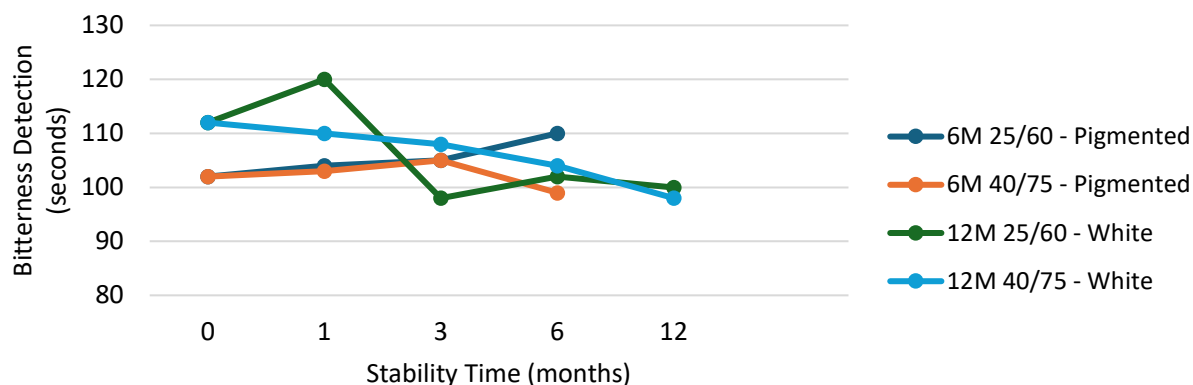


Figure 5. Taste Masking Stability for Opadry™ Coated Caffeine at Various Storage Conditions.



Product Summary

Opadry™ is an effective film coating system that has been shown to mask the unpleasant taste of multiple active ingredients with no effect on the release profile of the drug. Both the taste masking properties and the drug release properties have proven stable when stored under standard ICH accelerated stability conditions. The ingredients used to formulate the Opadry meet the compendia requirements of the major pharmacopoeia, and the product is available in a wide range of customized colors.

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