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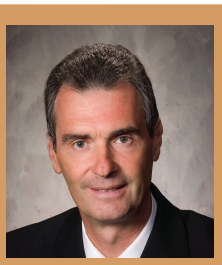

INTERVIEW WITH 3M DRUG DELIVERY SYSTEMS' DIVISION VP & GM
JAMES VAUGHAN

FEATURING
SPECIALTY PHARMA
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TABLET DESIGN

Investigation of the Influence of Tablet Shape, Geometry & Film Coating on Drug Release From Hypromellose Extended-Release Matrices

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ABSTRACT

Different tablet shapes were used to evaluate the effect of geometry on release of model drugs, with varying aqueous solubility and dose, from hypromellose hydrophilic matrices at constant as well as varying tablet surface area/volume ratios (SA/V). Results showed that drug release from matrix tablets of equal mass at constant SA/V ratios were similar among different tablet shapes. In contrast, matrices of the same geometry at varying SA/V ratios did not result in similar drug release profiles. The results of this study indicate that tablet design (shape and color) offers opportunities to refine release profiles, rebrand existing products, and create distinctive formulations, allowing greater benefits from the extended-release (ER) oral dosage forms.

INTRODUCTION

Hypromellose (hydroxypropyl methylcellulose, HPMC) has been widely used in the formulation of hydrophilic matrices for oral ER drug delivery due to its key features and advantages including global regulatory acceptance, stability, ease of manufacture, versatility, suitability for various drugs and release profiles, and availability of the polymer.[1] Drug release from HPMC matrices may be affected by several variables, including polymer type and level, drug particle size, dose and solubility, ratio of polymer to drug, filler type and level, and ratio of polymer to filler.[2-4] Tablet shape, geometry, and color are important factors determining identification, compliance, swallowability, and dose strength distinctions of oral formulations. Selection of specific tablet shape may improve the mechanical properties of the tablets, enhance aesthetic appearance, ease of handling, and packaging.[5] Tablet shape and coating are important parameters for product branding (brand recognition, preference, and "personality," eg, associating disease with the tablet shape or color).[6] Tablet shape, size, and surface area may affect drug-release profiles[7-8] and may be used for modulation of drug-release rate (eg, Geomatrix, Dome Matrix tablets) [2, 9] or for enhancing spatial control of drug release (eg, gastro-retention with specific shape of the tablet).[10-13] When a hydrophilic matrix tablet is developed, and the release profile is established with a certain tablet shape, there is usually reluctance to modify the product geometry. This is particularly true for drugs at the extremes of dose or solubility, for which the drug release is mainly controlled via diffusion or erosion, and may be more sensitive to other changes. A previous study examined the release of highly water-soluble drugs from HPMC matrices and demonstrated that when SA/V is held constant, the drug-release profiles are similar regardless of the tablet shape (round or oval).[7] A large proportion of tablets produced globally are film coated. Tablets are coated for a variety of reasons; such as elegance and aesthetics, improved swallowability, identification and branding, taste- or odor-masking, enhanced mechanical strength, and protection from moisture, light, or air. It has been shown that conventional immediate-release film coating does not affect drug release from HPMC matrices.[14]

The objective of the present study

TABLE 1

Formulation	Thickness (mm)	Hardness (kp)	Hardness* (MPa)	Surface Area (SA) (mm^2)	SA/V (mm^2/mm^3)
Metformin HCl Matrices					
Standard Concave round	6.34 ± 0.04	14.9 ± 0.5	1.737	509.36	0.612
Dumbbell	7.25 ± 0.05	16.1 ± 0.9	1.301	516.50	0.617
Caplet	6.70 ± 0.06	16.5 ± 0.7	1.375	513.98	0.611
Indapamide Matrices					
Standard Concave Round	4.77 ± 0.03	12.5 ± 0.5	4.066	154.09	0.974
Pentagon	4.14 ± 0.05	12.7 ± 1.0	4.495	158.90	1.041
Caplet	3.83 ± 0.03	10.0 ± 0.2	3.081	163.26	1.057

Compression force values of 17.5 to 23 kN and 11.5 to 13 kN were used for metformin HCl and indapamide matrices, respectively, depending on the shape in order to achieve similar range of hardness values (n=10). The tablet weights of 1000 mg and 200 mg were used for metformin HCl and indapamide matrices, respectively. *Hardness values are normalized to the cross sectional surface area of respective matrix tablets in the direction of tablet fracture.

Physical Properties of Metformin HCl & Indapamide Matrices With Constant Surface Area-to-Volume (SA/V) Ratios

was to evaluate the effect of various tablet shapes and geometry on drug release from HPMC matrices at constant, as well as variable SA/V ratios, using metformin HCl as a freely soluble drug and indapamide as a practically insoluble drug. In addition to the traditional round and caplet shapes, tablets with dumbbell and pentagon geometries were also evaluated. It was also aimed to investigate the effect of different aqueous film coating systems on the drug-release profile of HPMC matrix systems.

MATERIALS & METHODS

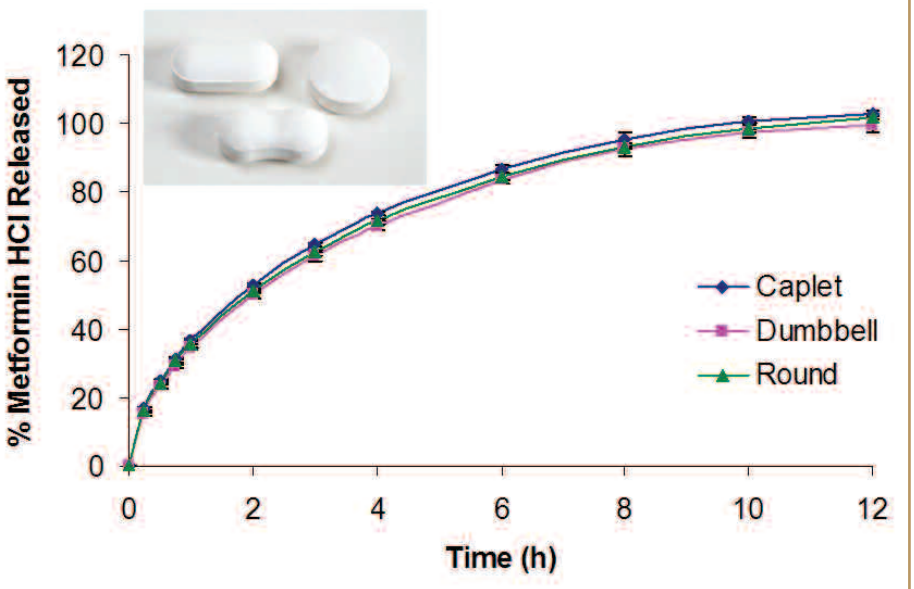
All the materials were used as received and included hypromellose (METHOCELTM, premium cellulose ethers, K100M Premium CR and METHOCELTM K15M Premium CR, International Flavors and Fragrances Inc. , USA; supplied globally by Colorcon Inc., USA), microcrystalline cellulose (Emcocel 90M, JRS Pharma, Germany), fumed silica (Aerosil 200, Evonik, Germany), magnesium stearate (Mallinckrodt, USA), lactose monohydrate (Fast Flo, Foremost, USA), metformin HCl (Wanbury, India), and indapamide (Jinan Shandong, China).

Preparation & Characterization of Hypromellose Matrices

All matrices were prepared by direct compression method (2 kg batch size). In preparation of metformin HCl matrices, microcrystalline cellulose (MCC) (19% w/w) and fumed silica (0.5% w/w) were passed through an ASTM mesh No. 35 sieve (500 micrometers) and were placed in a twin shell blender (Patterson Kelley, USA) along with metformin HCl (50% w/w) and METHOCEL K100M CR (30% w/w) and mixed for 5 minutes. Magnesium stearate (0.5% w/w) was then added to the blender and mixed for one minute.[15]

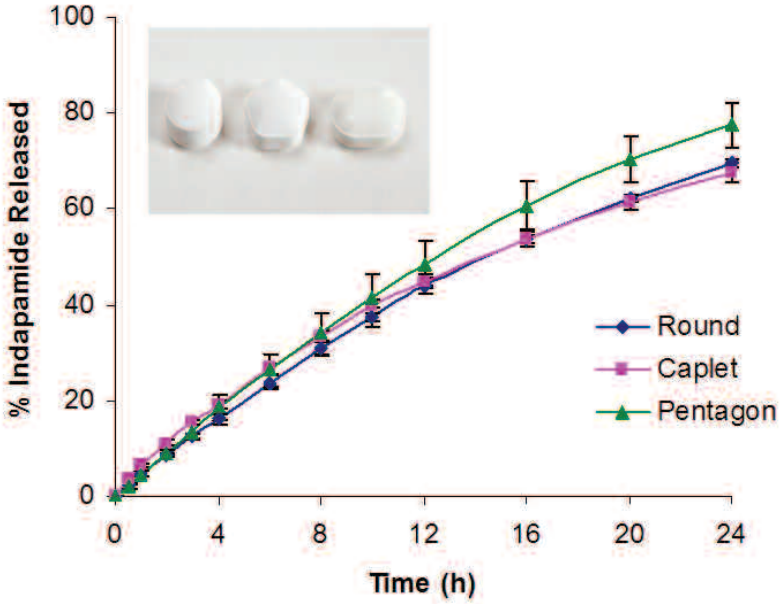
In case of indapamide matrices, drug (0.75% w/w) and half of the lactose (59.57% w/w) were blended in a high shear granulator (VG-25, Glatt Air Techniques, USA) for 5 minutes at an impeller speed of 200 rpm and a chopper speed of 500 rpm. The remaining lactose [sieved with fumed silica (0.5% w/w) through an ASTM mesh No. 35 sieve] was added to the bowl and mixed for 5 minutes. METHOCEL K15M CR (38.68% w/w) was then added and blended for an additional 5 minutes. Finally, magnesium stearate (0.5% w/w)

FIGURE 1



Drug Release Profiles for Metformin HCl Matrices at Constant SA/V Ratios
Constant tablet weight of 1000 mg was used for all shapes of metformin HCl matrices. Dissolution study was conducted using USP Apparatus II (paddle) with sinkers at 100 rpm in purified water, 1000 mL (n = 6).

FIGURE 2



Drug Release Profiles for Indapamide Matrices at Constant SA/V Ratios
Constant tablet weight of 200 mg was used for all shapes of indapamide matrices. Dissolution study was conducted using USP Apparatus I (basket) at 100 rpm and 0.05 M pH 6.8 phosphate buffer, 900 mL (n = 6).

was added, and the formulation was mixed for one minute, using an impeller speed of 400 rpm.[16]

Tablets were manufactured using an instrumented 10-station rotary press (Piccola, Riva, Argentina) operated at 20 rpm. For each drug, various tablet shapes were evaluated. For metformin HCl matrices, standard concave round (14.3 mm), caplet (19 X 9.3 mm), and dumbbell (19 X 9.1 mm) shaped tablets were examined. For indapamide matrices, standard concave round (7.1 mm), caplet (9.5 X 6.6 mm), and pentagon (8.2 X 7.9 mm) shaped tablets were examined. All tablets were evaluated for physical properties, including weight variation, hardness, thickness (Multicheck, Erweka, Germany), friability (Vanderkamp Friabilator, VanKel Industries, USA), and SA/V ratios (using the tooling specifications and relevant mathematical equations).

Constant SA/V Ratios

To evaluate the effect of constant SA/V ratios on drug release, various shapes of metformin HCl and indapamide ER tablets with constant SA/V ratios were compressed at target tablet weights of 1000 mg and 200 mg, respectively (Table 1).

Different SA/V Ratios

Different SA/V ratios were achieved on selected matrix shapes by varying the tablet weight in the range of 750 to 1440 mg for metformin HCl and 150 to 300 mg for indapamide matrices, depending on the tablet shape (Table 2). For each shape, the effect of three different SA/V ratios on the drug-release profile was evaluated. The tablet composition for each drug was the same as previously described.

Film Coating of ER Matrices

To evaluate the effect of film coating on drug release, the metformin HCl dumbbell shaped matrices (tablet weight = 1000 mg) and indapamide pentagon-shaped matrices (tablet weight = 200 mg)

TABLE 2

Formulation	Tablet Weight (mg)	Thickness (mm)	Hardness (kp)	Hardness* (MPa)	Surface Area (SA) (mm^2)	SA/V (mm^2/mm^3)
Metformin HCl Matrices						
Caplet	750	5.35 ± 0.05	9.7 ± 0.9	1.022	452.93	0.704
	1000	6.79 ± 0.04	16.2 ± 1.2	1.327	523.04	0.601
	1440	9.28 ± 0.06	23.5 ± 1.7	1.377	644.26	0.509
Dumbbell	750	5.86 ± 0.06	9.2 ± 0.7	0.940	449.27	0.709
	900	6.71 ± 0.03	11.8 ± 0.6	1.041	490.71	0.646
	1325	9.22 ± 0.03	18.2 ± 1.3	1.125	613.07	0.543
Indapamide Matrices						
Round	150	3.10 ± 0.03	8.5 ± 0.2	4.573	137.88	1.240
	200	3.91 ± 0.08	11.4 ± 1.0	4.670	158.08	1.045
	300	5.43 ± 0.04	17.5 ± 0.7	4.953	195.99	0.865
Pentagon	150	3.41 ± 0.06	7.4 ± 0.2	3.335	136.31	1.169
	200	4.20 ± 0.06	11.6 ± 1.1	4.022	154.04	0.990
	300	5.69 ± 0.04	17.8 ± 3.2	4.310	187.47	0.818

Compression force values of 18 kN and 13 kN was used for metformin HCl and indapamide matrices, respectively (n = 10).
***Hardness values are normalized to the cross sectional surface area of respective matrix tablets in the direction of tablet fracture.**

Physical Properties of Metformin HCl & Indapamide Matrices With Variable Surface Area-to-Volume (SA/V) Ratios

were selected and coated, using the four different fully formulated film coating systems (Colorcon, USA) viz; Opadry® II, high performance film coating system 32K10908, Opadry II 85F94544, Opadry® amb, aqueous moisture barrier film coating system 80W90677, and Opaglos® 2, high gloss film coating system, tablet core sealant product 97W90646. Each selected tablet shape was coated in a fully perforated coating pan (15-inch; Compu-Lab, Thomas Engineering, USA) to a weight gain of 4% w/w using standard coating parameters.

Dissolution Testing

The drug release from metformin and indapamide formulations was measured in a USP-compliant dissolution bath (VanKel VK7000, Varian Inc. USA), using the previously reported methods.[15-16] Metformin HCl matrices were tested using Apparatus II (paddle) with sinkers at 100 rpm, 1000 mL of purified water, and UV analysis at 233 nm. Indapamide matrices were tested using Apparatus I (basket) at 100 rpm, 900 mL 0.05M pH 6.8 phosphate buffer, and HPLC analysis. Similarity factors (f_2) were calculated in order to compare the dissolution performance of different matrix shapes and of the film coated tablets.[17]

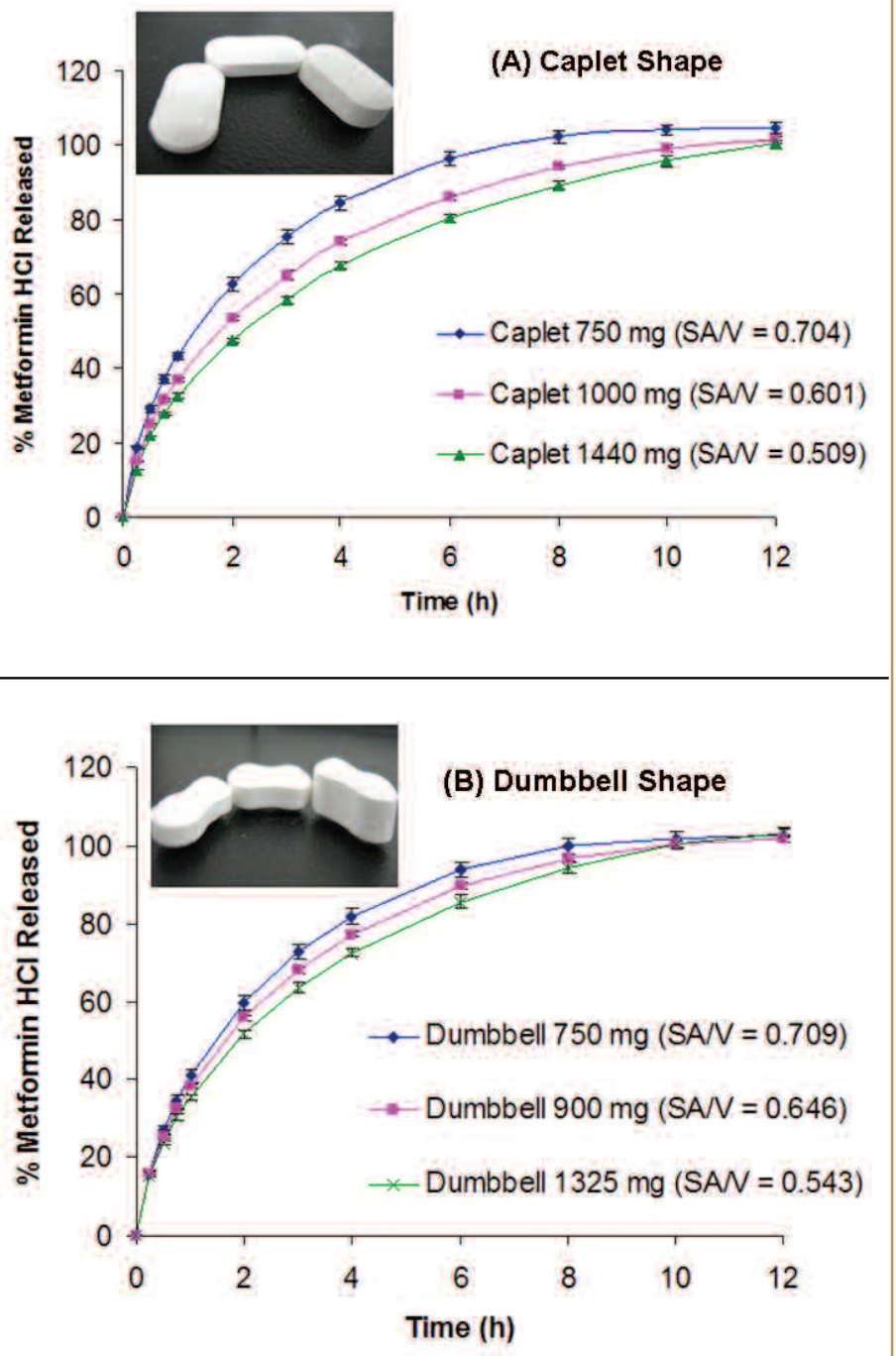
RESULTS & DISCUSSION

Effect of Constant SA/V

The influence of matrix geometry on drug release has been reported by Siepmann et al, in which they examined the effect of aspect ratio (radius/height) and the size of cylindrical matrices on drug release for diffusion controlled systems.[8] They stated that because small cylindrical tablets have a higher relative surface area, (ie, absolute surface area/absolute volume), the release from small tablets is faster than from large cylindrical tablets. Certainly, the aspect ratio (radius/height) is a relevant term when comparing the relative shape of cylinders, but it is seemingly not as valuable a term as the SA/V ratio may be when comparing the relative drug release from tablets of varying shapes. Reynolds et al examined the effect of SA/V ratio on drug release from HPMC matrix tablets; however, their investigation primarily focused on the diffusion-controlled drug release (for high solubility drugs).[7] In this study, the effects of SA/V ratio combined with tablet shape and film coating on drug release for both a freely soluble drug or a practically insoluble drug from HPMC matrices have been investigated.

All the formulated metformin and indapamide matrix tablets with constant SA/V ratios exhibited acceptable pharmaco-technical properties, including

FIGURE 3A & B



Drug Release Profiles for Metformin HCl Matrices with Variable SA/V Ratios
Dissolution study was conducted using USP Apparatus II (paddle) with sinkers at 100 rpm and purified water, 1000 mL (A) caplet shape, (B) dumbbell shape (n = 6).

low weight variation, good hardness, and low friability (Table 1). Figures 1 and 2 show drug-release profiles from each tablet shape for metformin HCl and indapamide ER matrices, respectively. The similarity factors (f_2) were calculated for different tablet geometries, utilizing the round shape as reference. The f_2 values for metformin HCl tablets were 88.2 (caplet) and 92.4 (dumbbell). For indapamide matrices, the f_2 values were calculated as 78.4 (caplet) and 64.0 (pentagon). Thus, the drug-release profiles were considered similar ($f_2 > 50$), indicating that changing tablet geometry did not influence the drug-release profile when SA/V ratios were held constant. This finding is of importance to the pharmaceutical industry from commercial and branding point of view as matrix tablet shape can potentially be altered for brand-enhancement purposes without significantly affecting the drug-release profile.

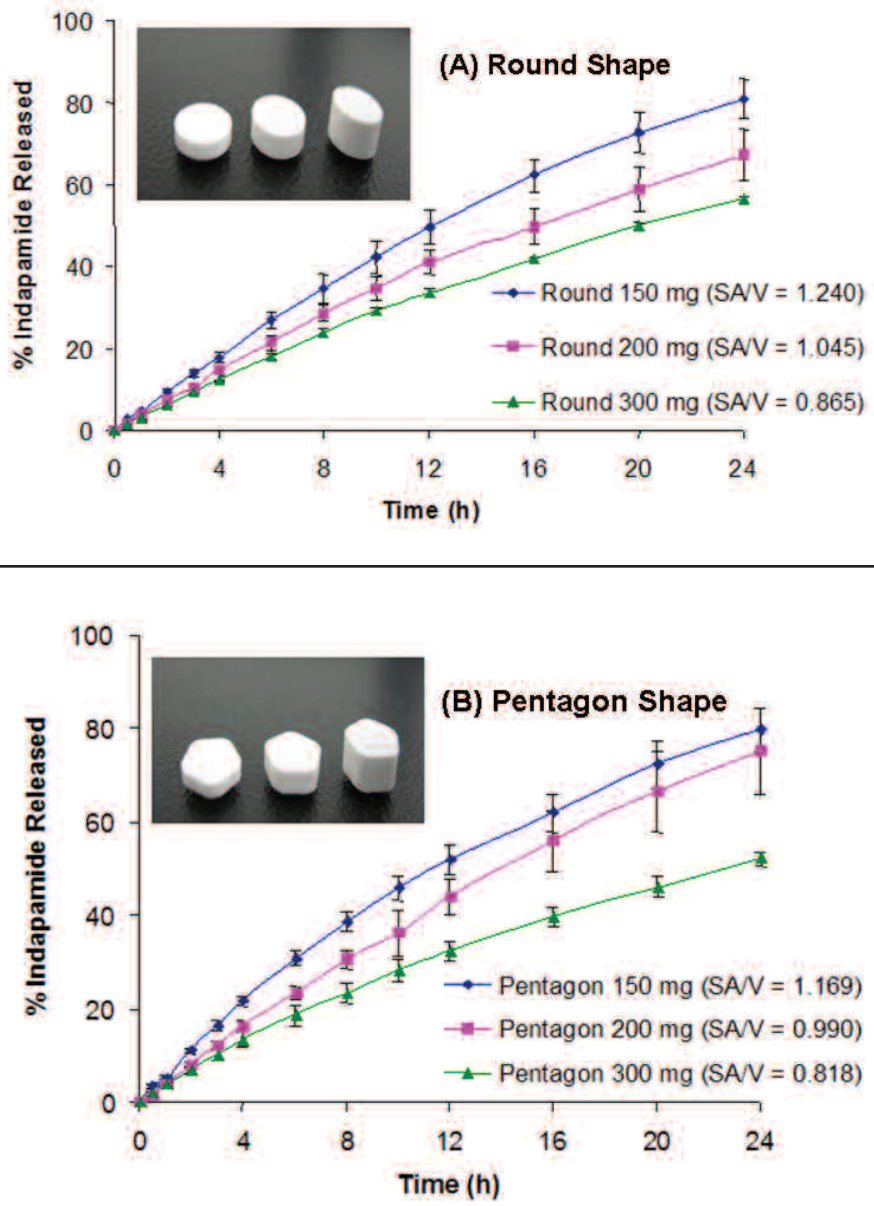
Effect of Variable SA/V Ratios

All of the formulated tablet compositions exhibited acceptable pharmaco-technical properties, including low weight variation, good hardness, and low friability (Table 2). Drug-release profiles for each tablet shape are shown in Figure 3 for metformin HCl matrices (caplet and dumbbell shapes), and in Figure 4 for indapamide matrices (round and pentagon shapes). Results show that increasing tablet weight led to a decrease in SA/V values and consequently a decline in release rate for both drugs. In the case of metformin HCl (freely soluble drug), this could be attributed to the shorter diffusion pathways in smaller tablets (higher SA/V ratios), while in the case of indapamide (practically insoluble drug), more surface area per unit volume is available for erosion to occur with smaller tablets. Furthermore, Table 2 shows a direct relationship between tablet weight and hardness. It has been shown that the effect of tablet hardness on drug release from hydrophilic matrices is expected to be minimal when tablets with sufficient strength and optimal levels of polymers are manufactured.[1,18] Therefore, varying SA/V ratios can directly influence the drug release from HPMC matrices. This finding is of importance to the pharmaceutical formulators in the design of dose-proportional formulas because optimal drug-release profiles may be achieved without further modification of a formulation by choosing an appropriate SA/V ratio for a tablet.

To evaluate the mechanism of drug release and to compare the performance of various matrix tablets, the dissolution profile for each drug and tablet shape was used. Data corresponding to 5% to 60% release presented a suitable fit to the Power Law model, as expressed in the following equation: $(M_t/M_{inf} = kt^n)$.[19]

M_t is the amount of drug released at time t, M_{inf} is the amount of drug released after infinite time, k is a kinetic constant, incorporating structural and geometric characteristic of the tablet, t is the release time, and n is the diffusional exponent indicative of the drug-release mechanism.

FIGURE 4A & B



Drug Release Profiles for Indapamide Matrices with Variable SA/V Ratios
Dissolution study was conducted using USP Apparatus I (basket) at 100 rpm and 0.05 M pH 6.8 phosphate buffer, 900 mL (A) round shape, (B) pentagon shape (n = 6).

For cylindrical tablets, n value of ~ 0.45 indicates diffusion control, while an n value of ~ 0.89 indicates erosion or relaxation control. Intermediate values ($0.45 < n < 0.89$) suggest that diffusion and erosion contribute to the overall release mechanism. The values of n and k are inversely related.

The values of n for metformin HCl matrices were between 0.56 and 0.63; for indapamide matrices, values of n ranged between 0.77 and 0.94. The obtained n values indicate an anomalous behavior corresponding to diffusion, erosion, and swelling mechanisms for all matrices. Based on these values, the drug release from metformin HCl matrices is more diffusion controlled, while for indapamide matrix tablets, erosion or relaxation mechanism is more dominant. The correlation coefficients (R^2) for all matrices exceed 0.99. For metformin HCl matrices, the high k values (above 31) is an indication of a burst drug release.[20]

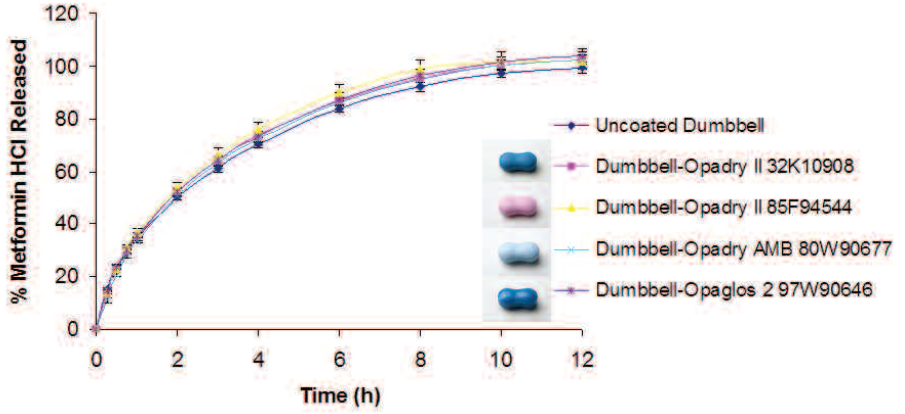
Effect of Film Coating

As previously discussed, application of film coatings to tablet formulations is a common practice in the pharmaceutical industry. Tablets are film coated for a variety of reasons, such as improving the stability of the formulation, taste-masking, enhancing the aesthetic appearance, identification and branding, and improving the packaging process. Low-viscosity hydrophilic polymers are generally used in film coating compositions and their application on hydrophilic matrix tablets is not expected to alter the drug-release profile. Depending on the choice of film coating system, tablets are generally coated to a weight gain of around 3% w/w. In the present study, however, tablets were coated to achieve a weight gain of ~ 4% w/w to cover the edges of odd-shaped tablets (pentagon and dumbbell), and to examine the effect of film coatings on release when applied at higher-than-desired weight gains. Figures 5 and 6 show that application of film coating systems did not significantly alter the drug-release profiles from metformin HCl matrices (f_2 values ranged from 71 to 82, coated versus uncoated) and indapamide matrices (f_2 values ranged from 75 to 96, coated versus uncoated), irrespective of the film coating system used. These results indicate that application of film coating systems of different chemistry have insignificant effect on hydration and gel-layer formation of hydrophilic polymers used in designing matrix systems, thereby resulting in similar drug-release profiles (coated versus uncoated). These results are in agreement with the findings of Levina et al on film coated, traditional-shaped matrix tablets.[14]

CONCLUSIONS

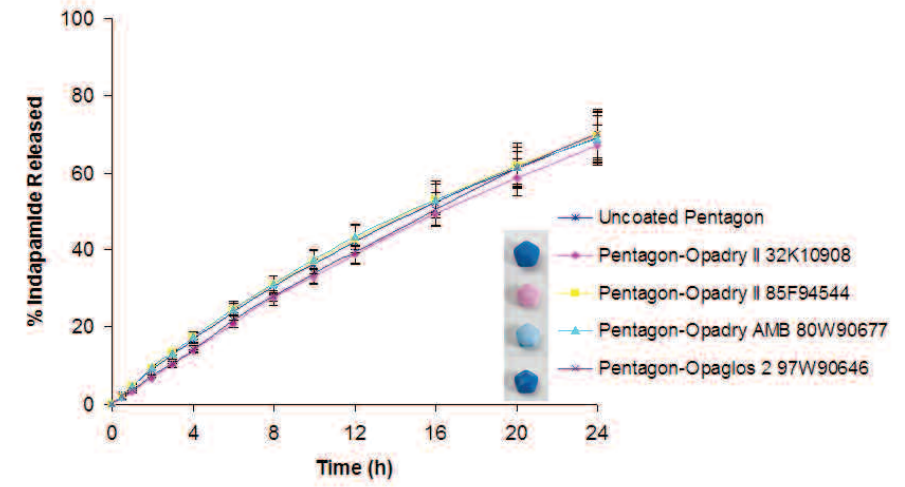
Tablet shape, geometry, and color are important factors determining identification, compliance, swallowability, and dose-strength distinctions of oral formulations. For HPMC ER hydrophilic matrices, SA/V ratio is more of an important factor compared to the tablet shape in controlling the drug release. Constant SA/V ratios yielded similar drug-release profiles, while different SA/V ratios led to correspondingly different drug release, with greater ratios resulting in higher release rates. Results indicate a direct relationship between SA/V ratios

FIGURE 5



Comparative Drug Release Profiles of Uncoated and Coated Metformin HCl Matrices
The corresponding tablet color is the actual color of the Opadry/Opaglos formula (n = 6).

FIGURE 6



Comparative Drug Release Profiles of Uncoated and Coated Indapamide Matrices
The corresponding tablet color is the actual color of the Opadry/Opaglos formula (n=6).

and drug-release rate from matrices, irrespective of drug solubility, dose, mechanism of drug release, and tablet shape. Application of film coating systems of varying chemistry did not alter the drug-release profiles from matrices (f_2 values > 70, coated versus uncoated tablets). This finding is of paramount importance to pharmaceutical formulators because by designing a particular size and shape of matrices, optimal drug-release profiles can be achieved without further modification of formulation. In conclusion, tablet design (shape and color) offers opportunities to refine release profiles, rebrand existing products, and create distinctive formulations, allowing greater benefits from the ER oral dosage forms.

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BIOGRAPHIES

Dr. Shahrzad Missaghi is Manager, Product Development at Colorcon. She earned her BSc in Pharmacy from Baha'i Institute for Higher Education (BIHE) in Iran and her PhD in Pharmaceutical Sciences from Temple University in Philadelphia, PA. Her research areas involve formulation and development of solid oral dosage forms with her main focus on modified-release technologies. Dr. Missaghi is a member of the Controlled Release Society (CRS) and the American Association of Pharmaceutical Scientists (AAPS). She has published a variety of abstracts and peer-reviewed articles and presented in various national and international conferences.

Mr. Piyush Patel is a Product Development Scientist at Colorcon. He earned his MPharm in Pharmaceutical Sciences from Curtin University of Technology in Australia in Nanotechnology Drug Delivery Research. Prior to joining Colorcon, he worked for Medico labs as an R&D Scientist developing OTC oral liquid dosage forms. He has contributed to poster and oral presentations in the areas of nanotechnology and hydrophilic matrix systems.

Dr. Sandip B. Tiwari is a Senior Manager, Product Development at Colorcon Inc., Harleysville, PA. Prior to joining Colorcon, he was a post-doctoral fellow at Northeastern University, Boston, MA, where he investigated the application of nanotechnology in drug delivery and diagnostics. Dr. Tiwari also worked at the Zydus Research Center, Ahmedabad, India, as an Associate Research Scientist and then as a Senior Scientist and Head of the Department of Novel Drug Delivery Systems. He has over 10 years experience in the pharmaceutical field and has participated in various stages of drug development during his career. He earned his PhD in Pharmaceutical Sciences from Mangalore University, India. He has written three book chapters and contributed over 80 research publications and conference presentations in the areas of controlled release technology, non-invasive drug delivery, and nanotechnology.

Dr. Thomas P. Farrell earned his BS in Chemistry from Duke University in 1985 and his PhD in Chemistry from Princeton University in 1989. He was employed by ARCO Chemical Company from 1989 to 1999, where he held positions of increasing responsibility within Specialty Chemicals & Polymers R&D, including Technology Manager. Dr. Farrell has been employed as Director, Product Development at Colorcon's Corporate Headquarters in West Point and Harleysville, PA, from 1999 to the present. He is an active member of the American Chemical Society, the Controlled Release Society, and the Association of American Pharmaceutical Scientists (AAPS). Dr. Farrell is the 2010 Chairman of the AAPS Excipients Focus Group. He is an inventor on five US Patents.

Dr. Ali Rajabi-Siahboomi is Senior Director of Scientific Affairs at Colorcon. He earned his BPharm and PhD in Pharmacy from University of Nottingham (UK). He has held various academic positions (7 years) in Nottingham and Liverpool JM Universities before joining Colorcon as Technical Director (Europe, Middle East, and Africa). His main research interests are in the area of solid dosage form pharmaceutics and pharmaceutical technology with an emphasis on oral drug delivery systems. He has published over 150 articles, book chapters, abstracts, and patents.