

## Taste Masking Performance and Stability of Opadry<sup>®</sup> tm, a Taste Mask Film Coating System

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### INTRODUCTION

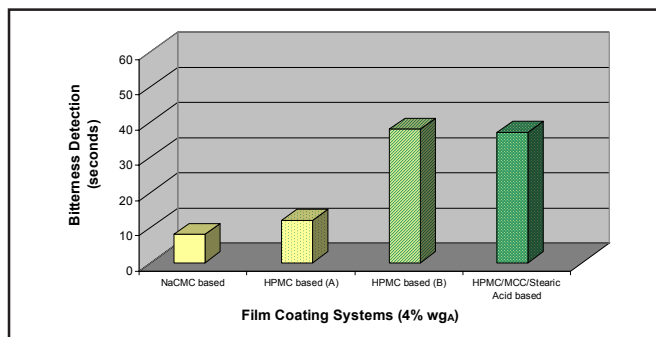
To evaluate the taste masking ability and stability of Opadry<sup>®</sup> tm, a fully formulated, aqueous film coating system. The stability of Opadry tm powders, along with Opadry tm coated caffeine tablets, was evaluated after storage at both ambient and accelerated conditions.

Trained sensory panelists were used to assess the ability of Opadry tm to mask the bitter taste of Bitrex<sup>™</sup> 0.002% and caffeine 200mg tablets. Dissolution profiles of coated caffeine tablets were also investigated over time to confirm there was no adverse effect on dissolution.

### BACKGROUND

In an earlier study the task masking performance of various commercial cellulosic based film coating systems was evaluated on a model bitter substrate (Bitrex at 0.002% level). Of the four systems we compared at 4.0% actual weight gain (wg<sub>A</sub>), the average time to detection of bitter taste was 25 seconds (See Figure 1).

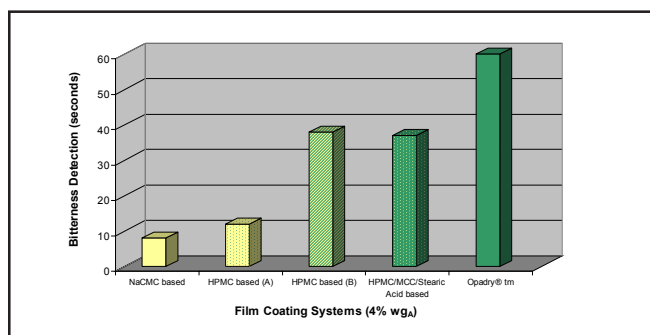
**Figure 1. Taste Mask Comparison of Commercial Cellulosic Film Coating Systems on Bitrex Tablets**



A need was identified to develop a film coating system that could mask the taste of bitter actives for an extended period of time without interfering with the immediate release profile of the drug. Opadry tm fills this need. It is a fully formulated, aqueous film coating system comprised of polymer, plasticizer and pigment, that meets compendial requirements of USP/EP/JPE for pharmaceutical applications. It possesses excellent strength and modulus of elasticity, characteristics on par with com-

mercial cellulosic film coating systems. Opadry tm effectively masks the taste of bitter substrates for ~60 seconds at 4% wg<sub>A</sub> (See Figure 2) without interfering with drug release.

**Figure 2. Taste Mask Comparison of Commercial Cellulosic Film Coating Systems on Bitrex Tablets**



At 5% wg<sub>A</sub> of Opadry tm, taste mask performance on Bitrex and other bitter actives extends to >85 seconds.

Two sets of coated tablets were evaluated for taste masking ability and for dissolution profiles. The first set of tablets were coated from stability batches of white and pigmented Opadry tm powders that were stored in commercial production packaging, at ambient and accelerated conditions, for 3 to 6 months.

The second set of tablets were coated with white and pigmented Opadry tm powders at Time 0, and then packaged in high-density polyethylene (HDPE) bottles, heat-sealed and stored at ambient and accelerated conditions for 3 to 6 months.

All tablets were coated to a 5% wg<sub>A</sub> using Opadry tm at 9% solids. They were coated in a 15" fully perforated side-vented coating pan.

For taste masking assessment, five sensory panelists were trained in a procedure which involved placing the tablet on the middle of their tongue and keeping it stationary for 45 seconds. After 45 seconds they could move it around in their mouths. The panelists tested each sample for *d* – time to detect bitterness and *e* – time to expel tablets, and recorded time in seconds. The results were

compiled, and the average and standard deviation for time to detect bitterness for each sample was graphed.

Opadry tm was also coated onto caffeine tablets to assess the effect on T-0 dissolution and dissolution stability. The dissolution method was based on the USP monograph for Acetaminophen and Caffeine tablets.<sup>1</sup> Dissolution profiles were compared using time for percent dissolved data ( $T_Q$ ). Stability Results

## STABILITY RESULTS

### Taste Mask Performance

Figure 3. Opadry tm White powder 6 Month Taste Profiles

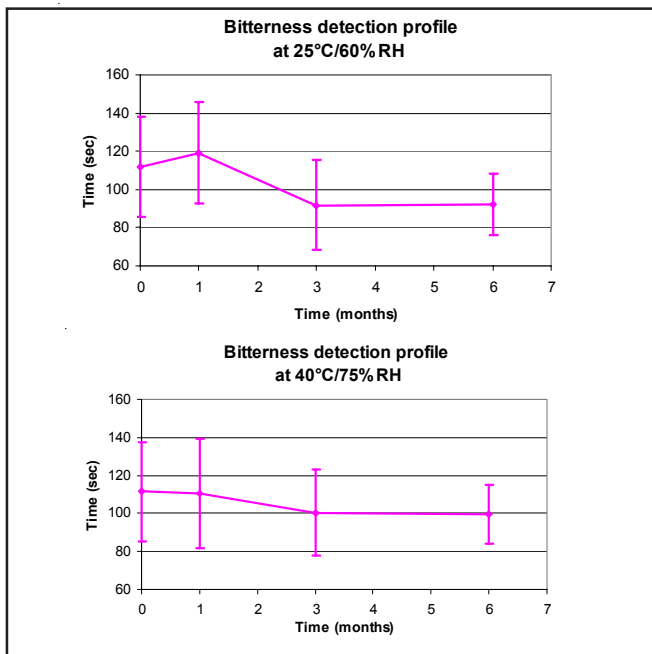


Figure 4. Opadry tm White coated tablet 6 Month Taste Profiles

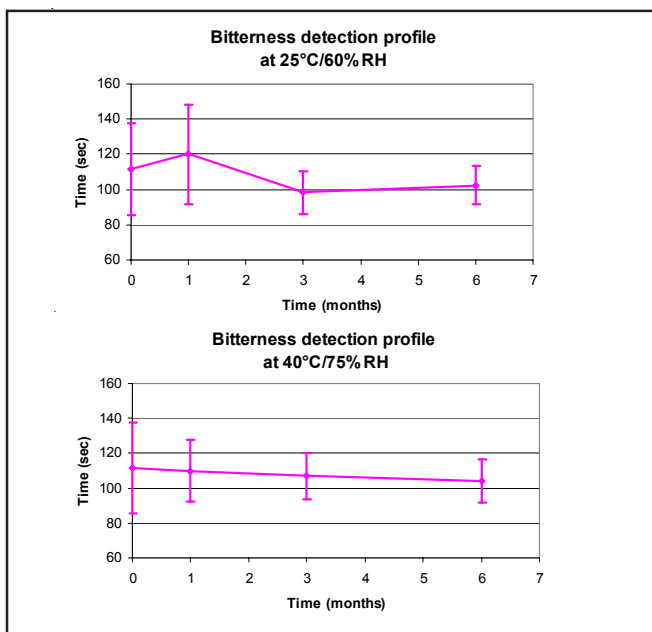


Figure 5. Opadry tm Pigmented powder 3 Month Taste Profiles

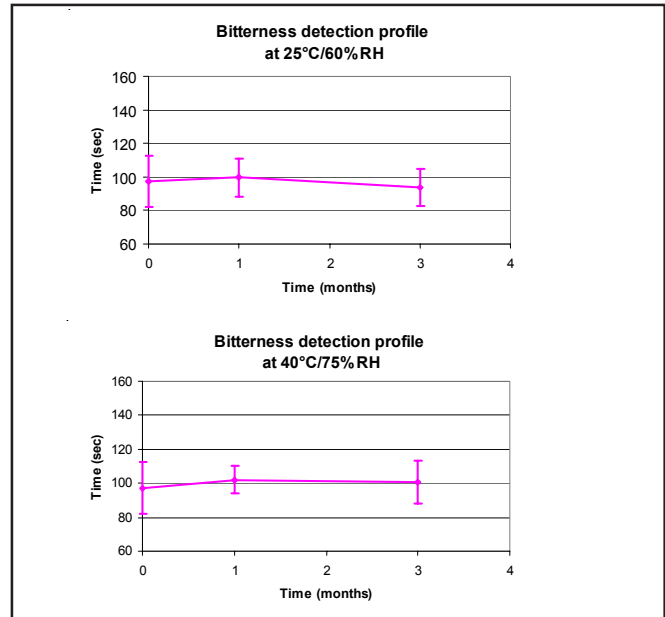
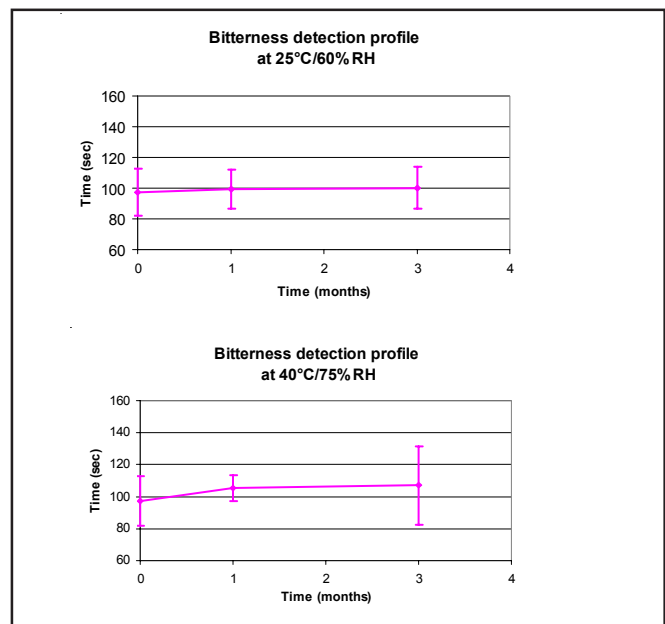


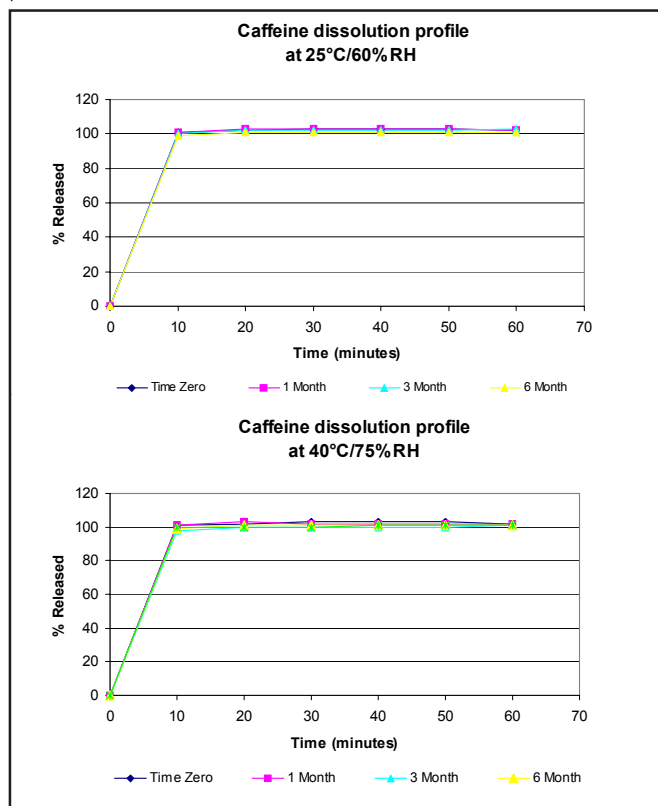
Figure 6. Opadry tm Pigmented coated tablet 3 Month Taste Profiles



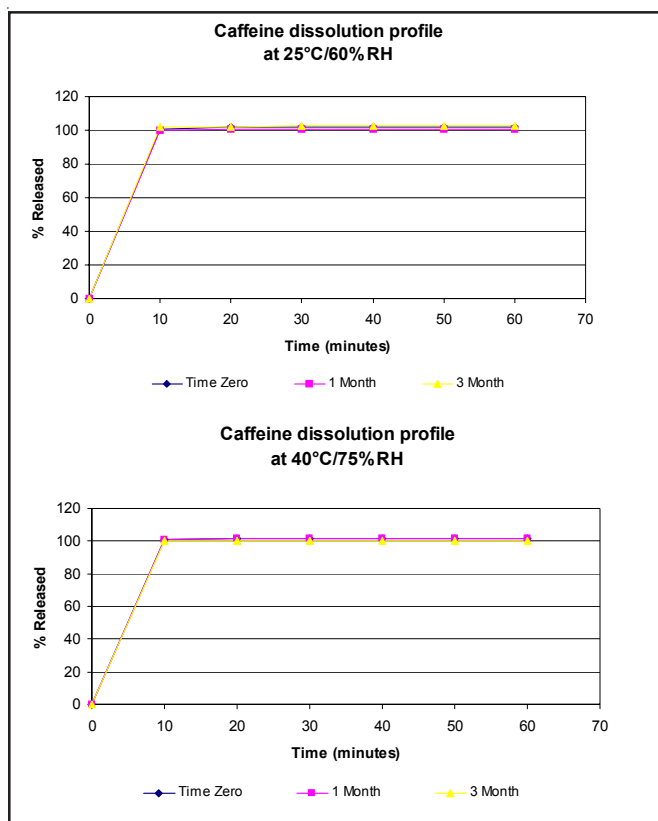
The coated caffeine tablets were evaluated by five trained sensory panelists (n=5) for bitterness detection. The taste mask results, for up to six months at both storage conditions, show an average time to detect caffeine bitterness of over 90 seconds for re-coated powders and 100 seconds for coated tablets. These times are significantly higher than the target time to detect bitterness of >60 seconds. The Opadry tm powders and coated caffeine tablets both remained very stable in maintaining their taste mask function. Similar taste mask results were found with acetaminophen 500mg, aspirin 325mg and Bitrex 0.002%.

## Dissolution Performance

**Figure 7. Opadry™ White Coated Caffeine tablet  
6 Month Dissolution Stability**



**Figure 8. Opadry™ Pigmented Coated Caffeine tablet  
3 Month Dissolution Stability**



The Opadry™ white coated caffeine tablets showed no change in their release profiles, after storage at both stability conditions, over 6 months time. After 10 minutes time 100% of the caffeine has been released for all samples tested.

The Opadry™ pigmented coated caffeine tablets also showed no change in their release profiles, after storage at both stability conditions, over 3 months time. After 10 minutes time 100% of the caffeine has been released for all samples tested.

Dissolution profiles were compared using time for percent dissolved data (TQ). TQ is defined as the time required for “Q” percent of drug to dissolve. Values for “Q” used here correspond to those found in the USP monograph for Acetaminophen and Caffeine tablets. The TQ values for caffeine are 75% dissolved in 60 minutes.

The dissolution profile results for acetaminophen and aspirin tablets also met their criteria through 3 months time. Opadry™ is unique in that the functional film provides an ability to taste mask bitter drugs, while having no adverse effect on the release of the active drug.

## CONCLUSIONS

Stability studies show that Opadry™ can successfully mask the bitter taste of caffeine tablets, as well as other bitter actives, for over 85 seconds in the mouth. Both the powder and the coated tablets show consistent taste mask ability over time and under accelerated stability conditions.

Additionally, Opadry™ film coatings have no adverse effect on the release and dissolution of coated caffeine tablets, both at T-0 and throughout stability testing.

Opadry™ consistently shows superior taste mask performance of bitter substrates when compared to commercial cellulosic film coating systems.

## ACKNOWLEDGMENT

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## REFERENCE

1. United States Pharmacopeia 27 - National Formulary 22

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