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EVALUATION OF DICLOFENAC SODIUM TABLETS FORMULATED WITH CO – PROCESSED *ACACIA-SIDA ACUTA* GUM

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ABSTRACT

The present study investigates the effect co-processing of *Acacia* gum with *Sida acuta* gum has on the drug release profile of diclofenac sodium tablets. *Acacia* gum powder was co-processed by physical admixture with *Sida acuta* gum powder in the ratio of 2:1 (F2) and 1:1 (F3) and also by co-precipitation with isopropyl alcohol of the mucilage formed from the physical admixtures respectively (F4 and F5). The co-processed excipients were characterized for solubility, angle of repose, true, bulk and tapped densities. Five batches of diclofenac sodium granules were formed using acacia alone (F1) and the four co processed excipients (F2 – F5) as 5%w/w binders respectively. The granules were evaluated for average particle size, angle of repose, bulk and tapped densities. The granules were compressed into tablets and evaluated for their disintegration time, % drug release profile, friability and hardness. The hardness value for batches F1 to F5 tablets were 6.099±2.609, 6.74±0. 565, 6.981±1.896, 7.046±2.487 and 5. 545±1.978 respectively. The mean disintegration time ± S.D for batches F1 to F5 ranged from 6.33±0.58 to 14.00±1.00 min. The % drug release for batches FI to F5 at 10 min time interval were 89, 48, 59, 65 and 50 % , at 20 min, were 100, 62, 61, 70 and 56 %, and at 60 min were, 100, 100, 72, 100 and 71 % respectively. *Acacia* gum co-processed with *Sida acuta* could be used to effect drug release retardation and this increases with increase *Sida acuta* gum ratio.

KEYWORDS: Co-processing, acacia, *Sida acuta* gum, co-precititation, diclofenac sodium.

INTRODUCTION

Development of new drugs is a very expensive and time – consuning venture, and this leads to shift of focus towards improving the life cycle of the already existing drugs in the market. To achieve these objectives, areas such as researching on newer technologies for drug delivery, trying non conventional routes for drug administration, using newer polymers, development of new co-processed excipients, extraction and characterization of newer excipients of natural origin are being explored for potential possibilities.[1]

Excipients are additives used to convert active pharmaceutical ingredients into pharmaceutical dosage forms suitable for administration to patients.[1,2] They may provide various functions such as binding, lubricating, gelling, suspending, flavouring, sweetening and bulking agent along with others. Factors such as the route of administration, type of the dosage form, as well as the active ingredient help to determine the appropriate excipients to be used.

Contrary to former opinion that excipients were inactive ingredients, they are now understood to be a key determinant of dosage form performance.[1,3]

Co processing is a mixture of two or more material by an appropriate process, Co processing of excipients may lead to formation of new excipients with added value. The new excipients so formed do not loose their physical structure and chemical stability.[4]

Co-precipitation is the simultaneous precipitation of a soluble component with a macro-component from the same solution by the formation of mixed crystals, by adsorption, occlusion or mechanical entrapment. The aim of co-precipitation, e.g., polymer-polymer interaction, is to produce a stable polymer with better properties than the individual polymers. Co-precipitation which is an example of solid dispersion is a recognized technique for increasing the dissolution of poorly water-soluble drugs so as to improve their bioavailability.[5]

Sida acuta Burm. F is a shrub that belongs to *Malvaceae* family. It is widely distributed in the subtropical regions where it is found in bushes, in farms and around habitations. *Sida* acuta plant is widely used in traditional medicine.[6] *Sida acuta* gum was isolated from powdered dried leaves of *Sida acuta*.[7] from the stem of the plant.[8] The effect of *Sida acuta* and Corchurus olitorius mucilage on the physicochemical properties of maize and sorghum

starches was studied by.[9] Sida acuta gum had physicochemical properties that showed that it could be used as pharmaceutical excipients such as a binder, suspending agent and swellable hydrophilic matrix. It could also be used for investigation in nanoformulation of some drugs in novel drug delivery alone or in combination with other biopolymers.[7]

Acacia is the dried gummy exudate from the stems and branches of Acacia senegal (Linne) Willdenow or of other related African species of Acacia (Fam. Leguminosae). A 1 g of acacia dissolves in 2 ml of water and the resulting solution flows readily and is acid to litmus.[10] Acacia appear as tasteless and odourless nodules or lumps, with colour vary from off-white to orange-brown. It dissolves in water at 30^0 C to form viscous solutions, which showed that they are natural gums of the hydrophilic colloid group. It is insoluble in common organic solvents (ethanol, acetone, ether, chloroform, benzene etc) and in oils, with which they form emulsions in aqueous suspension. The good solubility of the gum is also indicative of the absence of cross linking between polymeric chains. This is because gums having cross linked polymeric chains only swell in water, without dissolving.[11]

Sida acuta gum is poorly soluble in distilled water at room temperature when compared to *acacia* gum.[7] The fast swelling of the gum in water may be one of the reasons for its poor solubility. Particles at the outer surface absorb water, swell and this prevents water from reaching those in the interior easily.[7]

This study investigated the effect co-processing of *Acacia* gum with *Sida acuta* gum had on the drug release profile of diclofenac sodium tablets.

MATERIALS AND METHODS

Materials

Isopropyl alcohol, acetone, (Guangxing Guanghua Chemical, China), conc. Hydrochloric acid, (Haig Laboratory Chemical Corporation Wembley, MIDDX, England), Potassium dihydrogen orthophosphate, Dipotassium hydrogen phosphate (BDH Chemicals Ltd Poole England), Diclofenac, (Alpha Lab, Germany), acacia (T. Baker, U.S.A), sodium hydroxide (Loba Chemie, Mumbia, India), The leaves were collected from *Sida acuta* plants from bushes in the New G.R.A area of Trans – Ekulu, Enugu, Enugu state, Nigeria.

Isolation and Purification of *Sida acuta* Gum

The gum was isolated and purified according to the method used by.[7] The leaves from *Sida acuta* plant were dried, powdered, and passed through a sieve of aperture size 600 µm. A 200 g of the sieved dried leaves powder was mixed with 1500 ml of distilled water and allowed to macerate for 6 h. The mixture was boiled for 1 h at 100 °C to ensure complete break – up of cells to release the mucilage and kept aside for settling. After 2 h, the mixture was filtered, and to the filtrate (900 ml), equal volumes of isopropyl alcohol were added and kept in a refrigerator at 8–10°C for 6 h. To the marc left, 1000 ml of distilled water was added and kept for about 1 h to wash out the remaining mucilage. The mucilage (1200 ml) was separated from the marc using a muslin cloth and precipitated with equal volumes of isopropyl alcohol. The gum was purified by using isopropyl alcohol and acetone as reported by previous researchers. The gum was soaked into two volumes excess of isopropyl alcohol. The gum-solvent slurry was allowed to stand for 30 min. The precipitate was collected by filtration using muslin cloth. washed twice with isopropyl alcohol and once with acetone. Finally, it was dried in the oven at 40 °C for 8 h. The gum was stored separately in a clean, dry, and closed container.

Co-processing of *Acacia* and *Sida acuta* gums

Four formulations of co-processed *Acacia/ Sida acuta* gums (ADMX 2:1, ADMX 1:1, CO-PPT 2:1 and CO-PPT 1:1) were produced respectively. ADMX 2:1 was produced by thouroughly mixing 15 g of *acacia* gum and 7.5 g of *Sida acuta* gum in a mixing bottle. ADMX 1:1 was produced by thoroughly mixing 10 g of *Acacia* gum and 10 g of *Sida acuta* gum in a mixing bottle. CO-PPT 2:1 was produced by thouroughly mixing 15 g of *acacia* gum and 7.5 g of *Sida acuta* gum in a mixing bottle. The mixture was dissolved in 100 ml of distilled water and left for 2 hr to ensure complete dissolution. The gum solution was precipitated with equal volumes (100ml) of isopropyl alcohol and filtered using muslin cloth. The precipitate was washed with 100 ml of acetone and filtered with muslin cloth. The precipitated gum was dried in an oven at 50 ^{0}C for 2 h. CO-PPT 1:1 was produced in a similar except that 10 g each of *Acacia* and *Sida acuta* gum was used. The acacia powder and the co-processed gums were evaluated based on solubility of 1 % gum solution, true, bulk and tapped densities of the powder.

Formulation of Diclofenac Sodium Granules and Tablets

Five sets of granules were produced and compressed into the respective tablets formulations (F1 –F5) according to the formula on Table 1. Five formulations of diclofenac granules were formed using acacia alone (F1) and the four co-processed excipients (F2 – F5) as 5%w/w binders respectively. The diclofenac powder and the excipients were passed through 300 µm sieve respectively. The granules were formed by thoroughly mixing the diclofenac powder with lactose and corn starch. The respective co-processed binder powder was dissolved in little water to form the binder solution. The binder solution was added to the powder – mix and blended thoroughly to form a damp mass. The damp mass was passed through 1.18 mm sieve to form wet granules. The granules were dried in the oven at 50 ^{0}C for 2 h. The dried granules were passed through 710 µm sieve. The granules were blended with talc and magnesium stearate and compressed with a predetermined force into the respective tablets using a CJD 316 sixteen station rotary tablet press having 13 mm punch (Clit Jemkay Engs. Pvt, Ltd. Ahmedabad, India).

Table 1: Formula for the production of formulation F1 –F5 of diclofenac sodium tablets.

Ingredients	F1	F2	F3	F4	F5
Diclofenac Sodium	100 mg	100 mg	100 mg	100 mg	100 mg
Acacia	25 mg	0 mg	0 mg	0 mg	0 mg
Acacia/Sida Acuta (ADMX 2:1)	0 mg	25 mg	0 mg	0 mg	0 mg
Acacia/Sida Acuta (ADMX 1:1)	0 mg	0 mg	25 mg	0 mg	0 mg
Acacia/Sida Acuta (Co-PPT 2:1)	0 mg	0 mg	0 mg	25 mg	0 mg
Acacia/Sida Acuta ‘Co-PPT (1:1)	0 mg	0 mg	0 mg	0 mg	25 mg
Corn Starch	25 mg	25 mg	25 mg	25 mg	25 mg
Lactose	335 mg	335 mg	335 mg	335 mg	335 mg
Magnesium Stearate	5 mg	5 mg	5 mg	5 mg	5 mg
Talc	10 mg	10 mg	10 mg	10 mg	10 mg
Total	500 mg	500 mg	500 mg	500 mg	500 mg

Characterisation of Co – Processed *Sida Acuta* Gum – Acacia Powder

pH: A 1%w/v solution of acacia (F1) and the co – processed *Sida acuta* gum – acacia (F2 – F5) were prepared by dissolving 1 g of the respective gum powder in 100 ml of distilled water. Distilled water was used to calibrate a model HI 2211 pH/ORP meter (Hanna Instruments) after which it was used to determine the pH of the gum solutions. These were repeated three times.

Bulk and tapped densities: The acacia gum was sieved through a 300 µm sieve. A 10 g quantity of acacia gum was weighed and poured into a 50 ml measuring cylinder and bulk

volume recorded. The cylinder was tapped 100 times and the tapped volume recorded. The bulk and tapped densities were calculated. This was done three times. This process was also repeated three times using the respective co – processed gums.

Carr's Compressibility Index: This was calculated from the bulk and tapped densities for the respective formulations using equation 1.

$$Carr's\ Index = \frac{Tapped\ density - Bulk\ density}{Tapped\ density}\ X\ 100 \quad \text{---------- 1}$$

Hausner Ratio: This was also calculated from the bulk and tapped densities for the respective formulations using equation 2.

$$Hausner\ Ratio = \frac{Tapped\ density}{Bulk\ density} \quad \text{---------- 2}$$

Angle of Repose: This was determined by the Platform method. A hollow cylinder that was opened at both end, with a diameter of 5.5 cm was placed on top of a cream jar with diameter 5.5 cm on a table. A 20 g of acacia gum was poured into the cylinder on top of the cream jar. The hollow cylinder was removed by pulling it up from the cream jar. The acacia gum formed a cone on top of the cream jar. The height and diameter of the cone were recorded. The drained angle of repose, θ was determined using equation 3. This was done in triplicate. This process was also repeated using the respective co – processed gums in triplicate.

$$\theta = \mathrm{Tan}^{-1}\ \frac{h}{r} \quad \text{---------- 3}$$

Evaluation of Granules of Diclofenac for Formulations F1 – F5 Tablets

Different formulations of the diclofenac granules were characterised based on their angle of repose, bulk density, tapped density, Carr's compressibility index, Hausner's ratio and particle size distribution

Angle of Repose: This was determined by the funnel method. A funnel was clamped to a retort stand at a height of 7.5 cm above the table. A 10 g sample of diclofenac granules from formulation F1 was weighed and poured into the funnel with the tip closed. The funnel was opened and granules were allowed to flow through and they formed a cone on a paper placed on top of the table. The height and diameter of the cone were recorded. The angle of repose, θ was determined using equation 3. This was done in triplicate.

The angles of repose for diclofenac granules from formulations F2 – F5 were determined likewise.

Bulk and tapped densities: A 10 g diclofenac granules from formulation F1 was weighed and poured into a 50 ml graduated cylinder and bulk volume recorded. The cylinder was tapped 100 times and the tapped volume recorded. The bulk and tapped densities were calculated. This was done three times.

The bulk and tapped densities of diclofenac granules from formulations F2 –F5 were determined respectively using the same procedure.

Carr's Compressibility Index: This was calculated from the bulk and tapped densities for the respective formulations using equation 1.

Hausner Ratio: This was also calculated from the bulk and tapped densities for the respective formulations using equation 2.

Evaluation of Formulations F1 – F5 Diclofenac Tablets

Tablets of diclofenac formulations F1 to F5 were evaluated for their disintegration time, % drug release profile, friability and hardness.

Weight variation: Twenty tablets were selected randomly from respective formulations and weighed individually. The individual weights were compared with the average weight for weight variation.

Thickness: Ten tablets from each formulation were taken randomly and their thickness measured using a digital tablet thickness test apparatus (Veego tablet test apparatus, India).

Hardness: Five tablets were selected randomly from each formulation and hardness was determined using a digital tablet hardness test apparatus (Veego tablet test apparatus, India).

Friability: The friability of the prepared tablets was evaluated as the percentage weight loss of 10 tablets tumbled in a friabilator (Veego friability test apparatus, India) for 4 min at 24 rpm.

Disintegration tests: From each of the diclofenac formulations (F1 – F5), six tablets were picked at random and placed into the six respective tubes of the tablet disintegration test

apparatus (Manesty, Liverpool, England). The tablets were repeatedly lowered into, and lifted up from the disintegration medium composed of distilled water,maintained at 37 ± 1^0C, until all the tablets broke up and passed through the screen at the base of each tube. The mean disintegration value obtained for the six tablets was recorded for each of the formulations respectively.

Drug content: The drug content of compressed tablets was determined by UV Spectrophotometric method. Ten (10) tablets from each of the formulations of diclofenac tablets (F1 – F5) were accurately weighed and crushed in a mortar with pestle respectively. Quantity of powder that contained equivalent of 100 mg of diclofenac sodium was weighed and dissolved in 100 ml of phosphate buffer pH 6.8. These were fillterd through a 0.45-µm filter paper respectively. The respective filtrates were diluted with phosphate buffer pH 6.8. The respective drug contents were analyzed spectrophtometrically at 271.4 nm using a UV – VIS spectrophotometer (UV - 1800, Shimadzu Japan) and the absorbance value compared with a refrence standard curve of diclofenac.

In vitro dissolution studies: This was carried out using USP XX type 1 (Rotary basket) apparatus. One tablet of diclofenac sodium from formulation F1was weighed and placed in the basket of a single unit Copley dissolution test apparatus (Erweka Apparatebau GMBH, Heusengtamm, Germany). The basket was inserted into the dissolution chamber that contained phosphate buffer pH 6.8 maintained at 37 ± 1^0C as the dissolution medium and rotated at a speed of 100 rpm. A 5 ml sample was withdrawn and replaced with 5 ml of fresh pre- heated dissolution medium after 10, 20, 30, 45 and 60 min. The sample was analysed using UV spectrophotometer at a wavelength of 271.4 nm.

RESULTS AND DISCUSSION

Characterisation of Co – processed *Sida acuta* – acacia

From Table 2, the pH of a 1 % solution of F1 powder which contained acacia alone was 5.15 which was acidic. The pH of 1 % solution of the co-processed gums ranged from 6.72 to 7.47 which showed that addition of *Sida acuta* to acacia changed the pH of the solution from acidic to slightly basic. The solubility of a 1 % solution of F1, which contained acacia alone, was 90 %w/v, but the solubility of the co-processed gums ranged from 26.67 to 76.67 %w/v. This shows that addition of *Sida acuta* to acacia reduces the solubility of the resultant solution.

The angle of repose ranged from18.42 ± 0.00 to 31.60 ± 0.00. F4 and F5 showed excellent flow, F1 and F2 show good flow but F3 showed passable flow.

Hausner ratios for F1, F2, F4 and F5 were less than 1.25 which showed good flow. F3 had Hausner ratio of 1.36 ± 0.01 which showed a flow that can be improved upon by the adddition of a glidant.

F1 had Carr's index of 5.46 ± 1.84 which showed excellent flow. F4 showed good flow while F1 and F2 had fair to passable flow which can be improved upon by the addition of glidants. F3 had poor flow.

Table 2: Characterisation of the *Sida acuta* – acacia co – processed gum powder.

Formulations	F1	F2	F3	F4	F5
p H of 1%w/v	5.15	6.72	7.11	7.36	7.47
Solubility of 1 %w/v (%)	90.00	76.67	26.67	7.34	66.67
Angle of repose	28.60 ± 00	26.57 ± 0.00	31.60 ± 0.00	18.42 ± 0.00	20.00 ± 0.00
Bulk density	0.63 ± 0.00	0.58 ± 0.02	0.42 ± 0.01	0.63 ± 0.00	0.65 ± 0.01
Tapped density	0.77 ± 0.00	0.70 ± 0.03	0.57 ± 0.00	0.74 ± 0.03	0.69 ± 0.00
True density	1.59 ± 0.17	1.51 ± 0.18	1.46 ± 0.11	1.51 ± 0.10	1.42 ± 0.00
Hausner's ratio	1.22 ± 0.00	1.21 ± 0.08	1.36 ± 0.01	1.19 ± 0.04	1.06 ± 0.02
Carr's Compressibility Index	18.18 ± 0.00	17.20 ± 5.16	26.52 ± 0.46	15.62 ± 3.13	5.46 ± 1.84

Evaluation of formulations F1 – F5 diclofenac granules

The micromeritics of formulations F1 to F5 diclofenac granules were shown on Table 3. Granules for formulations F4 and F5 had angle of repose values of 26.57 ± 0.00 each which indicates good flow property. Granules from formulation F1 to F3 had angle of repose that was above 30, which indicates passable flow that can be improved on by the addition of a glidant.

Granules from all the formulations had Hausner ratio that was less than 1.25 which indicated good flow.

Granules from all the formulations had a Carr's index of less than 15 % which indicated that they all had excellent flow properties.

Table 3: Micromeritics of formulations F1 to F5 diclofenac granules.

Formulations	F1	F2	F3	F4	F5
Angle of repose	31.32 ± 4.12	31.32 ± 4.12	30.96 ± 0.00	26.57 ± 0.00	26.57 ± 0.00
Bulk density	0.44 ±0.01	0.50 ±0.01	0.47 ± 0.01	0.45 ± 0.02	0.52 ± 0.01
Tapped Density	0.47 ± 0.01	0.52 ± 0.01	0.50 ± 0.00	0.49 ± 0.01	0.55 ± 0.01
Hausner's ratio	1.05 ± 0.01	1.03 ± 0.02	1.08 ± 0.03	1.08 ±0.03	1.05 ± 0.02
Carr's compressibity index	5.09 ± 1.18	3.32 ± 1.41	6.93 ± 2.10	7.44 ± 2.37	4.45 ± 1.46

Evaluation of diclofenac tablets from Formulations F1 – F5

Thickness: The tablet thickness ranged from 3.11 ± 0.14 to 3.38 ± 0.27.

Hardness: The hardness values ± S.D for formulations F1 to F5 tablets were 5.55 ± 1.98 to 7.05 ± 2.49 kgf and respectively. The values were above 4 kgf, which signified that the tablets will be able to withstand the stress of further processing and transportation.

Friability: The friability for the formulations ranged from 0.35 to 0.39 % which is below the upper limit for friability (1 %). This shows that the tablets can withstand forces of abrasion during further handling and storage.

Disintegration test: As shown on Table 4, the mean disintegration time ± S.D for formulations F1 to F5 ranged from 6.33 ± 0.58 to 14.00 ± 1.00 min. All the formulations passed the disintegration test, as they disintegrated in less than 15 min. However, it is observed that the disintegration time of all the formulations containing co-processed acacia-*Sida acuta* gum as binder (F2 – F5) were higher than the formulation that contained only acacia as binder (F1). Among the formulations that contained co-processed acacia – Sida acuta gum as binder, F3 and F5 that contained 1:1 ratio of the gums produced higher disintegration time (14.0 ± 1.00 and 13.67 ± 3.79) than the formulations that contained the 2:1 ratio (F2 and F4). To produce tablets with equivalent disintegration time, lower concentrations of the co-processed gum will be needed.

Drug content: The percentage drug content for tablets from formulations F1 to F5 ranged 98.12 to 101.2 % as shown on Table 4. They are within the limits for diclofenac tablets.

Table 4: Tablet evaluation for formulations F1 to F5.

Formulations	F1	F2	F3	F4	F5
Weight (G)	0.50 ± 0.01	0.50 ± 0.03	0.50 ± 0.06	0.49 ± 0.01	0.49 ± 0.02
Thickness (Mm)	3.16 ± 0.14	3.11 ± 0.01	3.19 ± 0.03	3.16 ± 0.06	3.38 ± 0.27
Diameter (Mm)	13.03 ± 0.15	12.95 ± 0.00	12.98 ± 0.03	13.00 ± 0.00	13.02 ± 0.03
Hardness (Kg/F)	6.10 ± 2.61	6.67 ± 0.57	6.98 ± 1.90	7.05 ± 2.49	5.55 ± 1.98
Friability (%)	0.39	0.37	0.35	0.38	0.39
Disintegration time (Min)	6.33 ± 0.58	8.67 ± 1.15	14.0 ± 1.00	9.67 ± 0.58	13.67 ± 3.79
Drug content (%)	98.12	99.10	98.50	101.20	99.45

Weight variation: The percentage weight deviation from the mean for tablets from formulations F1 to F5 ranged from 0.00 to 3.92 %. The B.P states that for tablets having weight of 250 mg or more, a limit of ±5 % deviation from the mean of the twenty tablets used is allowed. Tablets from formulations F1 to F5 complied with BP standard.

In vitro dissolution test: The % drug release for formulations FI to F5 at 10 min time interval were 89, 48, 59, 65 and 50 % , at 20 min, were 100, 62, 61, 70 and 56 %, and at 60 min were, 100, 100, 72, 100 and 71 % respectively.

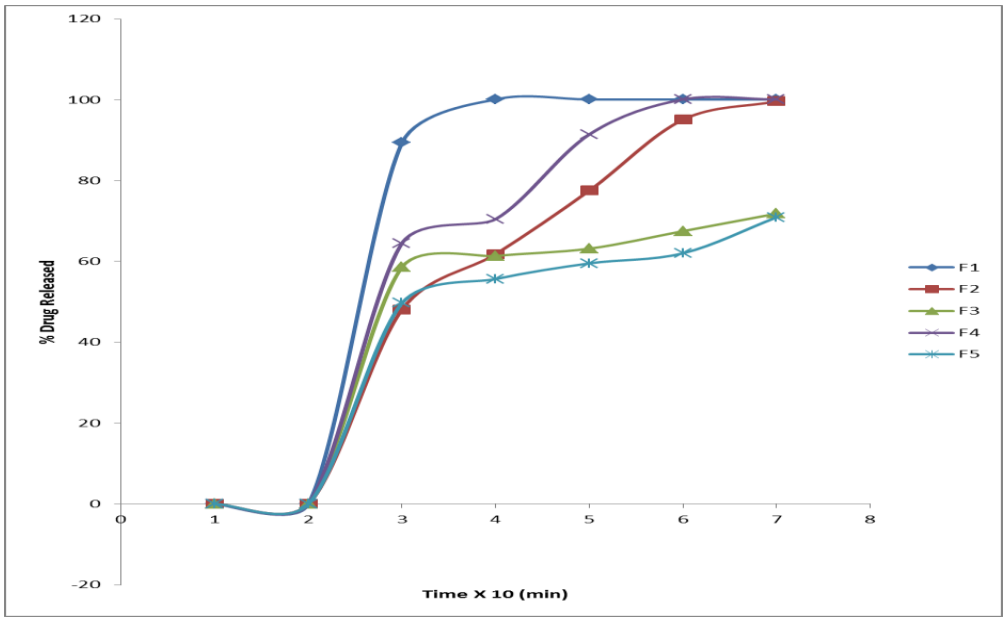

Fig. 2: In vitro % Drug release profile for Formulations F1 to F5.

CONCLUSION

Acacia gum co-processed with *Sida acuta* could be used to effect drug release retardation. The higher the ratio of *Sida acuta* gum in the co-processed excipient, the higher the level of drug release retardation achieved.

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