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STABILITY AND DISSOLUTION PROFILE OF TABLETS OF DICLOFENAC SODIUM DISPERSIONS WITH *PARKIA BIGLOBOSA*-DERIVED POLYMERS

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ABSTRACT

Background: Solid dispersion techniques is a method of enhancing dissolution of poorly water-soluble drug. The kneading method is a simple cost-effective way of preparing solid dispersions. Formulating tablet of solid disperse drug is a means enhancing patient access and acceptability of the product; using natural polymeric material like *Parkia biglobosa* derived polymer can lead to a cost effective and biocompatible product.

Aim: This work aims to present solid dispersion of diclofenac sodium with *Parkia biglobosa*-derived polymeric material prepared by kneading technique as tablet and evaluate the stability and tableting properties of the formed tablets.

Method: A direct compressible tablet was formulated using Avicel 101 as a direct compressible excipient. The tablets were evaluated for their tableting properties and dissolution testing in Simulated Gastric Fluid (SGF) and Simulated Intestinal Fluid (SIF). The impact of high temperature and long-time storage for six months on the stability of the formulation was also evaluated.

Results: The tablets formulated were found to be of excellent tableting properties, agreeing with official specifications. Tablets of the Modified *Parkia biglobosa* Mucilage (MPBM) showed a 12% drug release in the SGF sustained for about one hour. This is a 2-fold improvement in release profile compare to the diclofenac tablet formulated. The tablets formulated with PBM, MPBM and Polyvinylpyrrolidone (PVP) polymers release more than 45% of diclofenac sodium within 15 mins in the SIF.

Conclusion: Formulated Tablets showed excellent tableting properties with MPBM-K tablet showing a two-fold enhancement of the dissolution rate. The formulated tablets were stable at 45 ^{0}C for 24 h and over a period of 6 months storage with no significant change in drug content under these conditions with *p*-values of 0.201, 0.706, 0.611, 0.322 and 0.142, 0.787, 0.475 and 1.00 respectively which are greater than 0.05.

Key word: *Parkia biglobosa,* Mucilage, Solid dispersion, Kneading, Direct compression.

INTRODUCTION

Parkia biglobosa-derived polymeric materials are mucilages and carboxymethylated mucilages obtained from the seed of *Parkia biglobosa* (Mimosoideae-Leguminosae) commonly referred to as African locust bean [1]. They show promising properties for use as pharmaceutical excipient especially as solubility and dissolution enhancement polymers in solid dispersions of poorly soluble active pharmaceutical ingredients [2].

A Solid dispersion is a formulation that consist of a poorly water-soluble drug dispersed in at least one hydrophilic carrier,

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producing increased surface area, high drug dissolution rate and solubility [3]. A lot of active pharmaceutical ingredient whose solubility have been enhanced by solid dispersion technique have been presented in different pharmaceutical dosage forms [4]. Presentation of an active pharmaceutical ingredient that have been modified to enhance their biopharmaceutical property and this of great importance to exploring the market viability of such formulation [3].

Tablets are the most popular and widely utilized solid oral dosage forms because of the advantages of self-administration, stability, ease of handling, transportation and good patient compliance [5]. They constitute about 60-70 % of pharmaceutical dosage form available in the pharmaceutical market globally [6]. Presenting solid dispersion of diclofenac sodium in tablet form will be of great benefit to patient because of the ease of administration and compliance that tablet offers as dosage form [5]. This work aims to present the solid dispersion of diclofenac sodium with *Parkia biglobosa* derived polymer as tablets and evaluate the stability and dissolution enhancement of the tablet formulated.

METHODS

Materials

Pal Pharmaceutical Limited in Kano, Nigeria, gave us diclofenac sodium as a gift. Sinopharm Chemical Reagent Co., Ltd. provided the polyvinylpyrrolidone. (China). The *Parkia biglobosa* mucilage and modified *Parkia biglobosa* mucilage were obtained from a batch processed in our laboratory as previously reported [1]. All other reagents used in the experiment were reagent-grade.

Tablet Formulation

The tablets of batch size 100 was prepared by direct compression. The tablet formula is shown in table 1:1. The required amount of diclofenac solid dispersions ratio 1:1 with PBM (*Parkia biglobosa* mucilage), MPBM (Modified *Parkia biglobosa* mucilage, and PVP(Polyvinylpyrrolidone) prepared by kneading method was weighed. These samples were mixed thoroughly with the microcrystalline cellulose (Avicel PH101), sodium starch glycolate, magnesium stearate, and talc. The powdered mix was passed through a sieve number 120 µm and mixed. These mixtures were compressed using Erweka tableting machine EKO/1000 P with 10 mm round punch and die set at the compression pressure of between 8.5 to 10 KN.

Table 1: Tablet formula for solid dispersion ratio 1:1 prepared by kneading method batch size 100

Ingredients	PD (g)	PBM:K (g)	MPBM:K (g)	PVP:K (g)
Drugs	10.00	20.00	20.00	20.00
Avicel 101	7.40	6.14	6.14	6.14
Na Starch glycolate	2.00	3.00	3.00	3.00
Mg Stearate	0.20	0.30	0.30	0.30
Talc	0.40	0.60	0.60	0.60
Total weight	20.00	30.04	30.04	30.04

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Key: PD = Diclofenac sodium tablet, PBM-K = Tablets of the solid dispersion of diclofenac sodium with PBM ratio 1:1 prepared by kneading method, MPBM-K = Tablet of the solid dispersions of diclofenac sodium with MPBM ratio 1:1 prepared by kneading method, PVP-K = Tablet of the solid dispersions of diclofenac sodium with PVP ratio 1:1 prepared by kneading method

Evaluation of tablet properties

The tablets were kept in a desiccator for 24 h to allow for elastic recovery before the following tests were carried out.

a) Tablet thickness and diameter

The thickness and diameter of the tablets were measured using a digital caliper (Z – 540 – 1, U.S.A) 24 h after the tablets were produced. Twenty tablets of solid dispersion of diclofenac sodium with PBM, MPBM, and PVP ratio 1:1 tablet were randomly selected and the thickness and diameter measured. The means and standard deviations were calculated [7].

b) Weight uniformity test

Twenty tablets were randomly selected from the solid dispersion of diclofenac sodium with PBM, MPBM, and PVP ratio 1:1 was weighed together as well as individually. The mean weight and standard deviation were computed [8].

c) Tablet hardness

Six tablets each, randomly selected from the solid dispersion of ratio 1:1 tablet of diclofenac sodium with PBM, MPBM and PVP were determined using the Monsanto Hardness Tester. The mean crushing strength was then determined [9].

d) Friability test

Erweka tablet friability tester was used. Ten tablets were selected at random and their weights noted. The tablets were subjected to abrasion in the machine which was set to rotate at 25 rpm for 4 min, falling from a height of 6 inches at each rotation. The tablets were collected, dusted thoroughly, and re-weighed. The difference in weight was determined and the loss was expressed as a percentage [10].

e) Disintegration test

The procedure was carried out in a disintegration tester (Type ZT3, Erweka Germany) using distilled water thermostatically maintained at 37 ^{o}C as the disintegration medium. Six tablets were placed, one in each tube of which the lower end was fitted with a gauze disc made of rust-proof wire. The disintegration apparatus was set to operate at thirty cycles per minute. A cycle is made up of one complete up and down movement. The time for each of the six tablets to disintegrate and pass through the mesh was determined using a stopped clock [11].

f) Drug content test

Six (6) tablets were picked randomly from the batch of the formulated tablets of the physical mixtures and solid dispersion ratio 1:1 of PBM, MPBM, and PVP. Their mean weight and total weight were determined. The equivalent of one tablet was weighed from the powder and transferred into a 250 ml beaker. Phosphate buffer (100 ml) was added to the powder in the beaker and stirred until the powder dissolved. The solution was filtered through a 0.45 µm Whatman filter paper. The filtrate (1 ml) was pipetted and diluted with 99 ml of the phosphate buffer and the absorbance measured at 272 nm, the value obtained was used to calculate the drug content in

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reference to the calibration curve plotted for diclofenac sodium [12].

g) Dissolution test and drug release profile

An Erweka dissolution test apparatus fitted with a rotating basket rotating at 100 rpm was used. The dissolution media were 900 ml simulated gastric fluid (SGF) pH 1.2 and simulated intestinal fluid (SIF) pH 7.4 maintained at 37.0 ± 0.5 ^{o}C. The solid dispersion tablet of PBM, MPBM, and PVP 1:1 prepared by kneading were placed in the dissolution basket and allowed to rotate. At regular intervals, 5 ml of the solution was withdrawn with a pipette and replaced with a fresh equivalent volume of the dissolution medium. The withdrawn sample was filtered through a 0.45 µm Whatman filter paper and 1ml pipetted and diluted with 5 ml of the medium and absorbance measured at 272 nm was used to determine the drug content and percentage release in the SIF pH 7.4 while in the SGF pH 1.2 the absorbance was taken without dilution [13].

h) Kinetic modeling

The data from the dissolution studies were fitted into various kinetic models such as zero order, first order, Higuchi, Hixson-Crowell, and Korsmeyer-Peppas to define the order and mechanism of release of each of the formulations.

Effect of temperature

Six Tablets were weighed transferred into 250 mL clean beakers and corked. This was placed on a water bath maintained at 45 ^{0}C ± 2 ^{0}C at 100 % relative humidity for 24 h. The tablets in the beakers were crushed in a mortar and the equivalent of 100 mg was weighed out. This was dissolved in 100 ml of phosphate buffer pH 7.4 and 1 ml was measure with a pipette and diluted to 100 ml and the absorbance was determined at 272 nm. This was used to calculate the percentage of drug content [14].

Effect of 6 months storage

Six (6) tablets were weighed and placed in a beaker covered with a cork. This was stored at room temperature and atmospheric relative humidity for two months. The tablets were crushed in a mortar and the equivalent of 100 mg was weighed and transferred to a beaker. This was dissolved with 100 ml phosphate buffer pH 7.4 and 1 ml was measured with a pipette and diluted to 100 ml and the absorbance was determined at 272 nm. This was used to determine the percentage of drug content [15].

Statistical Analysis

The numerical data that result from various determinations were presented as descriptive statistics using bar charts, line graphs and statistically analysed using inferential statistics. Analysis of variance was performed at $p < 0.05$.

RESULTS

The tablets showed uniformity of weight, thickness, and diameter with friability values of less than 1%. Their crushing strength was determined to be PBM-K 6.67 KgF, MPBM-K 7.66 KgF, and PVP- K 5.25 KgF. The disintegration time varied, with values of 28. 41 min, 11.96 min and 48.19 min respectively for PBM-K, MPBM- K and PVP-K tablets as seen in table 2. The amount of drug released at 45 min (DR 45 min) in the SGF was as follows: 4.68% (PBM-K), 11.91% (MPBM-K), and 3.98% (PVP-K) as seen in Figure1. Figure 2 showed the amount of drug released at 45 min (DR 45 min) in the SIF to be as follows:

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69.45% (PBM-K), 65.67% (MPBM-K), and 38.40% (PVP-K).

The kinetic model of the release in the SGF is as follows: PD (diclofenac sodium tablet); Korsmeyer-Peppas model with r^2 (regression correlation factor) of 0.762 and n (release exponent) of 0.290, PBM-K; Hixson Crowell model with r^2 0.918 and n of 0.361, MPBM-K; Korsmeyer-Peppas model with r^2 of 0.795 and n of 0.284, PVP-K; Hixson Crowell model with r^2 of 0.970 and n of 0.293 seen in table 3.

Table 4 presents the kinetic model of the release in SIF which is as follows: PD (diclofenac sodium tablet); Korsmeyer-Peppas model with r^2 (regression correlation factor) of 0.952 and n (release exponent) of 0.383, PBM-K; Korsmeyer-Peppas model with r^2 of 0.971 and n of 0.757, MPBM-K; first-order kinetic with r^2 of 0.969 and n of 0.757, PVP-K; Higuchi model with r^2 of 0.967 and n of 1.157.

The release model mechanism (RMM) is shown is table 5, most of formulations followed the anomalous release mechanism and a single case of super case II release exhibited by PVP-K in SIF pH 7.4.

The drug content for the formulation were within the range of 100.79 to 98.41. The *p*-values obtained from the *t*-test comparing the initial drug content and content after the elevation of temperature to 45 ^{o}C were 0.201,0.706,0.611 and 0.322 (PD, PBM-K, MPBM-K and PVP-K), while that of the long-term storage for 6 months were 0.142, 0.787,0.475 and 1.00 (PD, PBM-K, MPBM-K and PVP-K) as seen in Table 6

Table 2: Tablet properties of solid dispersion prepared by kneading method

Parameters	Values			
	PD	PBM-K	MPBM-K	PVP-K
Weight Variation (mg)	200 ± 4.71	306 ± 5.16	302 ± 4.19	298 ± 6.32
Thickness (mm)	3.16 ± 0.03	4.69 ± 0.03	4.66 ± 0.08	4.99 ± 0.05
Diameter (mm)	8.03 ± 0.02	8.03 ± 0.07	8.03 ± 0.04	8.01 ± 0.01
Crushing strength (KgF)	5.83 ± 0.57	6.67 ± 1.15	7.66 ± 1.44	5.25 ± 0.29
Friability (%w/w)	0.99 ± 0.00	1.00 ± 0.48	0.96 ± 0.45	0.99 ± 0.47
Disintegration time (mins)	0.48 ± 0.00	28.41 ± 1.46	11.96 ± 3.58	48.19 ± 1.86

Key: PD: Formulated tablet Diclofenac sodium, PBM-K: Tablet of the Solid dispersion of Diclofenac with *Parkia biglobosa* mucilage, MPBM-K: Tablet of the Solid dispersion of Diclofenac sodium with Modified *Parkia biglobosa*, PVP-K: Tablet of the Solid dispersion of Diclofenac sodium with polyvinylpyrrolidone

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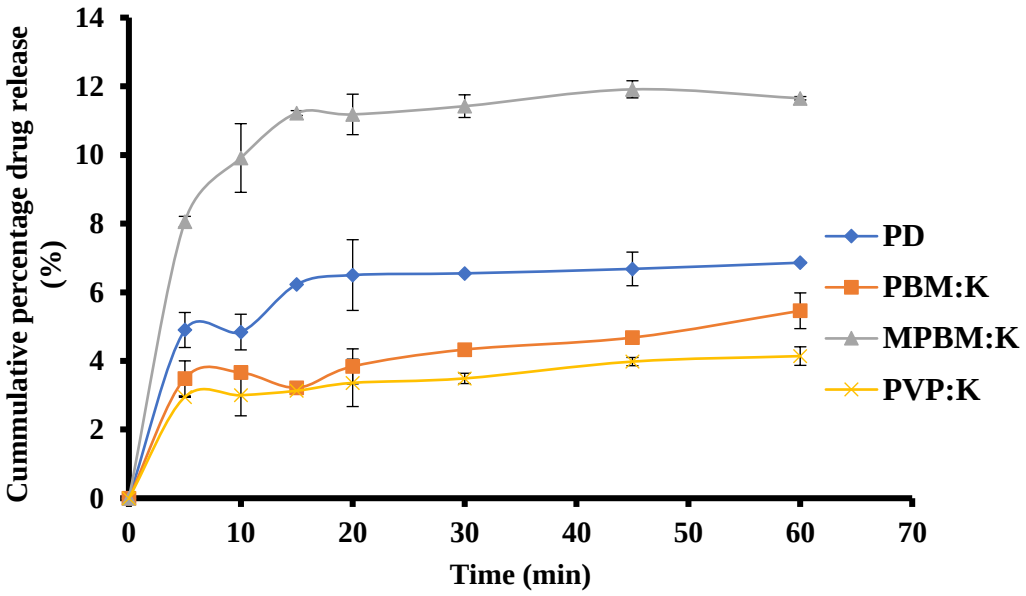

Figure 1: Release profile of the tablet of diclofenac sodium; tablets of the solid dispersions of diclofenac sodium with PBM, MPBM, and PVP ratio 1:1 prepared by kneading method in SGF pH 1.2

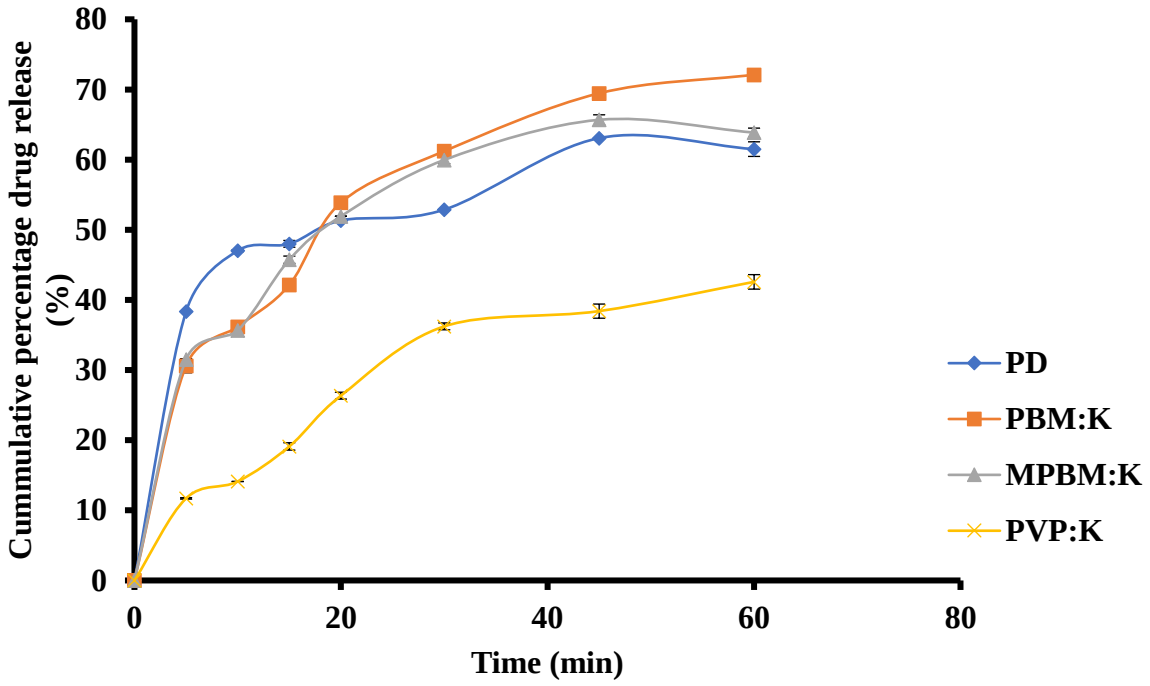

Figure 2: Release profile of the tablet of diclofenac sodium; tablets of the solid dispersions of diclofenac sodium with PBM, MPBM, and PVP ratio 1:1 prepared by kneading method in SIF pH 7.4

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Table 3: Release kinetics of the formulated tablets in SGF pH 1.2

Formulation	Zero-order (r^2)	First-order (r^2)	Hixson's Crowell (r^2)	Higuchi (r^2)	Korsmeyer Peppas (r^2)	N
PD	0.423	0.573	0.561	0.717	0.762	0.290
PBM-K	0.616	0.906	0.918	0.832	0.727	0.361
MPBM-K	0.398	0.534	0.529	0.700	0.795	0.284
PVP-K	0.521	0.925	0.970	0.784	0.907	0.293

Key: PD: Formulated tablet Diclofenac sodium, PBM-K: Tablet of the Solid dispersion of Diclofenac with *Parkia biglobosa* mucilage, MPBM-K: Tablet of the Solid dispersion of Diclofenac sodium with Modified *Parkia biglobosa*,PVP-K: Tablet of the Solid dispersion of Diclofenac sodium with polyvinyl

Table 4: Release kinetics of the formulated tablets in SIF PH 7.4

Formulation	Zero order (r^2)	First order (r^2)	Hixson's Crowell (r^2)	Higuchi (r^2)	Korsmeyer Peppas (r^2)	N
PD	0.553	0.887	0.882	0.824	0.952	0.383
PBM-K	0.782	0.949	0.931	0.964	0.971	0.757
MPBM-K	0.690	0.969	0.883	0.919	0.946	0.649
PVP-K	0.879	0.917	0.908	0.967	0.956	1.157

Key: PD: Formulated tablet Diclofenac sodium, PBM-K: Tablet of the Solid dispersion of Diclofenac with *Parkia biglobosa* mucilage, MPBM-K: Tablet of the Solid dispersion of Diclofenac sodium with Modified *Parkia biglobosa*, PVP-K: Tablet of the Solid dispersion of Diclofenac sodium with polyvinyl

Table 5: Release mechanism model of the tablets formulated

Formulation	pH 7.4		pH 1.2	
	n	RMM	n	RMM
PD	0.383	Anomalous transport	0.290	Anomalous transport
PBM-K	0.757	Anomalous transport	0.361	Anomalous transport
MPBM-K	0.649	Anomalous transport	0.293	Anomalous transport
PVP-K	1.157	Super Case II transport	0.293	Anomalous transport

Key: PD: Formulated tablet Diclofenac sodium, PBM-K: Tablet of the Solid dispersion of Diclofenac with *Parkia biglobosa* mucilage, MPBM-K: Tablet of the Solid dispersion of Diclofenac sodium with Modified *Parkia biglobosa*, PVP-K: Tablet of the Solid dispersion of Diclofenac sodium with polyvinyl, RMM: Release model mechanism

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Table 6: Effect of temperature at 45ºC and storage for 6 months on the stability of the formulated tablet.

Formulation	Initial drug Content %w/w	Stability At 45 ºC %w/w	*p*-Value	Stability After 6 months	*p*-Value
PD	100.79 ± 0.84	100.56 ± 0.00	0.201	100.38 ± 0.84	0.142
PBM-K	99.40 ± 0.27	99.01 ± 1.69	0.706	98.81 ± 0.84	0.787
MPBM-K	98.41 ± 0.27	94.71 ± 7.77	0.611	98.14 ± 0.56	0.475
PVP-K	99.77 ± 0.27	99.72 ± 0.00	0.322	99.77 ± 0.27]	1.000

Key: PD: Formulated tablet Diclofenac sodium, PBM-K: Tablet of the Solid dispersion of Diclofenac with *Parkia biglobosa* mucilage, MPBM-K: Tablet of the Solid dispersion of Diclofenac sodium with Modified *Parkia biglobosa*, PVP-K: Tablet of the Solid dispersion of Diclofenac sodium with polyvinyl

DISCUSSION

The tablets showed uniformity of weight, thickness, and diameter within the limits specified [13]. The thickness and diameter were seen not to show any significant deviation from their mean. This implies that there was a good flow and adequate die filling during the process of tablet compression [15].

The weight variation test applicable for tablets containing 50 mg or more of the active pharmaceutical ingredient was employed, the British Pharmacopoeia specify that not more than two tablets should deviate more than 7.5 % for 80 -250 mg tablet [13]. All the batches of the formulated tablet meet this specification which connotes proper mixing that could lead to uniform distribution of drug content in the formulation [13].

The crushing strength or hardness test determines the force needed to fracture or break the tablet along its diameter, the acceptable range of the hardness of oral tablet is 4 to 8 KgF [10]. The crushing strength of the tablets were determined to be PBM-K 6.67 KgF, MPBM-K 7.66 KgF, and PVP- K 5.25 KgF which falls within the acceptable range and imply that the tablets formulated have an optimal cohesiveness and structural strength [16]. An optimum crushing strength means that the tablets are optimally hard and will be able to disintegrate and release the drug for absorption [17]. A good crushing strength also implies that the tablets formulated could withstand the rigors of handling involved in further processing, packaging, transportation dispensing, and usage [10].

The friability test is a measure of the mechanical strength of a tablet and is associated with the ability of a tablet to remain intact at all stages of handling, production, packaging, warehousing, distribution, dispensing and handling. The weight loss accepted for the friability testing is less than 1% w/w [10]. All the formulated tablets passed the friability test showing a weight loss of ≤ 1%w/w. This means that the tablets formulated can resist fracture, abrasion and permanent deformation [18].

The tablets of PBM-K and PVP-K had disintegration time of more than 15 min while MPBM-K disintegrate in less than 15 min. For uncoated tablets, the specified disintegration time is less than 15 min [10]. Only MPBM-K passed the disintegration test agreeing with the assertion that carboxymethylation of *Parkia biglobosa* leads to polymer with greater porosity and

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moisture sorption that could serves as good disintegrants [1].

Invitro dissolution test assesses the rate of drug dissolution from solid dosage form and is intended to provide a step towards evaluation of the physiological availability of the drug [20]. For immediate release tablet, it is specified that not less than 75% of the drug should release in the SGF in 45 min. For gastro protected tablet not more than 10% of the drug should dissolve in 2 h and not less than 75 % should dissolve in the SIF in 45 min [20]. MPBM-K showed a 2-fold increase in amount dissolved compared to the diclofenac tablets, while PBM-K and PVP-K showed a retarded release of the diclofenac sodium. PD, PBM-K, MPBM-K and PVP-K showed an increase in dissolution profile in the SIF in this order MPBM-K>PBM-K>DS>PVP-K at 45 min. The tablet formulated with *Parkia biglobosa*-derived polymer did not meet the specification for an immediate release tablet but could serve for a gastro protection tablet because of the ability to retard the release of diclofenac sodium in the SGF exhibited by PBM-K and PVP-K tablet with subsequent improvement in release of all the formulation in the SIF. This agrees with the release pattern for solid dispersion prepared by kneading in the SIF that has been reported by Singh *et al*. [19].

The kinetic model of release follows the Korsmeyer-peppas model of release in the SGF and SIF except for PBM-K that followed the Higuchi model. The release mechanism mostly followed the anomalous transport except for PVP-K that followed the super case II transport model. Therefore, the release model mechanism in both the SGF and SIF is a non Fickian diffusion combining the process of erosion, swelling and diffusion [21].

The formulated tablets on visual examination were found to maintain no change in appearance and on determination of their content after subjection to 45 ^{o}C for 24 h and after 6 months, there was no statistically significant change in content as seen in the *p*-value obtain from the t-test.

CONCLUSION

Tablets of diclofenac sodium solid dispersion with *Parkia biglobosa*-derived polymeric material were found to be of excellent tableting properties with a 2-fold enhancement of dissolution rate in SGF exhibited by MPB-K. The formulated tablets were stable at 45 ^{0} C for 24 h and over a period of 6 months storage with no significant change in drug content under these conditions.

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