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*Research Article*

# Evaluation of Sesamum Gum as an Excipient in Matrix Tablets

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ABSTRACT

In developing countries modern medicines are often beyond the affordability of the majority of the population. This is due to the reliance on expensive imported raw materials despite the abundance of natural resources which could provide an equivalent or even an improved function. The aim of this study was to investigate the potential of sesamum gum (SG) extracted from the leaves of *Sesamum radiatum* (readily cultivated in sub-Saharan Africa) as a matrix former. Directly compressed matrix tablets were prepared from the extract and compared with similar matrices of HPMC (K4M) using theophylline as a model water soluble drug. The compaction, swelling, erosion and drug release from the matrices were studied in deionized water, 0.1 N HCl (pH 1.2) and phosphate buffer (pH 6.8) using USP apparatus II. The data from the swelling, erosion and drug release studies were also fitted into the respective mathematical models. Results showed that the matrices underwent a combination of swelling and erosion, with the swelling action being controlled by the rate of hydration in the medium. SG also controlled the release of theophylline similar to the HPMC and therefore may have use as an alternative excipient in regions where *Sesamum radiatum* can be easily cultivated.



## INTRODUCTION

Hydrophilic matrices are commonly used as oral drug delivery systems and are being increasingly investigated for controlled-release applications because they combine the advantages of not only being easy to formulate but are also economical to produce (Heller et al., 1983; Nokhodchi et al., 2012; Shojaee et al., 2013). The formation of a hydrated viscous layer around the tablet provides a barrier to drug release by opposing penetration of water into the tablet and also movement of dissolved solutes out of the tablet matrix (Bamba et al., 1979; Ghori et al., 2014; Asare-Addo et al., 2014). The physical properties of the hydrated gel layer and hydration behaviour of the polymer play a critical role in drug release (Melia, 1991), and can be influenced by factors such as change in pH.

Naturally occurring polymers are increasingly becoming the focus of research on hydrophilic matrices for oral controlled release (Naggar et al., 1992; Bonferoni et al., 1993; Kristmundsdo´ttir et al., 1995; Sujja-areevath et al., 1996; Talukdar et al., 1996; Khullar et al., 1998; Vervoort et al., 1998; Nep 2015). They hydrate and swell on contact with water forming the gel layer controlling drug release from the tablet matrices. Drug release from these matrices has been shown to be a complex interaction between swelling, diffusion and erosion (Harland et al., 1988; Peppas and Sahlin, 1989; Lee and Kim, 1991; Colombo et al., 1995; Reynolds et al., 1998).

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Gum from the leaves of *Sesamum indicum* have been evaluated as a binder (Jackson et al., 2012) and as matrix former in tablet formulations (Akpabio et al., 2011). To our best knowledge, however, there are no reports on the application of the gum extract from *Sesamum radiatum* as a matrix tablet formulation although the binding property of the gum has been reported in Allagh et al., (2005). The objective of this study was to compare the swelling, erosion and drug release from tablet matrices of gum from *Sesamum radiatum* with a popular matrix former such as HPMC K4M. By application of various mathematical models, it was possible to quantify the relative contributions of the diffusional and erosional mechanisms to the drug release process.

## MATERIALS AND METHODS

Methocel (HPMC K4M) was a kind gift from Colorcon (UK) and was used as supplied from the manufacturer. The particle size was, however, determined using the Sympatec laser diffraction particle size analyser (Clausthal-Zellerfeld, Germany) according to the methodology detailed by Asare-Addo et al., (2015). Particle size analysis showed the HPMC K4M to have a $d_{10\%}$ value of 26.79 µm, $d_{50\%}$ of 78.67 µm and $d_{90\%}$ of 141.63 µm. The results also showed $d_{99\%}$ to have a value of 171.10 µm. Lactose monohydrate (FlowLac® 100) was a kind gift from Meggle (Germany). Magnesium stearate (MgSt) was used as supplied from Merck (Germany). Anhydrous theophylline (TCI Chemicals, Europe) was used as the model drug. Dissolution buffers were prepared according to the USP 2003 using the following materials: potassium chloride (Acros Organics, UK) and hydrochloric acid (Fisher Scientific, UK) for pH 1.2, and potassium phosphate monobasic-white crystals (Fisher BioReagents, UK) and sodium hydroxide (Fisher Scientific, UK) for pH 6.8 media. Sesamum gum was extracted from sesamum leaves in our laboratory.

**Extraction of sesamum gum (SG):** To extract the mucilage, 1000 g of *Sesamum radiatum* leaves were macerated in 7.5 litres of distilled water containing 0.1 %w/v sodium metabisulphite for 30 min at room temperature. The mucilage was filtered from the leaves using a muslin cloth and thereafter precipitated with 96% ethanol. The precipitate was filtered and oven dried at 50°C for 24 hours. The dried SG was size reduced to a particle size of < 200 µm using a sieve shaker and stored in sealed plastic envelope before its use as a matrix former in the tablet formulations. All characterisations and release studies were conducted with the same batch of SG.

**Tablet Formulation, compression, hardness and dimensions:** The pure polymers (SGp and HPMC K4M) were compacted using a single punch tableting machine (Model MTCM-1, Globe Pharma US) at 6 different pressures (44.6, 70.0, 97.4, 125.7, 150.8, and 176.0 MPa) to determine the effect of compression force on the hardness of the pure polymer matrices. HPMC was used as a control due to its popular use in extended release matrices as a result of its robustness, stability, regulatory acceptance and cost effectiveness (Tiwari and Rajabi-Siahboomi, 2008; Nokhodchi and Asare-Addo, 2014). The matrix tablets containing theophylline as a model drug were formulated according to the unit formula in Table 1. Round convex tablets with a diameter of 10.0 mm and target weight of 250 mg were prepared by blending the appropriate amounts of ingredients as shown in Table 1 for 10 min in a Turbula® (Type T2C, Switzerland) blender. A batch size of 100 tablets were made meaning for the SG formulation, the blend contained, 12.5 g theophylline, 7.5 g SG, 4.75 g lactose and 0.25 g MgSt. The HPMC formulation blend contained 12.5 g theophylline, 7.5 g HPMC K4M, 4.75 g lactose and 0.25 g MgSt. The tablets were compressed at 125.7 MPa. The tablets were allowed a recovery period of 24 h before the hardness of the tablets was determined on a hardness tester (PharmaTest, Germany). The thickness and diameter of the matrix tablets was measured using digital callipers.

***Table 1.*** *Unit formula for matrix tablets by direct compression*

| Formulation | SG | HPMC |
|---|---|---|
| Theophylline (mg) | 125 | 125 |
| Sesamum gum (mg) | 75 | - |
| HPMC K4M (mg) | - | 75 |
| Lactose (mg) | 47.5 | 47.5 |
| Magnesium stearate (mg) | 2.5 | 2.5 |

**Bulk density, tapped density, true density and porosity of polymers and formulation blends:** The bulk and tapped densities of SG and HPMC pure polymers and formulation blends were determined by weighing 10 g of the material into a 100 mL measuring

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cylinder and, without disturbing the cylinder the volume was read to give the bulk volume of the powder. Thereafter, the measuring cylinder was tapped until the volume of powder was constant and the tapped volume of the material was read. The bulk or tapped density is the ratio of the weight of powder to the bulk or tapped volume respectively.

The true density of the polymers and formulation blends was determined using Micromeritics Accupyc II pycnometer 100 (Micromeritics, USA). The test was carried out using a multi-run system (10 runs) with a standard deviation of 0.005%. The results are presented as the mean and standard deviation of three determinations.

**Swelling and erosion studies:** Swelling and erosion was determined on a USP Apparatus II (paddle) dissolution bath (PharmaTest, Germany) set to 100 rpm and equilibrated at 37 °C. The dissolution media was deionized water, pH 6.8, or pH 1.2. The tablets were supported on pins at the bottom of the dissolution vessel. Dissolution media (900 mL) was measured into each of the six vessels of the bath and allowed to equilibrate for 30 min before starting the experiment. The experiment consisted of getting the tablets on to pre-weighed sinkers and allowing the tablets to dissolve in the medium at the chosen agitation rate for 30, 60, 120, 180 and 240 min before they were removed into a pre-weighed weighing boat. Excess dissolution medium was drained and blotted from around the sinker without touching the tablet. The sinker, tablet and boat were then weighed to establish the wet weight of the tablet. Thereafter, the tablets were dried to a constant weight in an oven at 50 °C. All experiments were done in triplicates.

**Modelling of swelling and erosion:** The relative swelling, the ratio of the wet weight to the initial weight was determined, as an indication of the extent of matrix swelling using equation 1.

$$Relative\ swelling = \frac{W_w}{W_i} \quad (1)$$

where $W_w$ is the wet weight of the tablet at a time $t$, and $W_i$ the initial weight of the tablet. The maximum measured dissolution medium uptake occurring over the duration of the experiment was estimated by subtracting the dry weight of the tablet from its wet weight at each time point (Tahara et al., 1995) as in equation 2.

$$Medium\ content = W_w - W_d \quad (2)$$

where $W_w$ is the wet weight of the tablet, and $W_d$ is the dry weight of the tablet, at a time $t$.

The ratio of dissolution medium uptake per weight of matrix remaining was calculated at each time point by subtracting the dry weight from the wet weight at each time point and dividing this value by the dry weight at that time point (equation 3) (Kavanagh and Corrigan, 2004).

$$\begin{matrix} Uptake\ of\ dissolution\ media \\ per\ weight\ of\ matrix\ remaining \end{matrix} = \frac{W_w - W_d}{W_d} \quad (3)$$

The values for dissolution medium uptake per unit matrix remaining were then fitted to a square root of time equation (equation 4):

$$\frac{W_w - W_d}{W_d} = K_1(t^{0.5}) \quad (4)$$

Where $K_1$ is the dissolution medium uptake rate constant and $t$ is the time.

The values of the dry weight data were fitted to the cube root relationship (Hixson and Crowell, 1931) to determine the apparent polymer erosion rate constant $K_2$ (equation 5).

$$\left(\frac{W_d}{W_i}\right)^{1/3} = 1 - K_2 t \quad (5)$$

where $W_d$ is the dry weight of the matrix at time $t$, and $W_i$ is the initial weight of matrix.

**In vitro release studies:** The dissolution profiles of theophylline from the tablet matrices was monitored on an automated USP dissolution apparatus II (paddle method). The dissolution medium was 900 mL of deionized water, 0.1 N HCl (pH 1.2) or phosphate buffer (pH 6.8) equilibrated to 37 °C with a paddle stirring speed of 100 rpm. Samples were withdrawn at selected time intervals from 5 min up to 720 min using a peristaltic pump and the

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concentrations of theophylline in the samples determined by UV spectrophotometer at 272 nm. All experiments were done in triplicates.

**Dissolution parameters (dissolution efficiency (DE) and mean dissolution time (MDT):** The mean dissolution time (MDT) and dissolution efficiency (DE) were determined according to equation 6 and 7 respectively (Al-hamidi et al., 2013, 2014; Mu et al., 2003; Khan, 1975).

$$MDT = \frac{\sum_{j=1}^{n} t_j \Delta M_j}{\sum_{j=1}^{n} \Delta M_j} \quad (6)$$

Where j is the sample number, n is the number of dissolution sample times, $t_j$ is the time at midpoint between $t_j$ and $t_{j-1}$ and $\Delta M_j$ is the additional amount of drug dissolved between $t_j$ and $t_{j-1}$.

$$DE = \frac{\int_0^t y \times dt}{y_{100} \times t} \times 100 \quad (7)$$

where $y$ is the drug percent dissolved at time $t$.

**Similarity factor:** The drug release profiles were compared by using similarity factor $f_2$ as shown in equation 8 (Moore and Flanner, 1996; Polli et al., 2004; Asare-Addo et al. 2010).

$$f2 = 50\ log\left\{\left[1 + \frac{1}{n}\sum_{t=1}^{n} w_t (R_t - T_t)^2\right]^{-0.5} X\ 100\right\} \quad (8)$$

where $n$ is the number of pull points for tested samples; $w_t$ is the optional weight factor; $R_t$ is the reference assay at time point $t$; $T_t$ is the test assay at time point $t$.

The drug release profile of HPMC (K4M) matrices was the reference. The $f_2$ values ranging from 50-100 indicate similarity between the two profiles. The closer the $f_2$ value is to 100, the more similar or identical the release profiles. Values of $f_2$ less than 50 indicate dissimilarity between two dissolution profiles (Polli et al., 1997; Pillay and Fassihi, 1998).

**Kinetics of drug release:** The kinetics of drug release was analysed using Korsmeyer-Peppas equation (Siepmann & Peppas, 2001). For cylinders, which were the shape of the tablet matrices made in this study, n ≤ 0.45 suggest Fickian diffusion, and values ≥ 0.89 suggest Case-II transport. Values between these two suggests anomalous transport occurring (Siepmann and Peppas 2001; Asare-Addo et al., 2013; Siahi-Shadbad et al., 2011; Ritger and Peppas 1987).

**Differential Scanning Calorimetry (DSC):** Free and bound water of the tablets was determined as reported previously (Asare-Addo et al., 2011; Kaialy et al., 2013). The flat faced 4 mm disks with target weights of 20 mg were produced from all formulation blends of polymers and compressed using a single punch tableting machine (as before at 2500 psi (785.4 MPa). A disc was placed in standard aluminium pans (40 µL) containing 25 mg of purified water, 0.1 N HCl (pH 1.2), or phosphate buffer (pH 6.8) and sealed with a lid then allowed to hydrate. The pure polymers were allowed to hydrate for up to 30 min (1, 5, 10 and 30 min) to determine the influence of time on bound and free water states. The tablet formulations were hydrated for 5 min before DSC analysis. This was to determine if the state of water in the matrices could relate to the dissolution profiles of the tablet formulations. DSC analysis was in three stages: first, sample was rapidly cooled to -30 ˚C at a rate of 55 ˚C/min to freeze any unbound or free water; secondly, sample was held at -30 ˚C for 5 minutes for equilibration and thirdly, sample was heated from -30 ˚C to 50 ˚C at 10 ˚C/min. The experiment was run under nitrogen atmosphere and a flow rate of 50 $cm^3$/min. All experiments were done in triplicates. 25 mg of purified water, 0.1 N HCl (pH 1.2), or phosphate buffer (pH 6.8) was placed in the DSC pans and sealed with a lid and allowed to go through the same process as the flat faced 4mm disks. The endotherms produced were integrated and this represented 100 % free water as the standard.

**Statistical Analysis:** Statistical significance (P<0.05) between test groups was determined by one-way analysis of variance (ANOVA) and Tukey post-hoc test (Primer of Biostatistics 4.0).

## RESULTS AND DISCUSSION

**Properties of formulation powders:** Some properties of the blend of formulation ingredients are shown in Table 2. The results show that sesamum gum polymer

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(SGp) and the formulation blend (SGf) exhibited higher porosites than HPMCp and HPMCf respectively (P<0.05). Also, harder compacts were formed by SGp and SGf (Fig. 1a and b) indicating that SGp is a highly compactible polymer forming matrices with higher hardness as compared with HPMCp. The results thus suggest that there may be increased number of inter-particulate hydrogen bonds during compaction for SGp as compared to HPMCp. What is interesting to note also is the reduction in matrices hardness with the addition of drug and lactose. This may be due to the reduction in hydrogen bonding as a result of the drug and lactose's incorporation suggesting that in the formulation, the compressibility of the drug and lactose predominates although harder compacts were made. This reduction occurs over a greater amount for SG than for HPMC (Fig. 1).

***Table 2.*** *Some Compression properties of the pure polymers, formulation mixes, Polymer compacts and tablet matrices (compact hardness prepared at 125.7 MPa). Values represent means ± SD*

| | True density (g/cm³) | Bulk density (g/cm³) | Tapped density (g/cm³) | Tablet Porosity (%)[a] | Compact Hardness (N) |
|---|---|---|---|---|---|
| SGp | 1.80± 0.04 | 0.11± 0.01 | 0.21± 0.03 | 52.79± 0.69 | 243.94± 15.0 |
| SGf | 1.59± 0.01 | 0.23± 0.01 | 0.47± 0.02 | 44.20± 0.46 | 116.41± 3.97 |
| HPMCp | 1.36± 0.03 | 0.31± 0.01 | 0.46± 0.04 | 40.91± 0.31 | 146.17± 5.46 |
| HPMCf | 1.45± 0.02 | 0.36± 0.01 | 0.65± 0.01 | 39.98± 0.29 | 97.77± 1.50 |

[a] ***at 125.7 MPa***

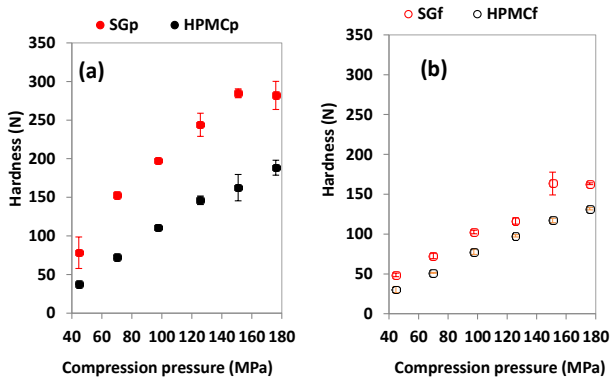


***Fig. 1:*** ***(a)*** *The mechanical strength (Hardness) of polymer compacts (HPMCp and SGp) and (b) compression profiles of the matrices (HPMCf and SGf).*

**Swelling and erosion of matrices:** The swelling and erosion profiles of the matrices of SGf and HPMCf in the different media are shown in Fig. 2. Both swelling and erosion of the matrices occur simultaneously in the different media with erosion predominating in SGf matrices after 2 hours of hydration at 100 rpm in deionized water and phosphate buffer (pH 6.8). The swelling of the SGf in pH 1.2 however, is reduced. This is likely to be due to the content of uronic acids in the polymer chains which lose their charge at low pH reducing the rate of hydration. This can also be seen in Fig. 3 which shows the profiles of relative swelling according to equation 1. The relatively higher erosion of SGf matrices in deionized water can be seen in Fig. 4. In all media the SGf matrices exhibited higher swelling than HPMCf matrices except after 4 hours in deionized water when swelling of the matrices was exceeded by erosion.

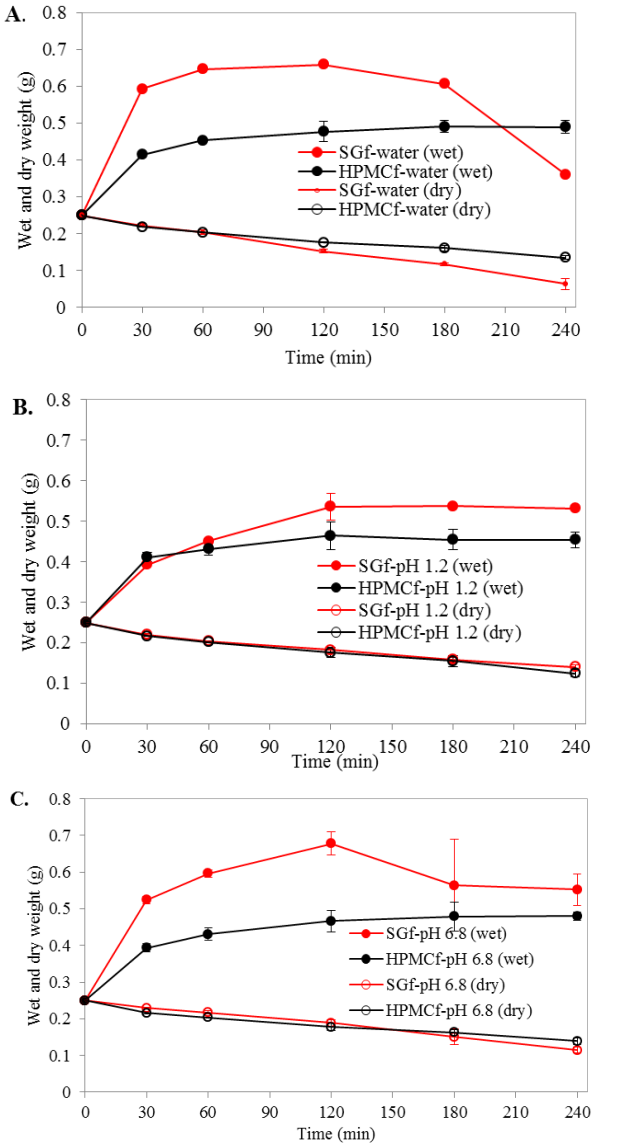


***Fig. 2****: Swelling and erosion profiles of SG and HPMC in A) deionized water B) 0.1N HCl (pH 1.2); and C) phosphate buffer (pH 6.8) showing wet weight and dry weights*

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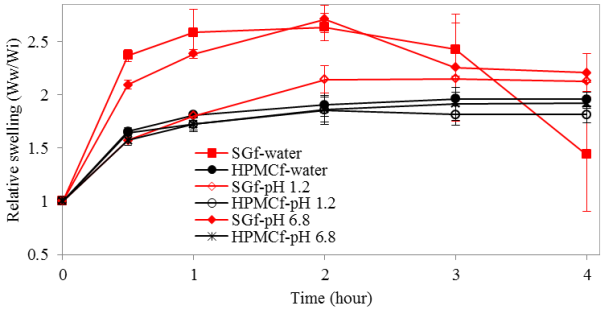


***Fig. 3**: Relative swelling profiles of SG and HPMC in different media*

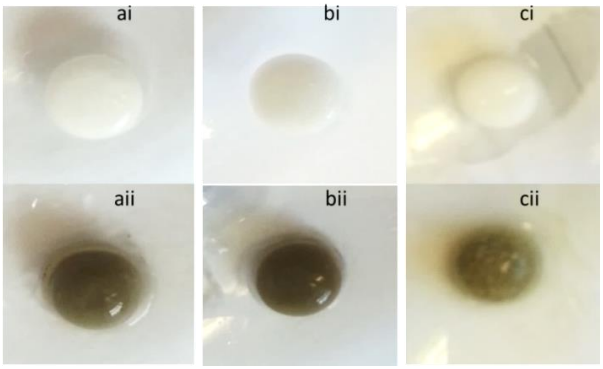


***Fig. 4:** Photograph of the swelling and erosion of matrices in (a) phosphate buffer (pH 6.8) (b) 0.1N HCl (pH 1.2), and (c) deionized water at 37 °C for 3 hours for (i) HPMC and (ii) SG*

**Modelling of swelling and erosion of matrices:** Earlier, it was shown that it is possible to describe the rate of dissolution medium uptake, per polymer unit remaining, in terms of a square root relationship (Eq. (4)) and the erosion of the polymer can be described in terms of a cube root equation (Eq. (5)). The dissolution media uptake per unit polymer remaining according to equation 3 was plotted against time as shown in Fig. 5A to describe the swelling of the matrices. This was fitted into square root of time equation (Eq. 4) and gave plots with better linearity for the HPMC matrices (Fig. 5B). Similarly, the profiles were fitted into the cube root equation (Eq. 5) to describe the erosion of the matrices (Fig. 5C). The regression coefficients from the plots are presented in Table 3.

From the results it can be seen that HPMCf matrices are best fitted into the square root of time equation indicating that the HPMC matrices predominantly swell during hydration in all media. Conversely, SGf matrices show that while both swelling and erosion occur in all media, erosion may predominate in deionized water or pH 6.8.

***Table 3:** Regression coefficients of the matrices from the plots according to square root of time and the cube root.*

| | Square root of time | | Cube root of time | |
|---|---|---|---|---|
| | R2 | K1 | R2 | K2 |
| SGf-water | 0.99 | 0.855 | 0.99 | 2.206 |
| SGf-pH 6.8 | 0.98 | 0.657 | 0.99 | 2.263 |
| SGf-pH 1.2 | 0.98 | 0.522 | 0.97 | 2.243 |
| HPMCf-water | 0.996 | 0.466 | 0.961 | 2.343 |
| HPMCf-pH 6.8 | 0.995 | 0.438 | 0.954 | 2.340 |
| HPMCf-pH 1.2 | 0.99 | 0.456 | 0.972 | 2.346 |

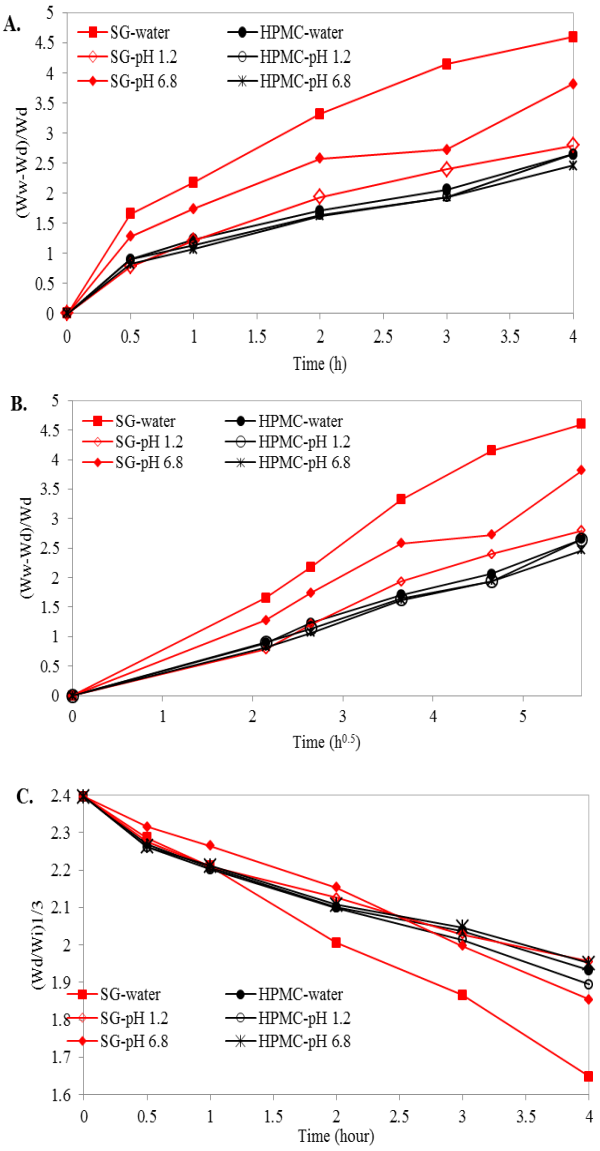


***Fig. 5:** Modelling of swelling and erosion of matrices according to A) equation 3 B) equation 4and, C) equation 5*

**Drug release from the matrices:** The release of theophylline from the polymer matrices was monitored in deionized water, 0.1 N HCl (pH 1.2) and phosphate buffer (pH 6.8). Fig. 6 shows the dissolution profile of theophylline from the matrices of SGf and HPMCf in the different media monitored. The release parameters $T_{50}$, dissolution efficiency (DE)

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and mean dissolution time (MDT) are shown in Table 4. Despite the propensity for initial burst release of very soluble drugs (such as theophylline) from HPMC matrices, the profiles show that none of the matrices exhibited any dramatic burst release of theophylline (Fig. 6) (Tiwari et al., 2003; Gohel et al., 2009; Huand and Brazel, 2001). The initial release from these formulations was thought to be a result of dissolution of the drug from the surface and near the surface of the matrix, which, occurred while the polymer was undergoing hydration to form the gel layer.

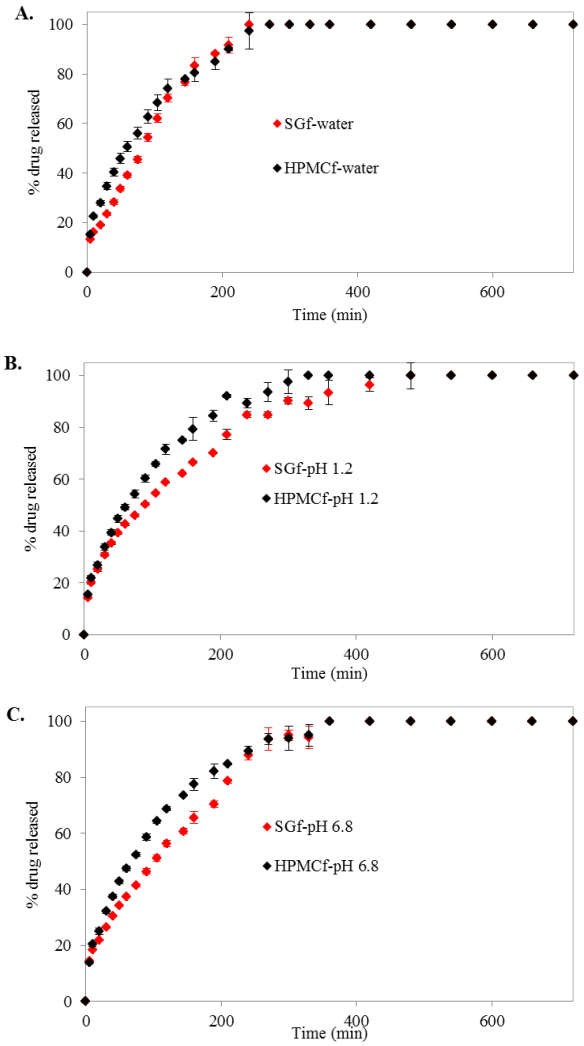


*Fig. 6: Release profiles of theophylline from SG and HPMC matrices at 100 rpm and 37 °C in A) deionized water.*

The results show that release of theophylline from the SGf matrices was slower than HPMCf matrices in all the media studied. This is further defined in Table 4. It can be seen that the time for 50% drug release ($T_{50}$) was lower for HPMCf matrices than for SGf matrices in all media, indicating that it takes longer to release 50% of the drug from the SGf matrices. The other dissolution parameters (DE and MDT) indicate that dissolution of the matrices was faster for HPMCf than SGf. Furthermore, it can be noted from the release profiles in deionized water (Fig. 6a) and pH 6.8 (Fig. 6c), that release from SGf matrices was similar to the HPMCf matrices at 160 min and 270 min for deionized water and pH 6.8 respectively. This concurs with the predominance of erosion occurring in both media after 180 min (Fig 2a and c). The release profiles of SGf were also compared with those of HPMCf in all media using similarity factor ($f_2$), and the results showed a similarity of the profiles of >50 for all media. Although release profiles showed similarity, the values obtained for f2 ranged between 51-54 which is a lot closer to the dissimilarity region as values closer to 100 are more ideal. The similarity values maybe due to the viscosity and strength of the gel layers produced.

***Table 4.*** *Dissolution parameters of the tablet matrices*

| Matrix | Media | T50 (min) | DE (%) | MDT (min) | Diffusional exponent, n | Similarity factor (*f2*) |
|---|---|---|---|---|---|---|
| **SG** | water | 80 | 87.45 | 90.38 | 0.485 | 54.28 |
| | pH 1.2 | 90 | 82.5 | 126.02 | 0.437 | 53.25 |
| | pH 6.8 | 105 | 83.41 | 119.48 | 0.428 | 51.31 |
| **HPMC** | water | 60 | 88.65 | 81.72 | 0.472 | - |
| | pH 1.2 | 60 | 87.58 | 89.41 | 0.457 | - |
| | pH 6.8 | 68 | 86.45 | 97.57 | 0.492 | - |

**Modelling of drug release:** The release kinetics for the polymer matrices are presented in Table 4. The results from the present study showed that theophylline release from the SGf and HPMCf matrices in all the media studied were typically non-Fickian (anomalous) with a best fit to Korsmeyer-Peppas model indicating that drug release was by a combination of diffusion and erosion. The release of theophylline from HPMC K4M matrix tablets has been reported (Asare-Addo et al., 2011; Sriamornsak et al., 2007) to fit well with both Higuchi equation and Korsmeyer–Peppas equation. The Higuchi model describes drug release that is largely governed by diffusion through water-filled pores in the matrices, while the Korsmeyer–Peppas model describes the combined effect of diffusion and erosion mechanisms for drug release (Korsmeyer et al., 1983).

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**DSC hydration results and theophylline release from matrices:** The hydration of the compacts of the pure polymers (SGp and HPMCp) and the formulation matrices (SGf and HPMCf) was monitored using DSC. The profile of percent bound water with increasing time (1, 5, 10, and 30 min) for the pure polymer compacts in deionized water are shown in Fig. 7 calculated from the thermographs in Fig. 8.

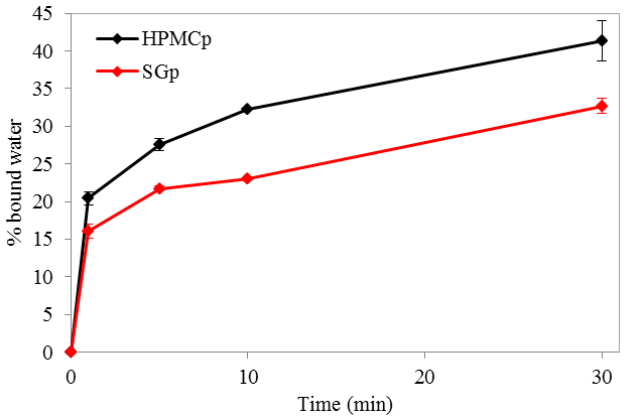


*Fig. 7: Representative water profiles of pure polymer compacts in distilled water*

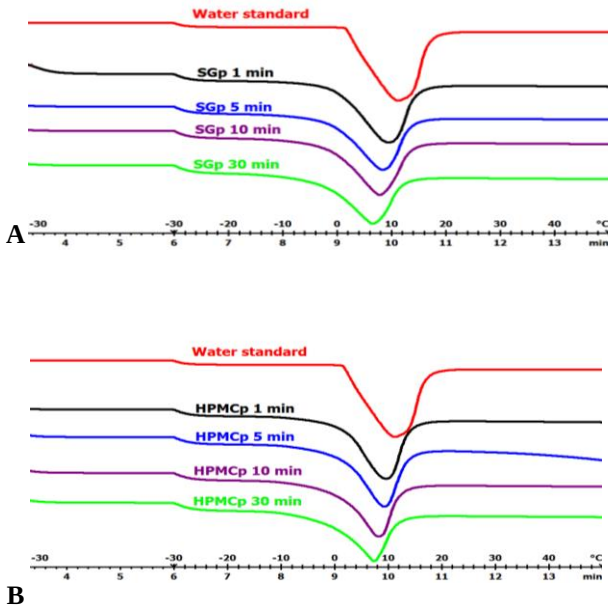


*Fig. 8: Representative DSC thermograms of the pure polymer compacts after hydration for 1, 5, 10, and 30 min in deionized water for A. SG and B. HPMC K4M*

During the first stages of dissolution, the water that penetrates into a tablet matrix acts as bound water. It has been explained (Aoki et al., 1995) that during the next stages of dissolution, the water content of the matrices increases and freezable water is detected at levels that are related to drug release. The thermographs for the pure polymers (Fig. 8) exhibited a slight shift to the left with an increase in hydration time and show HPMCp to bind more to water as compared with SGp. The amount of bound water occurring with time was also seen to increase.

The hydration values to determine bound and free water for the formulation matrices was taken at 5 min being the first time point of drug dissolution and utilized to establish any correlation between free water state and drug dissolution. This however was difficult to establish. The results (Table 5) showed that SGf and HPMCf matrices bound to deionized water more than pH 1.2 or pH 6.8. It can be seen that the amount of available water for hydration increased in pH 1.2 or phosphate buffer (pH 6.8) for all the matrices. Also HPMCf generally binds more to water in media pH 1.2 and deionized water as compared with SGf except in pH 6.8 when binding to water was the same. This was similar to the trend for the pure polymers SGp and HPMCp. Of interest is the fact that when comparing the amount of bound water at the same time point (5 min) for the pure polymer and formulation compacts, it was observed that the incorporation of drug and the lactose reduces the percentage of bound water.

***Table 5.*** *% bound water of the pure polymer compacts (SGp and HPMCp) and the tablet matrices (SGf and HPMCf) in all media at 5 min*

| Formulation | Water | pH 1.2 | pH 6.8 |
|---|---|---|---|
| SGp | 21.71 ± 0.34 | 13.8 ± 0.26 | 16.93 ± 0.13 |
| SGf | 10.96 ± 1.47 | 6.61 ± 0.84 | 9.0 ± 1.5 |
| HPMCp | 27.43 ± 0.88 | 18.46 ± 0.18 | 22.22 ± 0.42 |
| HPMCf | 13.02 ± 2.22 | 9.8 ± 1.87 | 8.98 ± 0.73 |

## CONCLUSIONS

The present study showed that sesamum gum is a highly compressible and compactible polymer with superior compression and compaction properties to HPMC K4M. The material hydrates in deionized water, pH 1.2 and pH 6.8 to form a gel layer that controls drug release from the matrix tablets. Swelling and erosion both occur in sesamum gum matrices and drug release was non-Fickian (anomalous) fitting well to the Korsmeyer-Peppas model. In developing countries where *Sesamum radiatum* is cultivated, the gum from the leaves of the plant could be developed as a suitable alternative to HPMC K4M to retard the release of drug from tablet matrices.

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