



Effective Taste Masking Solutions from Colorcon

Organoleptic properties such as appearance, taste, and aroma are important factors that need to be considered when developing a pharmaceutical dosage form. These properties can often affect consumer preference and compliance for a particular dosage regimen, most notably in the case of high dose, poor tasting drugs.

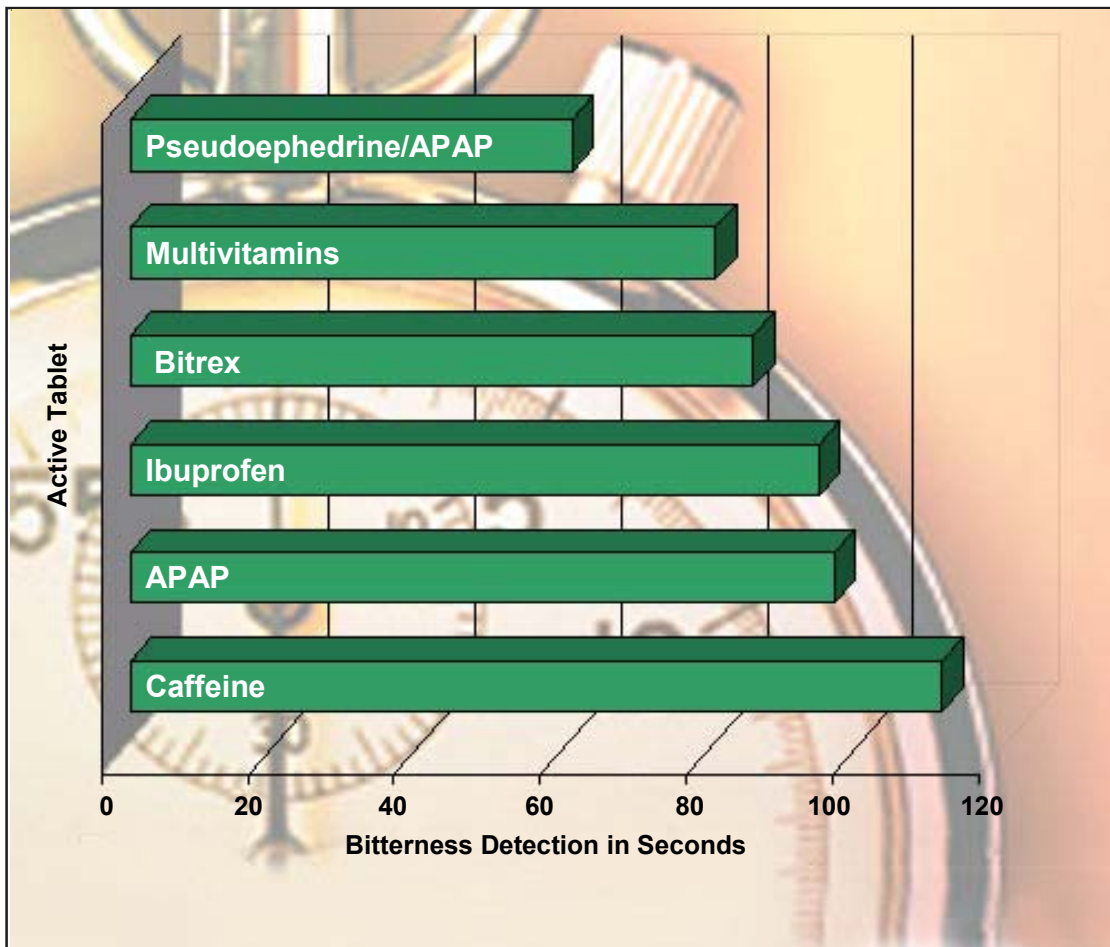
For many years water soluble film coatings have been employed to improve the appearance of solid oral dosage forms. However, masking unpleasant tasting compounds in tablets has presented many unique technical and commercial challenges. Current approaches to taste masking these types of products may involve the use of high levels of non water soluble coatings. This can add significant cost to the product and may

affect drug dissolution rates or bioavailability. In response to this unmet need, Colorcon has developed Opadrytm.

Product Performance

Opadrytm has demonstrated taste masking efficacy on a variety of actives common in marketed products. The Opadrytm 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 below 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 Opadrytm.

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



[†] Patient is term applied to sensory panelists who participated in the evaluation of the Opadrytm product.

^{††} All tablets coated to a 5% weight gain, weight of the coating to the weight of the tablet.

Efficacy at Low Coating Levels

In order to demonstrate taste masking performance five sensory panelists were trained in a procedure that involved placing the tablet on the middle of their tongue and keeping it stationary for 45 seconds. The panelists were administered placebo tablets formulated to contain the bitter compound, Bitrex™.

These tablets were coated with a variety of commercially available Colorcon products that have traditionally been utilized for taste masking applications. Coating weight gains employed were based upon previous attempts to mask the unpleasant taste of the active while maintaining an immediate release profile.

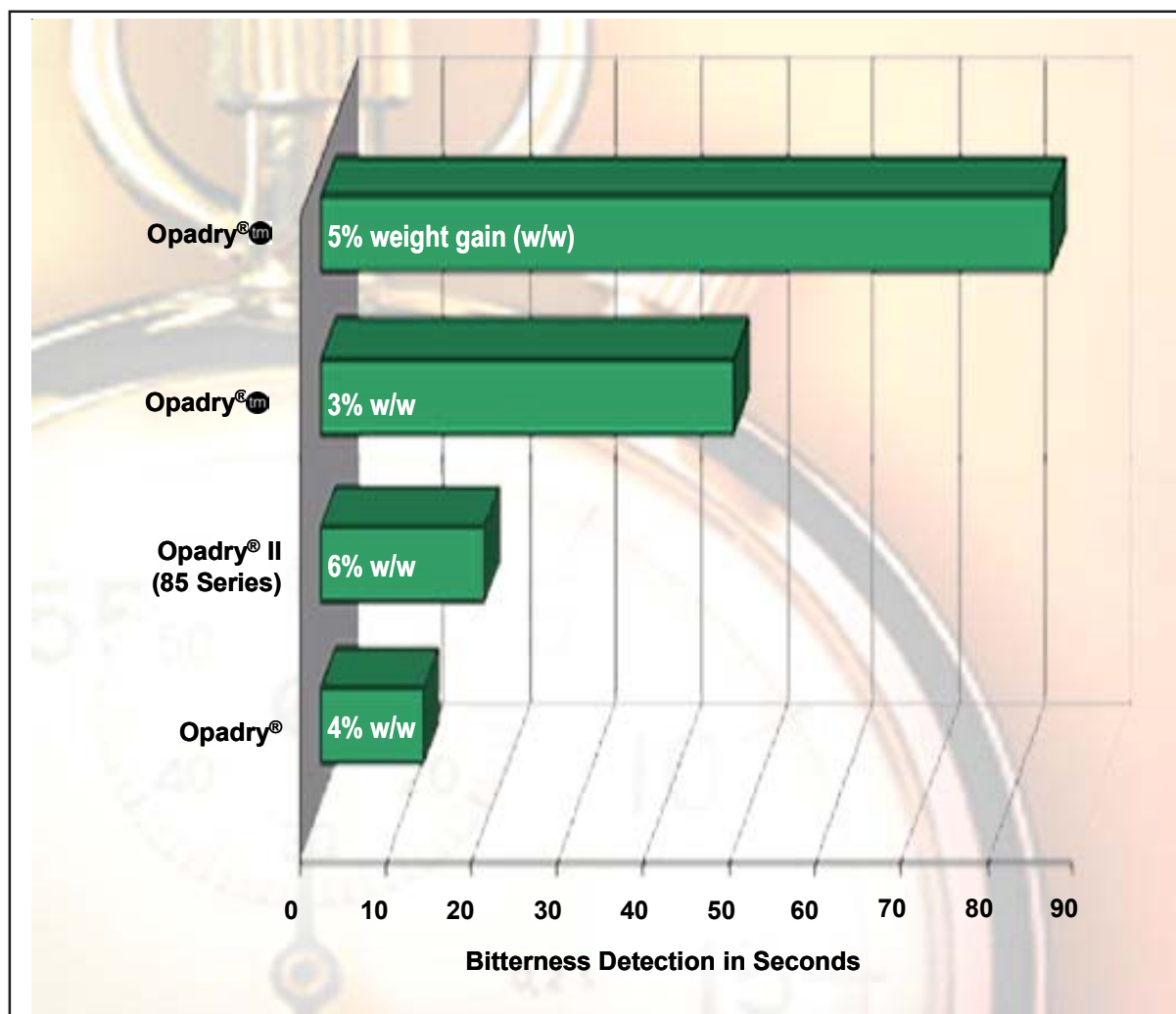
The panelists then recorded the time taken to detect the bitterness of the active formulated in to the coated tablet. The results were compiled and graphed for comparison.

As the graph shows in Figure 2 the Opadry™ exhibited the best performance when compared to each of the candidate coating formulations evaluated in the study.

The Opadry™ produced outstanding results, masking the objectionable taste of the active for greater than 40 seconds, at weight gains commonly required to impart a uniform color application on an uncoated tablet (i.e. 3% wg).

Opadry™ produced superior results, masking the unpleasant taste for greater than 60 seconds, when the same tablets were coated to a somewhat higher application amount (i.e. 5% wg).

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



† The polymers typically applied to create a modified release product.

Produce an Immediate Release Profile

Opadry™ provides excellent taste masking properties at standard film coating levels between 3-5% wg. 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™ 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 below.

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

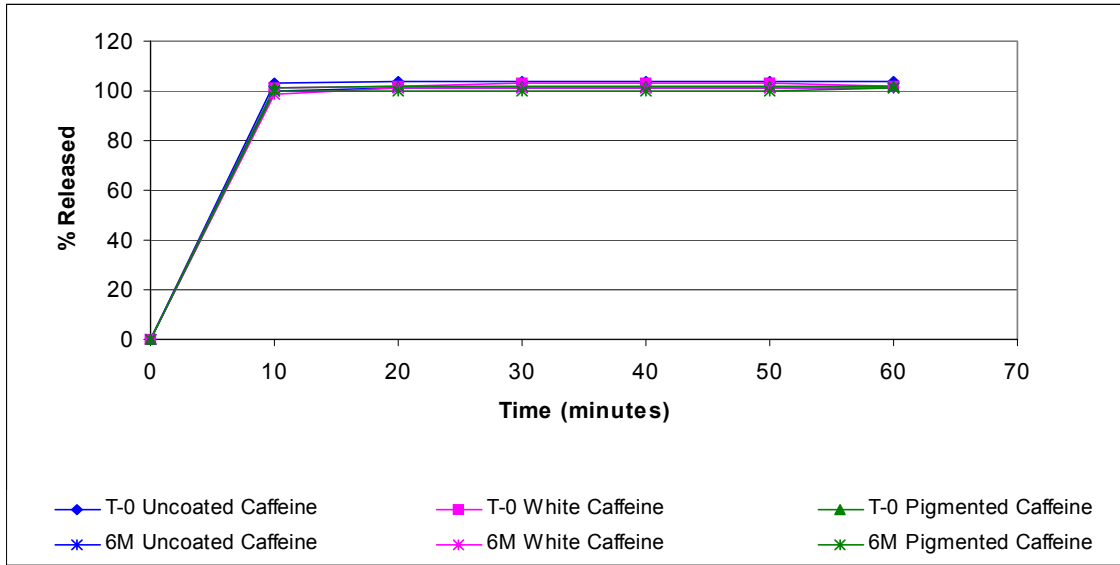
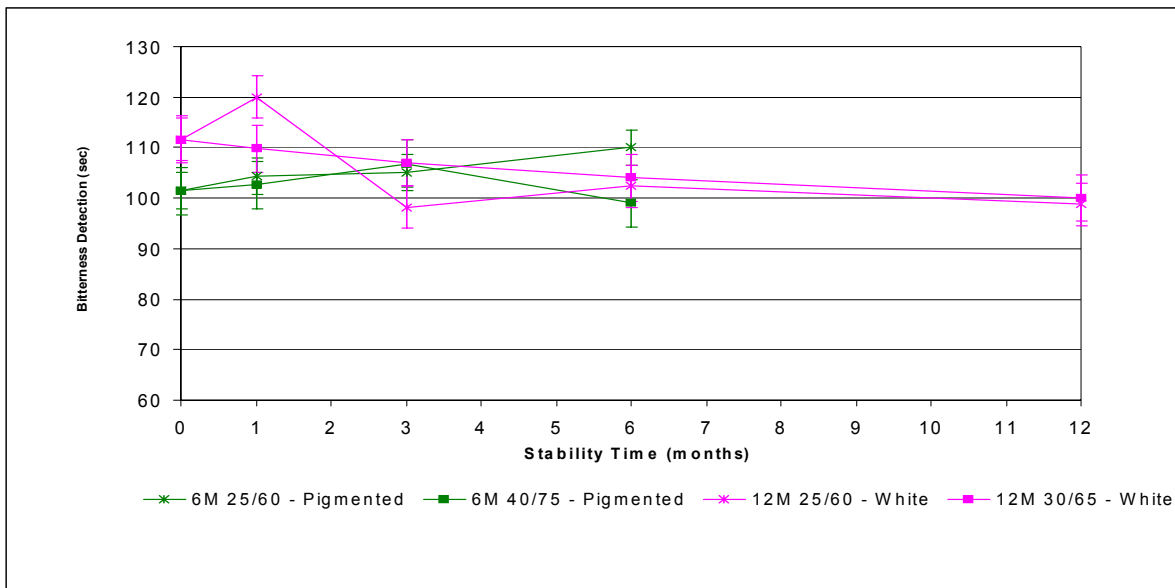


Figure 5. Taste Masking Stability for Opadry™ Coated Caffeine at Various Storage Conditions.



† Model solid oral dosage forms evaluated include pseudophedrine / APAP, multivitamins, ibuprofen, APAP, Bitrex™ and caffeine.

†† USP monograph for acetaminophen and caffeine coated tablets.

Global Approval for Pharmaceutical Products

The Opadry™ base formula is comprised of ingredients that meet the compendia requirements of the major pharmacopoeia in the United States, Europe and Japan. A summary table of the approvals for use in various regions of the world is displayed in Figure 6.

Ingredients derived from GMO's are not contained in this film coating system. Further, animal derived materials are not used in any Opadry™ formulations.

Figure 6. General Regulatory Approval by Region.

	Region				
Approved for Use	North America	Europe	Japan†	China	India
Pharmaceuticals	Yes	Yes	Yes	Yes	Yes
Dietary supplements regulated as foods	Yes	No			

† Consult your Area Technical Manager for specifics.

Color Matching

This new offering from Colorcon is a fully formulated, aqueous film coating system. Customized colors can be formulated to meet your specific requirements.

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.

Opadry™ is backed by the world class service and support of Colorcon.

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