Dissolution Comparison - Acetaminophen and Ibuprofen Cores Following Accelerated Storage Stability Testing

PURPOSE

To understand the comparative dissolution performance of acetaminophen and ibuprofen tablets coated with a 3% weight gain of Opadry® 200 (200F280000 and Opadry® II, 85 series (85F18422) following 6 months accelerated storage stability.

MATERIALS AND METHODS

The white coating dispersions were prepared with 20% solids in purified water and mixed following the recommended reconstitution procedure for 45 minutes. Tablets were coated in an O'Hara Labcoat I with a 15" pan insert and one VAU Spraying System spray gun. The coating process parameters used to prepare the coated tablets are shown in Table 1.

Table 1. Coating Process Parameters

Coating Process Parameter	Value
Inlet Air Temperature (°C)	65
Tablet Bed Temperature (°C)	45
Airflow (m^3/hr)	250
Atomizing Air Pressure (bar)	1.5
Pan Speed (rpm)	22
Spray Gun to Bed Distance (cm)	10
Fan Air (bar)	1.5
Spray Rate (g/min)	20

Dissolution testing of acetaminophen (APAP, 500 mg caplets, LNK International, Inc.) and ibuprofen (IB, 200mg, 9.53 mm round tablets, LNK International, Inc.) was conducted according to USP recommended guidelines (Table 2). Both uncoated and coated tablets with a 3% weight gain of either Opadry 200 or Opadry II 85 series were tested following 3 and 6 months storage at 40°C / 75% RH.

Table 2. FDA Recommended Dissolution Methods

Active	USP Apparatus	Speed (RPM)	Medium	Volume (mL)
Acetaminophen	II (paddle)	50	Phosphate buffer, pH 5.8	900
Ibuprofen	II (paddle)	50	Phosphate Buffer, pH 7.2	900

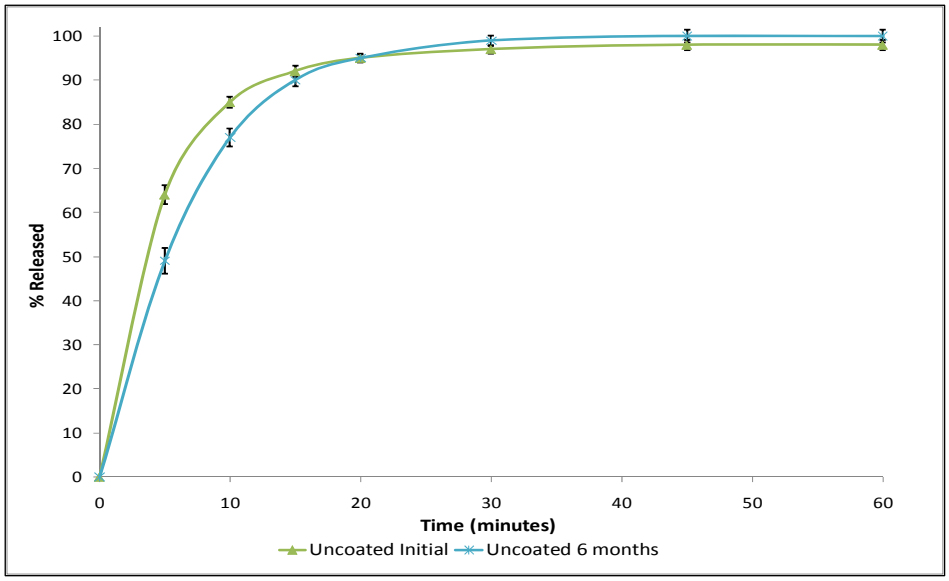
Dissolution profiles of the coated and uncoated cores were compared using f_2 analysis.[1,2] An f_2 value between 50 and 100 indicates similarity between two dissolution profiles.

RESULTS

Acetaminophen

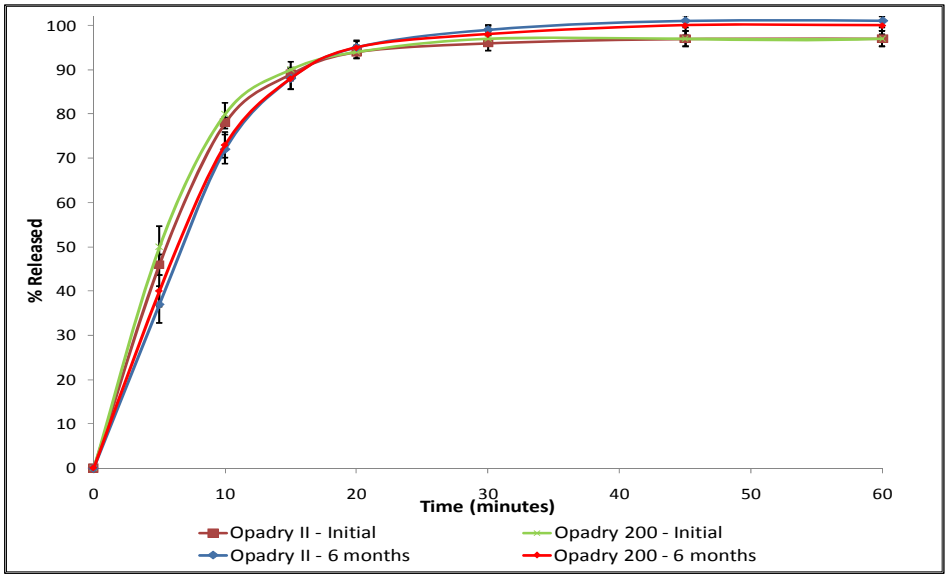
The dissolution performance of uncoated acetaminophen tablets initially and following 6 months at 40°C / 75%RH is shown in Figure 1.

Figure 1. Dissolution of Uncoated APAP Cores Initially and Following 6 Months Storage at 40°C / 75%RH



Accelerated storage of the uncoated APAP cores at 40°C /75%RH indicates a slight slow down in dissolution of the uncoated cores, but full release is still obtained within 30 minutes and the profiles are essentially similar with an f_2 value of 62.

Figure 2. Dissolution of APAP Cores Coated with Opadry II 85 and Opadry 200 Initially and Following 6 Months Storage at 40°C / 75%RH

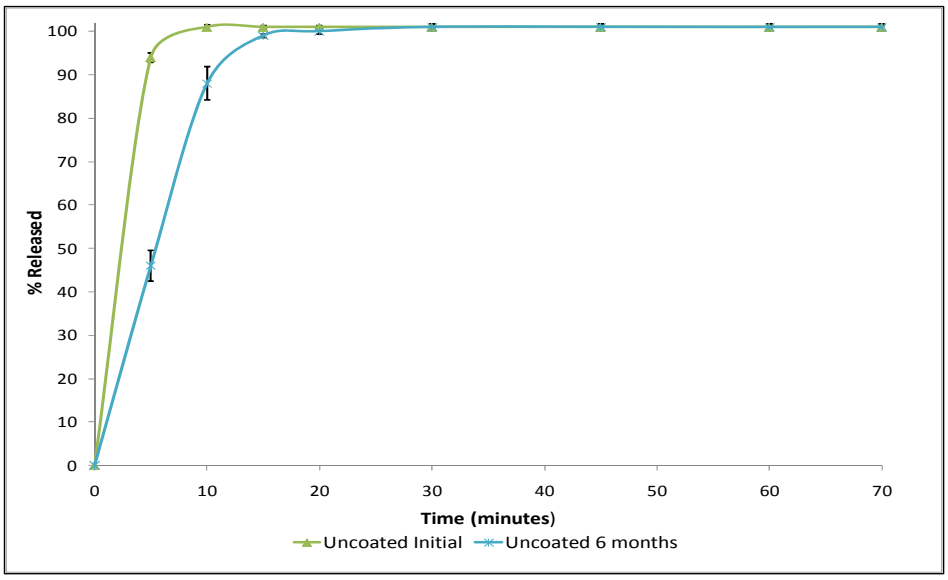


Accelerated storage stability had minimal impact on coated APAP cores dissolution. Both Opadry 200 and Opadry II 85 series coated tablets gave full release within 30 minutes, and provided essentially similar dissolution to uncoated tablets following 6 months at 40°C / 75% RH with f_2 values of 73 and 67, respectively.

Ibuprofen

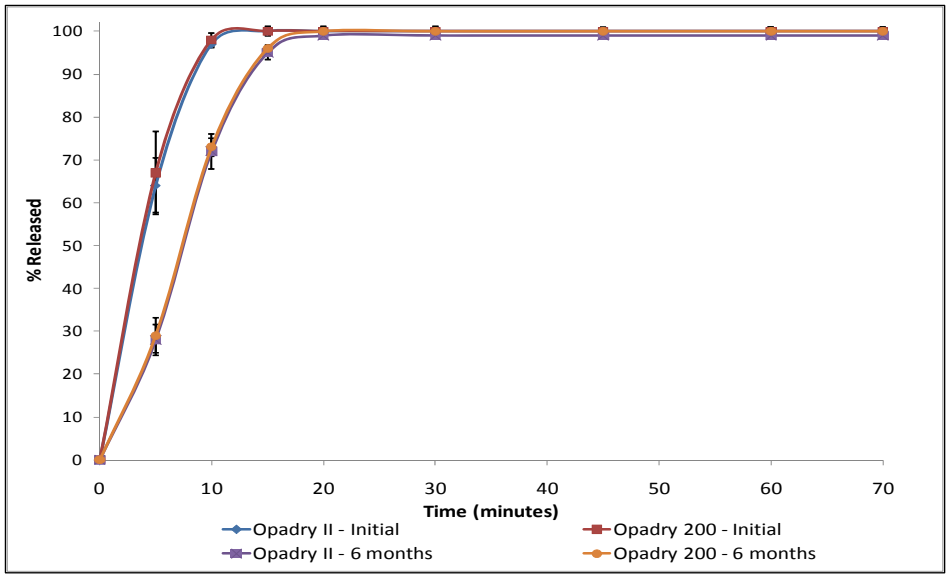
The dissolution performance of uncoated acetaminophen tablets initially and following 6 months at 40°C / 75%RH is shown in Figure 3.

Figure 3. Dissolution of Uncoated Ibuprofen Cores Initially and Following 6 Months Storage at 40°C / 75%RH



Accelerated storage of the uncoated ibuprofen cores at 40°C /75%RH indicates a slow down in dissolution, but full release is still obtained within 30 minutes. The f_2 value comparing the dissolution profiles in Figure 3 is 39.

Figure 4. Dissolution of Ibuprofen Cores Coated with Opadry II 85 Series and Opadry 200 Initially and Following 6 Months Storage at 40°C / 75%RH



The coated ibuprofen cores demonstrate a similar slow down in dissolution to the uncoated cores following 6 months accelerated storage stability at 40°C / 75% RH. Both Opadry 200 and Opadry II 85 series coated tablets gave full release within 30 minutes, and provided similar dissolution to uncoated tablets with f_2 values of 56 and 54, respectively. These f_2 values indicate borderline similarity to the uncoated core, but the f_2 correlation between the two coated tablet profiles was 93 indicating that Opadry 200 gave equivalent release to that of Opadry II 85 series.

CONCLUSIONS

The dissolution behavior of both acetaminophen and ibuprofen cores remains consistent throughout the 6 months accelerated testing period. Coated cores match the uncoated cores dissolution performance at all time points, and no differential release performance is noted between Opadry® 200 and Opadry II 85 series with either API.

REFERENCES

1. Federal Register, Food and Drug Administration, Volume 60, No. 230, 1995, p. 61642
2. Moore, J.W. and Flanner, H.H., Mathematical Comparison of Dissolution Profile, Pharm. Tech., 20(5) (1996) 65-74

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