

Film coating potential of okra gum using paracetamol tablets as a model drug

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The purpose of this work was to study the film coating potential of okra gum extracted from pods of *Abelmoschus esculentus* plant using paracetamol as a model drug. Core tablets of paracetamol were obtained from a pharmacy shop in the locality and the physicochemical properties such as weight, hardness, friability, and disintegration time were evaluated. Aqueous coating suspensions of okra gum and hydroxypropylmethylcellulose (0.6%w/v) were prepared and used to coat the tablets in Hi-coater. The coated tablets were evaluated for weight uniformity, diameter, thickness, hardness, friability, disintegration time, and moisture uptake at controlled humidity. The coating remained intact, durable, and resistant to chipping when challenged to catastrophic fall or rubbed on a white paper. The coated tablets had lower friability, increased disintegration time (24 min) compared to the core (3 min) and improved hardness, but there was no difference in the dissolution profile of the samples from the batches containing okra and hydroxypropylmethylcellulose as film formers. Changes were observed in some of the physicochemical properties of the formulations containing okra gum as with the known film former and it was convenient to conclude that these changes were due to the effect of the mechanical properties of the film formers. It was our conclusion that okra gum is a promising natural, biodegradable, cheap and eco-friendly film former in aqueous tablet film coating operation, particularly when masking of taste or objectionable odor in a solid dosage formulation is desired.

Key words: Biodegradable polymer film coating, natural, okra, potential

INTRODUCTION

Film coating is a very important unit operation in the pharmaceutical industry.^[1] Film coatings are used for many reasons including improvement of aesthetic qualities of dosage forms, masking unpleasant taste or odor, easing digestion, improving stability, and modifying the release characteristics of the drug.^[2-3] This unit operation can be applied to a variety of pharmaceutical products such as tablets, beads, pellets, granules, capsules, and drug crystals.^[4] Film layer may be formed from either polymeric solution (organic-solvent or aqueous based) or aqueous polymeric dispersion (commonly called latex). Polymer is the main ingredient in the majority of film-coated formulations, and it may be from different (natural, synthetic or semi-synthetic) origins, including cellulosics, acrylics, vinyl, and combination polymers.^[2,4] Natural polymers have advantages over synthetic and semi synthetic polymers in that they are cheap and easily available, nonirritant, biodegradable, biocompatible, and eco-friendly.^[5]

Okra gum is a natural polymer extracted from the pods of *Abelmoschus esculentus*. *A. esculentus* (syn. *Hibiscus esculentus*) is a plant native to tropical Africa, Asia, and Northern Australia. *Abelmoschus* is a genus of about 15 species of flowering plants in the mallow family *malvaceae*. It was formerly included within the hibiscus but now classified as a distinct genus.^[6] The stem, leaves, and pods of this plant have mucilage. The performance of okra gum as a sustained release excipient was comparable to those of sodium carboxymethylcellulose (NaCMC, 500 mPa) and hydroxypropylmethylcellulose (HPMC) when some researchers employed it as a mini matrix in a sustained release tablet formulations of furosemide and diclofenac sodium^[7] and paracetamol.^[8] The binding,^[9] disintegrating,^[10] and bioadhesive^[11] properties of okra have been studied. A study has been made of the effects of drying methods on the physicochemical characteristics and compressibility of okra powder and the release properties of its metronidazole tablet formulation.^[12] To date there is no published study on the film coating potential of okra gum. The purpose of this paper is to report the preliminary investigation on the film coating potential of okra gum by using it to film coat paracetamol tablets as the model drug.

MATERIALS AND METHODS

Materials

Paracetamol tablets (bond pharmaceuticals Ltd,

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Nigeria) were purchased from a retail pharmacy, hydroxypropylmethylcellulose (methocel® E5 premium LV lot no. SC25012402 from Dow, USA) titanium oxide, talcum powder, and polyethylene glycol 4000 were of British Pharmacopia standards, Fresh okra pods were obtained from the Farin-gada market Jos, Nigeria.

Methods

Extraction of *A. esculentus* gum

The pods of *A. esculentus* were washed in water and sliced with knife into small pieces. The slices were soaked in water for 24 h to extract the gum and the gum thereafter was filtered out of the bulk using muslin cloth. The filtrate was extracted with 96% ethanol several times to complete the extraction process. The chlorophyll was removed by rinsing the gum in hot ethanol. The gum was air dried, pulverized, and packaged into polythene container for further use.

Evaluation of some physicochemical properties of okra gum powder

Bulk and tapped densities

A 20.0 g bulk volume sample of *A. esculentus* gum powder was transferred into a 100 mL measuring cylinder and the volume, which was the mean of the reading from several sides, was calculated. The cylinder was tapped for 250 times when there was no observable decrease in volume. The bulk and tapped densities were calculated as the mean of five determinations from the equation:

$$P = \frac{m}{V} \quad (1)$$

where p is density (g/cm^3), m is the mass (g) of the data gum, and V is the volume of the powder in the cylinder

Carr's 'percent compressibility'¹³⁾ and the Hausner ratio¹⁴⁾ were calculated using the equation $t - b/t \times 100$ and t/b respectively. t and b are respectively the tapped and bulk densities.

Angle of repose

An open ended plastic cylinder (internal diameter 4.92 cm; outer diameter 5.6 cm; height 10.7 cm) was used. The cylinder was placed on a flat base and filled with a sample of the powder. The height, h , and radius, r , formed by the powder on removal of the cylinder were taken and the average of five determinations was used to calculate the angle of repose:

$$\theta = \tan^{-1} h/r \quad (2)$$

Loss on drying

A 10.0 g of *A. esculentus* gum was heated in a hot air oven (GallenKamp, England) at 105°C. Loss on drying (LOD) was the difference between the initial weight and the final weight of the sample expressed as a percentage:

$$\% \text{LOD} = \frac{\text{initial weight} - \text{final weight}}{\text{initial weight}} \times 100 \quad (3)$$

Solubility test

A 1.0 g of powdered gum was weighed and suspended in the solvent and was agitated for 24 h over a magnetic plate. A 1.0 ml from the supernatant was filtered and dried at 50°C. The gain in weight of previously tarred porcelain was taken as the amount of solute in the filtrate and this was used to calculate the solubility of the substance in 100 ml of the solvent.

The pH of 1% suspension was determined using digital pH meter 3310 (Genway) at 25°C.

Viscosity

The viscosity of 0.6% w/v suspension was determined with Brookfield LVDV-III+ digital rheometer (Brookfield Engineering Lab. Inc., MA, USA). The mucilage was placed in a 600 mL beaker supplied by Brookfield Engineering Laboratory and the temperature was maintained at 25°C with the aid of thermostatic water bath, and RV3 spindle was employed at varying revolutions.

Evaluation of core tablets

Weight uniformity of tablets

The evaluation was carried out on 20 tablets selected randomly and their individual weights were taken on an analytical balance (Explorer E02140, Ohaus Corporation, USA).

Friability of tablets

10 tablets weighed previously were transferred to Erweka friabilator (Erweka, GmbH, Germany) and allowed to experience a catastrophic fall at 25 rpm for 4 min. Friability was taken as the percent loss in weight of the tablet.

Hardness/Crushing strength of tablets

This destructive test was conducted on 10 tablets using Mosanto hardness tester.

Tablets disintegration time test

The disintegration time studies were carried out on the tablets using Erweka apparatus (Erweka ZT 70, Germany). One tablet was placed on each of the six tubes of the apparatus suspended over deionized water (disintegration medium, maintained at 37°C).

Dimensions

The diameter and the thickness of 10 tablets were obtained using vernier caliper.

Preparation of coating suspension

A 0.62% w/v okra gum mucilage was prepared by dispersing the powder in about 80% of water to be used at 60-70°C with continuous stirring on a magnetic stirrer. Polyethylene glycol 4000 (1%w/v) was added to the mucilage and allowed to mix

over a magnetic stirrer for 3 h. Titanium dioxide and talcum powder (1%w/v each) were dispersed in the remaining volume of water over a magnetic stirrer for half an hour and the mixture was added to the mucilage and stirred to mix. The suspension was filtered through sieve number 140 equivalent to 106 μm (ASTM E-11, Cole Parmer, USA) before use. Similar suspension was prepared with hydroxypropylcellulose.

Viscosity of coating suspension

The viscosity of 0.6%w/v suspension was determined with Brookfield LVDV-III+ digital rheometer (Brookfield Engineering Lab. Inc., MA, USA). The mucilage was placed in a 600 mL beaker supplied by Brookfield Engineering Laboratory and the temperature was maintained at 25°C with the aid of thermostatic water bath, and RV2 spindle was employed at varying revolutions.

Film coating

The coating was carried out on Hi-Coater model HCT-30 (Freund Industry Co. Ltd, Japan) to which the computerized pump drive (Masterflex, Cole-Parmer, IL, USA) was attached. The batch size was 500 g tablet and the coating parameters were as follows: flow rate was 2.5 mL/min, inlet air and outlet temperatures were respectively 26 and 58°C while the pan speed was 10 rpm and the atomizing air pressure was 0.4 g/cm².

Evaluation of coated paracetamol tablets

The physicochemical properties of the coated tablets such as weight uniformity, hardness, friability, and disintegration time were evaluated as described above for the uncoated tablets. In addition, the disintegration test was carried out in the HCl solution (pH 1.2) and phosphate buffer solution (pH 7.2) to gain insight into the functionality of the film coat.

Dissolution studies

The dissolution of paracetamol tablets was carried out on Hanson SR8 Plus (Hanson Research, CA, USA) using USP paddle method at 50 rpm. The absorbance reading at 249 nm was obtained online with the aid of UV 160 UV-Visible spectrometer (Shimadzu, Japan) interfaced with the spectroscopy software version 3.0 (Shimadzu Scientific Instruments, Inc., Japan).

RESULTS AND DISCUSSIONS

Okra gum and some of its physicochemical properties

Okra gum is a crystalline-like solid, off-white in color, but grayish if the chlorophyll is not completely removed. The gum is obtained from the edible pod of *A. esculentus* and 1% w/v has a pH of 5.75. Table 1 shows some of its physicochemical properties. The bulk and tapped densities were respectively 0.69 and 0.8 g/cm³ while the Carr's compressibility index and the Hausner quotient were respectively 13.75% and 1.16. While the derived values of Carr's, Hausner, and angle of repose are used to predict the flowability of powder,^[15]

flow rate gives better information on the actual flow of the powder and this value was 6.1 g/s. Solubility of a polymer in a wide range of solvent systems will promote flexibility in formulation, being able to produce coatings that have suitable mechanical properties and appropriate solubility in the gastrointestinal tract so that the drug bioavailability is not compromised.^[16] Table 2 shows that okra gum was more soluble in water than in organic solvents and the solubility of the gum in the solvents evaluated were in the order: water > ethanol: water (1:2) > ethanol: water (1:1) > diethyl ether > ethanol > chloroform. The okra gum did not form a true solution with water but rather mucilage, and this behavior in water is quite different from what is seen when the substance is mixed with organic solvents such as diethyl ether and chloroform where it get suspended for a while and settles down, if not stirred. The data showed that mixture of

Table 1: Some physicochemical properties of okra gum and coating suspensions

Description	Value		
a. Okra gum			
Bulk density (g/cm ³)	0.69		
Tapped density	0.80		
Carr's compressibility (1%)	13.75		
Hausner ratio	1.16		
Flow rate (g/sec)	6.1		
Angle of repose	12.0°		
pH (1%)	5.75		
Solubility (g/100ml) at 25°C in:			
Water	0.1316		
Chloroform	0.0607		
Diethyl ether	0.0804		
Ethanol	0.0754		
Ethanol: water (1:1)	0.0893		
Ethanol: water (1:2)	0.1213		
b. Coating suspensions			
	Viscosity (cP)	Torque (%)	RPM
Okra	373.6	46.7	50
	275.6	68.9	100
HPMC	118	50.3	50
	88.8	79.6	100

Table 2: Some physicochemical properties of film coated paracetamol tablets

Description	Batch		
	Core	Okra	HPMC
Uniformity of weight (mg)	542(0.61)*	543(0.41)*	543(0.42)*
Hardness (N)	7.0(0.02)	8.50(0.03)	9.0(0.03)
Friability (%)	7.38	0.1	0.1
Disintegration time (min)	3.0	11.25	14.5
Diameter (mm)	11.0	11.5	11.5
Thickness (mm)	2.49	2.62	2.64

*Coefficient of variation

ethanol and water improved the solubility of okra compared to using ethanol alone, but the improvement depends on the ratio of the two solvents. The table also shows the rheological properties of okra suspension and the coating suspensions. The coating material displayed a shear thinning behavior. The viscosity decreased with an increase in the speed of the spindle, and the torque also increased linearly with an increase in spindle speed, indicating a non-Newtonian flow without thixotropy. This rheological property of the film-coating agent explains why it was able to stick to the tablet surface after the removal of stress without falling off.

The film-coated tablets

Table 2 describes some physicochemical properties of film-coated paracetamol and the core tablets. The average weights of the tablets were between 542 and 545 mg with minimal coefficient of variation, and the increase in weight of coated tablets was not more than 0.5%. The tablets were generally good looking with smooth coats, and a rub of the coated tablet against a white paper did not reveal any peel. The friability of the coated was 3.9% for both formulation okra and HPMC, while the corresponding value for the core tablet was 7.38%. None of the formulations had a satisfactory friability profile of $<1\%$ ^[17] but there were changes in the friability profile in the order: HPMC $<$ okra $<$ core and the tablets could not have been drawn from the same batch. It is important that tablets have low friability so as to withstand the stress that they may encounter during transport and handling and not to break in the hands of patients before they are taken. There were marked changes in the hardness of the tablets between formulations. Paracetamol tablets coated with HPMC had better hardness compared to those coated with okra, which in turn was better than those from the core tablets, and the disintegration time increased from 3 min (core) to 14.5 min (formulation with HPMC) with the order being: HPMC $<$ okra $<$ core. Use of phosphate buffer increased the disintegration time of the formulations with okra and HPMC. It has been shown that coatings affect the physicochemical properties of the tablet to varying degrees,^[18-21] and these changes are suggestive of the effect of the coating materials on the tablets. The dissolution profile of the tablets is shown in Figure 1. All the formulations achieved had over 75% of the active pharmaceutical ingredient released into the dissolution medium and 96.3% dissolution was achieved within 30 min irrespective of the formulation. One of the limitations to more solid deposition in film coating is the viscosity of the film former, from which okra gum suffers. At more than 0.6% w/v, okra gum was too viscous to be atomized. With extended coating time, low concentrations of film forming agents can give 3-5% w/w or more solid deposit without efficiency. In this study, the weight gain due to film coating was 1.2 ± 0.07 w/w. It might appear that the coating of the tablets at the coating concentration was not sufficient enough to hinder or delay dissolution, as one would expect, but this can be an advantage when considering film coating for the purpose of taste or odor masking without the desire to significantly

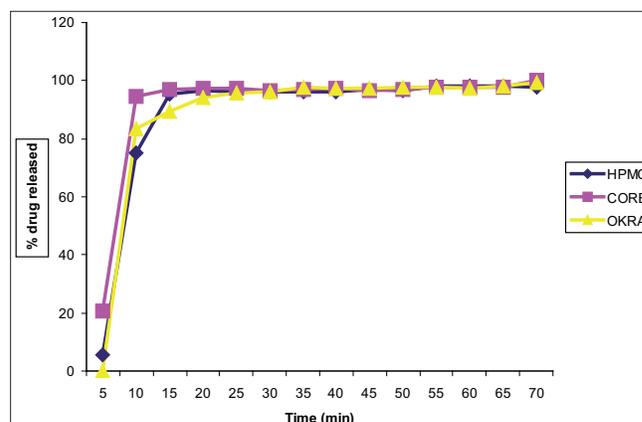


Figure 1: Dissolution profile of paracetamol coated tablets

alter the dissolution profile. In most cases, drugs need to disintegrate and be dissolved before being absorbed from oral solid dosage form. The study showed that the samples were not drawn from the same batch and that the differences in the physicochemical properties of the tablets were due to the effect of okra gum and HPMC, which were used as film formers in the formulations, imparting mechanical properties to the tablets to cause those changes.

CONCLUSION

The potential of okra gum as a film-coating agent was investigated using paracetamol tablets as model drug. The tablets were evaluated for some physicochemical properties such as uniformity of weight, friability, disintegration time, and dissolution profiles. There changes in the friability, hardness, and disintegration time of coated were compared to the core. Generally, tablets that were coated with HPMC had better physicochemical properties than those containing okra, which in turn was better than the core tablets. Overall, the observed differences in physicochemical properties in the formulations did not lead to differences in the dissolution profiles of the three formulations, making it convenient to use either okra or HPMC at this concentration as a film former when taste and odor masking are the major considerations.

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