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Development and evaluation of a tripartite novel excipient for direct compression of salbutamol tablets

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Abstract
The purpose of the study was to develop and evaluate a tripartite novel excipient for direct compression of salbutamol tablets. Various batches (A-E) of the novel excipient was prepared by co-processing varying concentrations of okro gum with gelatinized maize starch and lactose using co-precipitation method. The novel excipient powders were subjected to some physicochemical evaluations. Batches (F-H) of the physical mixture of the novel excipient ingredients were also prepared. The novel excipient and physical mixtures were used to prepare batches of salbutamol tablets by direct compression. The flow properties of their powder mixes and post-compression tablet parameters were evaluated. Drug-novel excipient compatibility was investigated using FTIR. The various batches of the co-processed novel excipient exhibited good flow properties with the following parameters; Carr's index (≤ 25.30), Hausner's ratio (≤ 1.25), angle of repose (≤ 25º), swelling index (> 5.22) and hydration capacity (> 4.26). The flow properties were directly proportional to the concentration of okro gum in the excipient or physical mixture. Only batches B-E tablets met official BP specifications with regard to all tablet parameters evaluated. All the batches of tablets exhibited rapid release profiles except batches D and E tablets with some level of slow release. FTIR analyses revealed no interaction between the novel excipient and salbutamol. The co-processed excipient developed in this study was found to be a promising directly compressible vehicle for the preparation of compressed tablets for poorly compressible drugs such as salbutamol.

Keywords: Co-processing, novel excipient, flow properties, post-compression parameters

INTRODUCTION

Co-processing can be defined as combining two or more established excipients by an appropriate process (Gohel *et al.*, 2002) leading to the formation of excipients with superior properties compared to the simple physical mixtures of their components. The main aim of co-processing is to obtain a product with added value related to the ratio of its functionality/price. It is one of the ways new excipients come to market without undergoing the rigorous safety testing of a completely new chemical (Russell *et al.*, 2004).

Co-processing also opens opportunity for development and use of single multifunctional excipient rather than multiple excipients in formulation. Currently many excipients are being co-processed directly with active pharmaceutical ingredients to develop a composition ready for direct compression, e.g., co-spray drying of acetaminophen, mannitol, erythritol, maltodextrin and a super disintegrant in spray

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dryer yields powders that give tablets with improved disintegration in combination with acceptable physicochemical powder properties, tablet hardness and friability (Gonnissen *et al.*, 2008).

Also some of the excipients can be co-processed to give better physiochemical properties, e.g., granules of carbopol and MCC prepared from dried sodium hydroxide solution is pressed into tablets used for treatment of gastro-oesophageal reflux (Chaudhari *et al.*, 2012). Newer excipients are being developed to aid in targeted drug delivery e.g., the peptide dalargin is targeted to the brain using polyisobutyl cyanoacrylate whose surface is modified with polysorbate 80 (Alyautdin *et al.*, 1995). The availability of a large number of excipients for co-processing ensures numerous possibilities to produce tailor-made "designer excipients" to address specificity, functionality and requirement (Marwaha *et al.*, 2010).

Okro [*Abelmoschus esculentus* (L) Moench] is known in many English speaking countries as lady's finger. It is a flowering plant in the mallow family. It is valued for its edible green pod. The geographical origin of okro is disputed with supporters of West African, Ethiopian and south Asian origin. The plant is cultivated in tropical, subtropical and warm temperate regions around the world (Natural Research Council, 2006). The specie is an annual and perennial plant growing to 2 m tall and is related to species as hibiscus. The okro plant is a vegetable that grows very fast in all soil types, but a well-drained fertile soil with adequate organic matter results in high yield (Akinyele *et al.*, 2007; Bakre and Jaiyeoba, 2009).

There are reports of the use of okro starch and the powder of the dried pod as a disintegrant in tablet formulations (Bakre and Jaiyeoba, 2009; Ramu *et al.*, 2010). Other researchers have also explored the matrix forming ability of its mucilage or gum (Bakre and Abimbola, 2013; Reddy and Shruthi 2013; Zaharuddin *et al.*, 2014; Reddy *et al.*, 2014). The limitations of existing excipients and the search for newer high functionality excipients especially from natural sources initiated this study with the aim of developing a new excipient for direct compression by co-processing okro gum, gelatinized maize starch and lactose. This investigation also evaluates the properties of salbutamol tablets prepared with the new excipient.

EXPERIMENTAL

Materials. Okro gum was processed from okro pods purchased from a local market in Benin City, Nigeria. Salbutamol powder was courtesy of Vitabiotic Industries, Lagos State, Nigeria, starch and lactose (BDH Chemical Ltd, Poole, England), magnesium stearate and talc (International Co. Ltd, Anhui, China) were used as received. Other reagents employed in the study were of analytical grades.

Extraction of okro gum. Okro gum was extracted from the pod of the fruit following an earlier reported method of Tavakoli *et al.*, (2008) with slight modification. The fruits were washed, sliced and sun-dried for several days. The dried pieces were blended and macerated in distilled water for 10 h with intermittent stirring. The macerated content was filtered through a white muslin cloth and the gum precipitated with acetone. The precipitate was dried under vacuum and finally under dry silica in a desiccator. The dried flakes were reduced in a mortar, screened into fine powder and weighed before been kept in an airtight container. The weight of the powder was used in calculating the yield of the extraction process.

Preparation of maize starch mucilage. Maize starch mucilage (20 %w/v) was prepared by weighing 20 g of maize starch BP into 500 ml beaker. Sufficient distilled water was added up to 100 ml and the content stirred to form a slurry. The beaker was

transferred to a water bath thermostated at 55 °C. The slurry was heated with continuous stirring until a gel of uniform consistency was formed. The gel was then transferred from the beaker onto a tray, spread thinly and dried in the oven at 60 °C for 48 h. The resulting flakes were pulverized with a blender (Phillips, Switzerland) and stored in an airtight container under dry silica gel until use.

Co-processing of excipients. Various batches (A-E) of the co-processed excipient were prepared using varying concentrations of the okro gum powder. To prepare batch A, lactose and okro gum powders were separately passed through a 510 µm sieve (Endecotts, England). Fifty grams of the screened lactose was dispersed in 250 ml of distilled water in a 1 L beaker maintained at 70 °C and stirred until complete dissolution. Okro gum powder (1 %w/w based on lactose weight) was weighed and dispersed in 25 ml of water at 50 °C and stirred for complete hydration. The okro gum dispersion was poured into the lactose solution and the mixture stirred for 10 min and then co-precipitated by pouring twice its volume of chilled absolute ethanol with continuous stirring. After 10 min, a 10 %w/w (based on the weight of lactose) dispersion of maize starch mucilage powder in 25 ml of chilled ethanol was poured into the mixture as stirring was going on. Stirring continued for 10 min and the beaker transferred to an ice bath where stirring continued for another 15 min. Thereafter it was left in the ice bath undisturbed for 8 h. The resulting product was filtered, tray dried at 60 °C for 2 h in a hot air oven and then passed through an 850 µm sieve to obtain the required granules which were further dried at 60 °C for 30 min. The procedure was carried out with 2, 3, 4 and 5 %w/w (based on lactose weight) okro gum powder to obtain batches B-E, respectively, of the co-processed excipients.

Characterization of co-processed excipient. Batches of the co-processed excipients prepared were characterized by determining the bulk and tapped densities, compressibility index, Hausner's ratio, angle of repose, flow rate, moisture content, particle density, swelling index and hydration capacity.

Bulk and tapped densities. A 30 g quantity of the novel excipient powder was poured gently into a graduated measure. The volume of the powder was read and the bulk density calculated. The measure containing the 30 g of the novel excipient powder was tapped 100 times on a wooden platform. The volume was noted and used in calculating the tapped density.

Carr's index and Hausner's ratio. The difference between the tapped and bulk density of the novel excipient powder divided by the tapped density was calculated and the ratio expressed as percentage to give the Carr's index. The ratio of the tapped density to the bulk density of the novel excipient powder was calculated as the Hausner's quotient.

Angle of repose. The hollow tube method was used. A short hollow tube of 3 cm in internal diameter sitting on a circular horizontal surface of same diameter was filled with the powders of the novel excipient. The tube was withdrawn vertically and excess powder allowed to fall off the edge of the circular horizontal surface. The height of the heap was measured. The angle of repose, θ, was calculated using Equation 1.

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

Where h is the height of the heap of granules and r is the radius of the circular base

Flow rate. An Erweka flow tester (Model: GT, GmbH, Germany) was used. The time taken for 50 g of the novel excipient powder to pass through its orifice was recorded. This was carried out in triplicates and the mean values recorded.

Particle density. A 25 ml specific gravity bottle (glass pycnometer) was filled with liquid paraffin, cleaned of any residual liquid paraffin and weighed (a). The bottle was emptied, rinsed with acetone and dried. About 1 g (b) of the co-processed excipient powder was poured into the bottle and then filled with liquid paraffin. It was weighed (c) after cleaning off the residual paraffin from the bottle. The various weights recorded were used to calculate the particle density of the novel excipient using Equation 2.

$$\rho = b/[(a+b)-c]S \quad \ldots . \quad (2)$$

Where, ρ is the particle density of the novel excipient and S is the specific gravity of liquid paraffin

Moisture content. A 1 g quantity of the co-processed excipient was dried in a hot air oven for 4 h at 105 ºC. The initial weight of the granules and the weight after drying were recorded and used to calculate the moisture content.

Swelling capacity. The method described in BP (2009a) was utilized. Briefly, 5.0 g weight of the co-processed excipient powder with a tapped volume (Va) in a 100 ml measuring cylinder was dispersed with 1 ml of 96 % ethanol and 25 ml of distilled water and thereafter made up to volume with more water. The cylinder was firmly closed and shaken vigorously every 10 min for 1 h. The dispersion was allowed to stand undisturbed for 3 h and the volume of the sediment (Vb) noted. The swelling capacity was computed with Equation 3.

$$\text{Swelling capacity (\%)} = [(Vb - Va) \div Va]\ 100. \ldots \quad (3)$$

Hydration capacity. A 1.0 g weight of the co-processed excipient was introduced into four 15 ml centrifuge tubes. The tubes were corked after 10 ml of water was added. The tube contents were shaken for about 2 min, allowed to settle for 10 min and centrifuged at 1000 rpm for 10 min using a bench centrifuge. The resulting supernatant was decanted and the sediment weighed. The hydration capacity was determined with Equation 4.

$$\text{Hydration capacity (\%)} = [(Wb - Wa) \div Wa]\ 100 \ldots \quad (4)$$

Where, Wb and Wa are the weights of the sediment and the dry co-processed excipient powder, respectively.

Preparation of physical mixtures of the co-processed excipients. Fifty grams of lactose, 1 %w/w of okro gum powder and 10 %w/w maize starch mucilage (all based on lactose weight) were screened through a 710 µm sieve and mixed intimately in a mixer (Moulinex, France) to obtain a physical mixture of the co-processed tripartite excipient as batch F. Similar procedure was carried out with 2 and 3 %w/w of okro gum powder to obtain batches G and H, respectively. The physical mixtures were stored in airtight containers until use.

Tablet formulation by direct compression. Salbutamol tablets were prepared by direct compression using the formulae in Table 1. A total of eight batches of tablets were prepared with five batches (A-E) made with the corresponding batches of the co-processed excipient (A-E) and three batches (F-H) with their corresponding physical mixtures. The tablets were prepared by weighing the required quantities of salbutamol powder and the co-processed excipient or their physical mixture into a mortar and mixing intimately with a pestle. Specific screened quantities of magnesium stearate and talc were added stepwise and mixed thoroughly. The powder mix of batches F-H was slugged using a heavy-duty tableting machine (Karl Kohl Technical Supplies, Germany) and the resulting slugs were broken down into granular sizes with a mortar and pestle. Pre-compression parameters of all the batches were evaluated before being compressed into tablets using a single punch tableting machine (Manesty Machines, UK) at 30 arbitrary units (AU) of compression. One hundred tablets were prepared per batch and were kept in air

tight containers and stored in a desiccator until evaluation

Compatibility studies. Drug-excipient compatibility was investigated using FTIR analysis on the powder mix of the co-processed excipient and salbutamol powder. FTIR analysis of the sample was done using FTIR-4100 Spectrophotometer (Shimadzu Co. Japan). Using the potassium bromide (KBr) tablet method; 5 mg of the sample was blended with KBr to 200 mg. The powder was compressed using a sigma press into a tablet shape. The tablet was placed in the sample compartment and the IR scan was obtained over a range of 4000 - 500 cm^{-1}.

Pre-compression evaluations. The various batches of the salbutamol powder mix were subjected to the following pre-compression evaluations: bulk and tapped densities, Carr's (compressibility) index, Hausner's ratio, angle of repose and flow rate using similar procedures employed with the co-processed excipient powder.

Post-compression evaluations. The following tests were carried out on the compressed tablets using standard procedures: tablet weight uniformity, crushing strength, friability, disintegration time, moisture sorption and dissolution studies.

Weight uniformity. The weight of each of 20 tablets was determined from each batch using an electronic balance (Mettler Toledo, Switzerland) and the mean weight and standard error were computed.

Crushing strength. The hardness of each of ten tablets per batch was determined (Campbell Electronics, Model HT-30/50, India). The mean hardness and ± standard deviation were calculated.

Friability. The weight of ten tablets was determined on the electronic balance. The tablets were then placed in the drum of a friabilator (Erweka GmbH, Germany) revolving at 25 rpm which exposed the tablets to rolling and repeated shock resulting from free fall within the apparatus. After four minutes, the tablets were brought out, dedusted and reweighed. The weight was then recorded and friability calculated as percentage loss in weight.

Disintegration time. The BP tablet disintegration unit apparatus (Manesty Machines Ltd, Liverpool, England) was used. The disintegration times of six tablets per batch of the tablets were determined in distilled water at 37 ± 0.5 °C. The time taken for the tablets to break into its primary particles, which passed through the mesh of the apparatus was recorded and their average times computed.

Moisture sorption. The moisture sorption properties of the tablets were determined using static gravimetric method. A tablet from each batch was dried at 80 °C for 4 h. The tablet was weighed, placed in a Petri dish and exposed to a 100 % relative humidity condition for 48 h in a desiccator containing distilled water at 32 °C. The weight of the tablet at the end of 48 h was recorded and moisture sorption calculated as percentage gain in weight.

Dissolution studies. The *in vitro* dissolution analyses of the various batches of the salbutamol tablets were carried out using the USP XXIII basket method. A dissolution apparatus (Caleva ST7, UK) containing 900 ml of 0.1 M HCl solution maintained at 37 ± 0.5 °C with a revolution speed of 50 rpm was used. Samples (5 ml) were withdrawn from the dissolution fluid at specific time intervals over a period of 60 min and each time replaced with an equivalent volume maintained at same temperature (37 ± 0.5 °C). The withdrawn samples were filtered and diluted appropriately with 0.1 M HCl solution. The resulting solutions were subjected to spectrophotometric analysis at λmax of 276 nm (T70, PG Instruments Ltd). The amount and the percentage of drug

released at each time interval was calculated using the equation from the standard calibration plot obtained from pure salbutamol powder.

Statistical analysis. Descriptive statistics was done for all data using Microsoft Excel (2007). Mean and standard deviations of triplicate determinations were computed and reported. Differences between mean was determined using ANOVA while $p < 0.05$ was considered significant.

RESULTS AND DISCUSSION

Properties of the co-processed excipients. The physical properties of the various batches of the co-processed excipient are shown in Table 2. The Carr's indices of 14.28 - 25.30 % indicated good flowability. The values of the Hausner's ratio, angle of repose and flow rate also indicated that the batches prepared had good flow properties. The particle density of the various batches ranging from 0.65 - 1.11 g/cm^3 would suggest a wide size range of its particles. Newmann (1967) had postulated that a wide particle size range results in low particle density when void spaces created by powder particles are not filled by smaller particles, leading to consolidation of the powder particle. The increase in particle density of the novel excipients with increase in the amounts of okro gum could be attributed to the formation of larger particles with the smaller particles filling the void spaces created by larger ones. The increasing moisture content of the novel excipient with increasing amounts of okro gum further supports the formation of larger particles which may trap water and result in high moisture content (Olayemi *et al.*, 2008) because moisture contents as high as 3 - 4 %w/w are appropriate to produce maximum disintegration and dissolution of tablets (Pilpel *et al.*, 1978). The swelling and hydration values of the excipient would indicate a possible candidate as a disintegrant, though the increase in the swelling capacity of the batches with increase in the amounts of okro gum mass suggest that the gum possesses little swelling ability. However, a combination of all the parameters would indicate that the co-processed novel excipient promises to be a good candidate as a directly compressible vehicle for direct compression of tablets.

Properties of the powder mix. The physico-chemical properties of the powder mixes are shown in Table 3. Their values show that increase in powder flowability was directly proportional to the increase in okro gum concentration in the novel excipient. There was increase in the flow rate and bulk densities and a decrease in the angle of repose, tapped densities, Carr's index and the Hausner's ratio with increase in okro gum concentration in the novel excipient. This is consistent with the formation of larger granules as the concentration of okro gum in the novel excipient increased, leading to larger voids in between the larger granules. This increase in particle sizes would also lead to decrease in surface free energy of the powder particles and decrease in frictional forces between the particles leading to faster flow (Iwuagwu *et al.*, 1986).

Compatibility studies. The FTIR spectrum of pure salbutamol (Figure 1 (a)) powder showed characteristic peaks at 619.15, 1112.93 and 3414.00 cm^{-1}. These peaks observed for salbutamol remained unchanged when compared with the spectral data of the powder mix (Figure 1 (b)). This observation ruled out the possibility of chemical interaction and complex formation between salbutamol and the novel excipient during the mixing process.

Tablet properties. Table 4 shows some post-compression parameters of the salbutamol tablets formulated. The tablet weight variation values indicated no significant differences ($p > 0.05$) in the weights of tablets from the various batches. But there were significant

differences in the tablet hardness and friability. These differences could be attributed to the different amounts of okro gum in the novel excipient used since no binder was used in the formulation.

All the tablets from all the batches gave hardness values between 3.3 - 7.5 kp for the novel excipient batches and 2.2 - 4.3 kp for the physical mixture batches. The values increased with increased concentration of okro gum in the formulations, but they did not all met official specification as the British Pharmacopoeia, (2009b) specifies a range of crushing strength values between 5 - 8 kp as optimum for a satisfactory tablet.

Also, the friability values of the tablets decreased with increasing concentrations of okro gum in the novel excipient. However, only batches B, C, D and E tablets met the BP specification of a maximum loss of 0.8 - 1 % of the weight of the tested tablets without capping, lamination or breaking up in the course of the test (BP, 2009b).

All the formulated tablets disintegrated within 15 min (Table 4) as specified by BP (2009b) for uncoated tablets, but the results showed an increase in the disintegration time with increase in the concentration of okro gum in the novel excipient used. Previous studies have shown that okro gum forms a matrix system in tablet formulations (Kalu *et al.*, 2007; Bakre and Abimbola, 2013; Newton *et al.*, 2014), this could explain the increase in disintegration time with increasing amounts of the gum as larger amounts will result in a superior matrix network system in the tablet that will be difficult to breakup.

Moisture sorption, one of the indices for understanding the capacity of a tablet to swell and disintegrate in the presence of water, was found to decrease with increasing concentration of the novel excipients. This would be expected of the tablets considering their disintegration time values. If a matrix tablet is indeed formed, the matrix network will hinder penetration of water molecules into the tablet and this hindrance will increase with increased matrix integrity. Another point of note is the wetting of the matrix forming material. The swelling and hydration values of the novel excipient seems to suggest a novel excipient that does not swell and not easily hydrated. The non-significant increase in these values with increased concentration of okro gum would imply that the swelling and hydration characteristics of the novel excipient are conferred on it by the okro gum. A combination of these factors in a tablet may necessarily lead to less water sorbed by the tablets with increasing amount of okro gum in the novel excipient used in their preparation.

Results from the dissolution studies (Figure 2) showed that the dissolution of salbutamol decreased with increase in concentration of okro gum in both the novel excipient and the physical mixture tablets. This might be due to the fact that dissolution correlates with disintegration. However, batches D and E tablets, formulated with the novel excipient containing 4 and 5 % okro gum showed some measure of delayed release. The batch C tablets made with novel excipient containing 3 % okro gum showed a steady release of drug within the 1 h of testing. All the batches of tablets except batches D and E tablets passed the BP dissolution test for conventional tablets which specifies that at least 75 % of the drug should be in solution after 45 min (BP, 2009b).

Okro gum as a controlled or sustain release agent has been investigated and confirmed by some studies (Reddy and Shruthi, 2013; Zaharuddin *et al.*, 2014; Reddy *et al.*, 2014). The fact that five batches (A, B, F, G and H) of the formulated tablets behaved as conventional tablets may be attributable to the concentrations of okro gum in the novel excipient and the physical mixture. This same reason could also be given as to why the sustained release of salbutamol was seen to increase with increased amount of okro gum

in the novel excipient used in formulating the tablets. As the gum concentrations used in the co-processed excipient increased, its ability to form a matrix system of superior integrity would have also increased, hence the release profiles of tablets prepared with the excipient would be expected to progress from fast to slow release with higher amount of the okro gum. Similar okro gum concentration-dependent drug release have been reported by other researchers though most of them worked with higher concentrations of the gum and achieved a longer time of sustained release (Bakre and Abimbola, 2013; Reddy and Shruthi 2013; Zaharuddin *et al.*, 2014; Reddy *et al.*, 2014).

Conclusion. The co-processed novel excipient and their powder mix exhibited superior flow properties that were proportional to the concentration of okro gum over their physical mixtures.

Table 1: Formula of prepared salbutamol powder mixes and tablets

Ingredients	Quantities (mg/tablet)							
	A	B	C	D	E	F	G	H
Salbutamol	4	4	4	4	4	4	4	4
Co-processed excipient	290	290	290	290	290	-	-	-
Physical mixture	-	-	-	-	-	290	290	290
Magnesium stearate	3	3	3	3	3	3	3	3
Talc	3	3	3	3	3	3	3	3
Total	300	300	300	300	300	300	300	300

Table 2: Some physical properties of the co-processed excipient

Properties	Batch				
	A	B	C	D	E
Bulk density (g/cm^3)	0.48	0.48	0.49	0.49	0.49
Tapped density (g/cm^3)	0.60	0.60	0.60	0.59	0.56
Carr's index (%)	25.30	25.30	22.44	20.40	14.28
Hausner's ratio	1.25	1.25	1.22	1.20	1.14
Angle of repose (°)	25	24	23	22	20
Flow rate (g/sec)	5.0	5.2	5.5	5.5	5.8
Particle density (g/cm^3)	0.65	0.71	0.85	0.90	1.11
Moisture content (%)	5.0	5.0	6.0	7.0	9.0
Swelling capacity	5.22	5.45	5.95	6.05	6.10
Hydration capacity	4.26	4.44	4.86	5.16	5.54

Table 3: Pre-compression properties of the different batches of powder mixes

Batch	Bulk density (g/cm^3)	Tapped density (g/cm^3)	Carr's index (%)	Hausner's Ratio	Angle of repose (°)	Flow rate (g/sec)
A	0.501 ± 0.02	0.627 ± 0.03	11.00 ± 0.11	1.25 ± 0.11	27.27 ± 0.11	5.11 ± 0.62
B	0.504 ± 0.02	0.615 ± 0.02	10.82 ± 0.10	1.22 ± 0.12	26.34 ± 0.12	5.24 ± 0.10
C	0.496 ± 0.05	0.620 ± 0.01	10.53 ± 0.02	1.25 ± 0.11	25.15 ± 0.11	5.31 ± 0.82
D	0.531 ± 0.04	0.621 ± 0.01	11.20 ± 0.01	1.17 ± 0.11	25.58 ± 0.11	5.96 ± 0.64
E	0.633 ± 0.01	0.785 ± 0.03	10.40 ± 0.10	1.24 ± 0.10	23.25 ± 0.13	6.33 ± 0.80
F	0.550 ± 0.02	0.829 ± 0.02	21.80 ± 0.05	1.50 ± 0.12	37.80 ± 0.15	4.20 ± 0.44
G	0.530 ± 0.03	0.810 ± 0.01	22.21 ± 0.02	1.53 ± 0.15	36.13 ± 0.12	4.30 ± 0.35
H	0.520 ± 0.02	0.832 ± 0.03	23.10 ± 0.02	1.60 ± 0.11	36.23 ± 0.12	4.50 ± 0.72

± Standard deviation

Table 4: Post-compression parameters of the formulated tablets

Batch	Weight variation (g)	Crushing strength (kp)	Friability (%)	Disintegration time (min)	Moisture sorption (%)
A	0.1030	3.3 ± 0.50	1.20 ± 0.10	2.68 ± 0.53	101 ± 0.63
B	0.1101	6.0 ± 0.78	1.00 ± 0.08	5.35 ± 0.44	92 ± 0.61
C	0.1021	6.2 ± 0.70	0.90 ± 0.03	6.11 ± 0.32	87 ± 0.20
D	0.1018	6.5 ± 0.79	0.90 ± 0.01	9.40 ± 0.33	84 ± 0.82
E	0.1032	7.5 ± 0.46	0.85 ± 0.03	12.00 ± 0.20	78 ± 0.13
F	0.1100	2.2 ± 0.26	1.80 ± 0.06	1.00 ± 0.25	115 ± 0.35
G	0.1041	2.8 ± 0.30	1.50 ± 0.05	1.03 ± 0.41	110 ± 0.48
H	0.1121	4.3 ± 0.55	1.40 ± 0.05	3.03 ± 0.27	95 ± 0.87

± Standard deviation

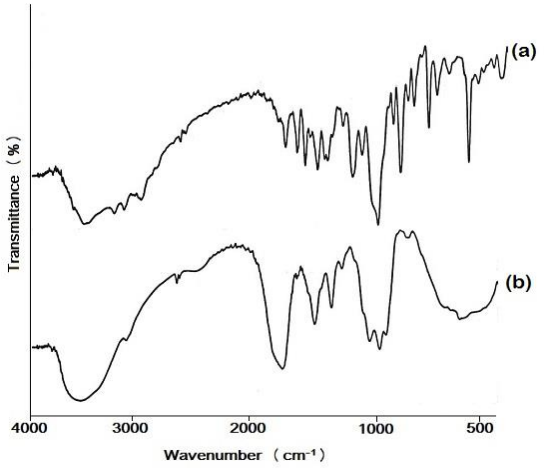

Figure 1: FTIR spectra of (a) pure salbutamol powder, (b) powder mix of salbutamol and novel excipient

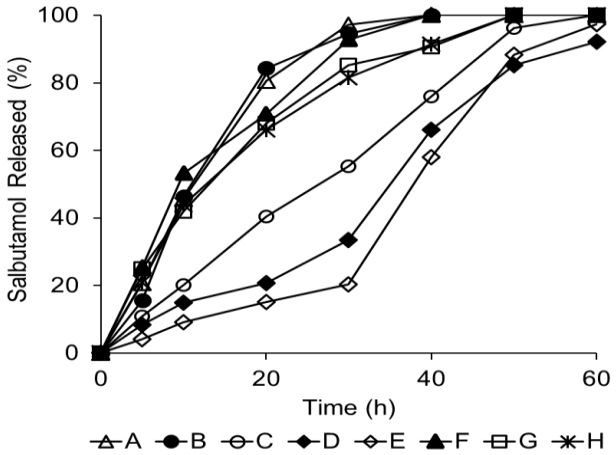

Figure 2: Dissolution profiles of the various batches of the salbutamol tablets

The tablet parameters of batches B, C, D and E met official BP specifications, and salbutamol release from the tablets was delayed with increasing concentrations of okro gum in the novel excipient used in the tablet formulation. The co-processed excipient developed in this study show some promise as a directly compressible vehicle for the preparation of compressed tablets of poorly compressible drugs such as salbutamol.

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