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Research Article

Proportional Estimation of Pregelatinized Starch as Disintegrant In Different Tablet Formulations.

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ABSTRACT
Tablets are widely used due to the advantages like easy in administration, compactness, and dosage precision and economical. As this much advantages the main and important part plays by the disintegrate in tablet. The release of the drug is totally depends on the disintegrants. Mostly in tablet formulation the starch is widely used as disintegrant with ideal properties like strong adhesiveness, thickening, strong gelling, swelling and foaming properties. As this much of ideal properties but some properties like poor flow, less compressibility and compability. In the present study pregelatinized starch was employed as a disintegrating agent in Diclofenac and Paracetamol tablet. The prepared starch were evaluated for angle of repose, bulk density, tapped density, Carr's compressibility index, Hausner's ratio. The prepared tablets were evaluated for thickness, drug content, weight variation, and friability and disintegration time and dissolution profile. Batches of tablets containing equivalent concentration of sodium starch glycolate were employed as standard. From this we concluded that as a disintegrant pregelatinized starch showed comparable results in Diclofenac and Paracetamol tablets with the standard.

Keywords: Diclofenac, Paracetamol, pregelatinized starch, sodium starch glycolate

INTRODUCTION

The most preferred route of administration is oral drug delivery among all the routes for the systemic delivery of drugs. The Excipients are the additives used to convert pharmacologically active compounds in to pharmaceutical dosage forms suitable for administration to patients.[1]

Among the excipients disintegrants are added because these are the agents added to tablet formulations to promote the break-up of the tablet into smaller fragments in an aqueous environment, thereby increasing the available surface area and promoting a more rapid release of the drug substance.[2] Native starches are widely used as binders and disintegrants in solid dosage forms.[3]Each starch is named according to its plant source, e.g. potato starch, maize starch, cassava starch, rice starch. Starch have the great affinity for water and swell when moistened, thus facilitating the rupture of the tablet structure and the release of the drug. [4]

Native starches possess the disadvantage that it is having is poor flow ability. Modifications on starches are carried out to enhance their physicochemical properties like viscosity, texture, stability, flow ability among many desired functional properties for many industrial applications.

Pregelatinized starch is the simplest starch modification, prepared by heating the slurry, roll drying, and spray drying or, extrusion process.[5] In the present study tablets were evaluated using pregelatinized starch as disintegrant for comparison tablets were also prepared employing sodium starch glycolate, a super disintegrants.

MATERIALS AND METHODS

Materials

Paracetamol, Diclofenac sodium were gift samples from obtained from pharmaceutical industries.

Sodium Starch Glycolate (Samar), Talc (Loba chemical pvt. Lim.), Magnesium stearate (Samar), Mannitol (Samar), Microcrystalline cellulose (Finar). Pregelatinised corn starch were used as tablet excipients and procured from commercial scale. All other sources were of Pharmacopoeial grade.

Methods

Preparation of pregelatinized starch;

A quantity of corn starch was weighed (50g) and 10 ml of purified water was added and placed over a boiling water-bath. It was continuously stirred and 30 ml of water was added again with continuous stirring. This process was continued until the starch was well prepared using 73 ml of

water in all. The paste was spread over a wide porcelain tile and dried in a hot air oven at 60^0c for 24h. The resulting pregelatinized starch was milled in a laboratory blender and sieved with mesh size 0.25 mm.[5]

Preparation of tablets

The various formulation of tablets are carried out by using the conventional direct compression method tablets of Diclofenac (100 mg) and Paracetamol (125 mg) were prepared mannitol as diluent, talc and magnesium stearate as lubricants microcrystalline cellulose as anti-sticking agent. Pregelatinized starch was included in the formulations as disintegrants. For comparison tablets were also prepared employing sodium starch glycolate (a super disintegrant) as disintegrant in the tablets. The mixtures were compressed into tablets on a tablet punching machine (Hicon).[6, 7]

Table 1: Formulation design of Tablet

INGREDIENTS	F1	F2	F3	F4
PARACETAMOL	-	-	125	125
DICLOFENAC SODIUM	50	50	-	-
PREGELATINIZED STARCH	-	10	-	10
SODIUM STARCH GLYCOLATE	10	-	10	-
MICROCRYSTALLINE CELLULOSE	125	125	30	30
TALC	5	5	5	5
MAGNESIUM STEARATE	6	6	6	6
MANNITOL	4	4	4	4
TOTAL WEIGHT (MG)	200	200	170	170

EVALUATION PARAMETERS

Evaluation of pre compression parameters:

The various pre compression parameters of prepared granules were estimated by determine the angle of repose, cars index, Hausner's ratio etc. by using the following method.

Angle of Repose

The angle of repose of granules was determined by the funnel method. The accurately weight granules were taken in the funnel. The granules were allowed to flow through the funnel freely on to the surface. The diameter of the granules cone was measured and angle of repose was calculated using the following equation:

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

Where, θ = angle of repose, h = height of the cone, and r = radius of the cone base

Bulk Density

Bulk density (Db) was determined by measuring the volume (Vb) of known weighed quantity (W) of granules using bulk density apparatus and can be calculated by using the formula:

$Db = W/Vb$

Tapped Density

Tapped density (Dt) was determined by measuring the volume (Vt) of known weighed quantity (W) of granules and can be calculated by using the formula:

$Dt = W/Vt$

Hausner's ratio

The Hausner's ratio was determined using the following relationship

Hausner's ratio = Dt/Db

Where,

Dt is the tapped density and Db is the bulk density.

Carr's Index

The Carr's index (% compressibility) was determined using the following relationship

Carr's Index (%) = $(Dt - Db \div Dt) \times 100$

Where,

Dt is the tapped density and Db is the bulk density.

Evaluation of Tablets

Thickness

The thickness of the tablets was determined by Vernier calipers. Five tablets from each batches were used and the average values were calculated.

Drug content

From each batch of tablets prepared, five tablets were accurately weighed and powdered. Tablet powder equivalent to 20 mg of drug was taken for assay into a 100 ml conical flask and extracted with 3:10 ml quantities of methanol. The methanolic extracts were filtered and collected into a 50 ml volumetric flask and the volume was made up to 50ml with methanol. The solution was then suitably diluted with phosphate buffer of pH 7.8 in the case of Paracetamol and with phosphate buffer of pH 6.8 in the case of Diclofenac sodium. The absorbance of the solutions was measured at 249 nm for Paracetamol and at 276 nm for Diclofenac

sodium. Drug content of the tablets was calculated using the standard calibration curve in each case.

Weight variation

The weight variation test of the tablets was performed as per I.P. twenty tablets of each type were weighed using an electronic balance (Wensar) and average weights were calculated.

Weight variation = (Wavg -Winitial / Wavg) × 100

Where,

W avg= Average weight of tablet, W initial= Individual weight of tablet

Table 2: Weight Variation

Average weight of tablets(IP)	Average weight of tablets(USP)	Maximum % difference allowed
Less than 80mg	Less than 130mg	10
80mg-250mg	130mg-324mg	7.5
More than 250mg	More than 324mg	5

Hardness

Pfizer hardness tester was used for measuring the hardness of the formulated tablets. From each batch five tablets were taken at random and subjected to test.

Friability

Friability was measured by the help of Roche friabilator (Hicon). 10 tablets were taken and their weight determined. Then they were placed in the friabilator and allowed to make 100 revolutions at 25rpm. The tablets were then dusted and reweighed. The percentage weight loss was calculated by using the following formula.

$F = (Wo - W \div Wo) \times 100$

Where,

Wo = Weight of tablets before friability

W = Weight of tablets after friability

Disintegration

Six tablets were taken in disintegration apparatus (Singhla). Six glass tubes that are 3 inches long open at the top and held against a 10 mesh screen at the bottom end of the basket rack assembly. To test the disintegration time one tablet was placed in each tube, and the basket rack was positioned in a 1litre beaker of water at $37^0C \pm 20^0C$ such that the tablets remain2.5 cm from the bottom of the beaker. A standard motor driver device was used to move the basket assembly up and down through a distance of 5-6cm at a frequency of 28-32 cycles per minute.

Dissolution

In-vitro dissolution studies of the tablets were carried out in USP dissolution apparatus type II (Hicon) by employing a paddle stirrer at 50 rpm using 900 ml of pH 6.8 phosphate buffer at 37 ± 0.5^0C as a dissolution medium. One tablet was used in each test. Aliquots of 5 ml each were withdrawn at specified time intervals (5, 10, 15, 20, 30, 45 and 60) and replaced with equal volume of fresh medium. The withdrawn aliquots were analyzed for drug content spectrophotometrically at λmax 275nm and 257nm in UV spectrophotometer (Wensar). Drug concentration was calculated and expressed as cumulative percent of the drug released.

RESULT AND DISCUSSION

The formulations were designed using optimum quantities of carefully selected excipients based on experience and the as found in the literatures. The table no. 1 shows the complete composition which is used for the formulation composition of tablet formulations. In this study we used the Diclofenac sodium and Paracetamol powder are for the formulation. Apart from this the excipients like Micro crystalline cellulose, lactose, talc and magnesium stearate were used for formulations. Sodium starch glycolate was used as a standard super disintegrant, whereas pregelatinized starch is also used as test disintegrant.

Flow properties of formulated tablet

All the powder mixture belonging to different formulations were tested for micrometrics studies in order to determine the flow properties. All the powder mixture showed good flow with formulations represented in Table No:

Table 3: Precompression evaluation

Formulations	Angle of Repose (0)	Bulk density(g/cc)	Tapped density(g/cc)	Hausner's ratio	Carr's index
F1	23.76	0.42	0.63	1.34	16.34
F2	25.89	0.45	0.61	1.37	14.89
F3	30.14	0.53	0.56	1.28	18.97
F4	29.18	0.57	0.53	1.22	17.85

Evaluation of physical parameters

The physical properties of all the tablets are within the limits and hardness range in between. The assay result showed the percentage of drug. The results are given in following table 4.

Table 4: Physical Parameters Evaluation

SNO	Tests	F1	F2	F3	F4
1	PHYSICAL APPERANCES a) Colour b) Surface texture c) Shape d) Cracks	White Smooth Flat Absent	White Smooth Flat Absent	White Smooth Flat Absent	White Smooth Flat Absent
2	Weight variation test	202±0.49	198±1.53	170±.59	169.17±0.43
3	Hardness (kg/cm^2)	4.49	3.99	5.10	5.17
4	Friability (%)	0.431	0.720	0.790	1.09
5	Thickness (mm)	3.422	3.43	2.77	3.37
6	Disintegration test (sec)	75	73	67	62
7	Assay (%)	100.10	100.07	99.47	100.35

In Vitro Dissolution Studies of Different Formulations

The formulations F1 to F4 were tested for the *in-vitro* dissolution studies the F1 formulation shows 79.79 % of drug release while the f2 shows the 80.88% of drug release. Apart from this while we compared the formulation F3 shows the 77.41% of drug release and the F4 shows the 81.11% of drug release with in the one hour. Form this it is concluded that the formulations which contains the pregelatinized starch showed the excellent drug release as compared to the formulation contain the sodium starch glycolate. The result obtained are shown in Table no 5.

Table 5: In-Vitro Dissolution Studies of Different Formulations

SN	TIME Min.	F1(Diclofenac + Sodium Starch Glycolate)	F2(Diclofenac + Pregelatinized starch)	F3(Paracetamol + Sodium Starch Glycolate)	F4(Paracetamol + Pregelatinized starch)
1.	5	18.32 ±0.5	20.30 ±1.05	20.22 ±1.32	26.14 ±0.63
2.	10	30.40 ±1.09	33.84 ±0.51	24.74 ±1.05	33.01 ±0.85
3.	15	38.52 ±0.3	40.42 ±0.63	38.01 ±0.33	45.88 ±0.38
4.	20	42.86 ±1.10	53.11 ±0.78	42.89 ±0.94	57.18 ±0.78
5.	30	60.12 ±0.9	65.89 ±0.45	59.80 ±0.55	62.36 ±0.45
6.	45	70.23 ±0.2	77.04 ±0.98	65.33 ±1.21	71.04 ±0.12
7.	60	79.79 ±0.27	80.88 ± 0.45	77.41 ±0.31	81.11 ±1.1

All values are the mean of three readings ± SD

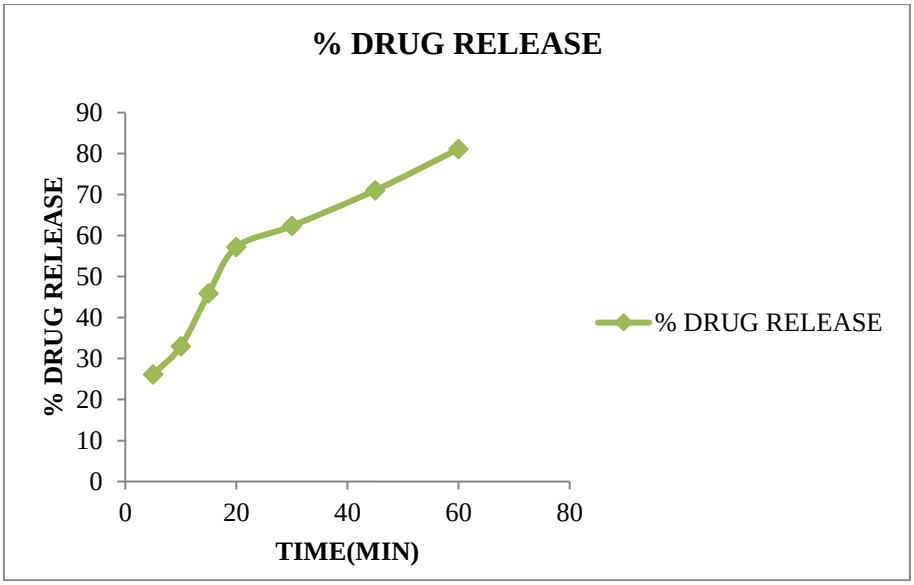

Fig. 1: Dissolution profile of Diclofenac tablet incorporating Sodium Starch Glycolate as disintegrant

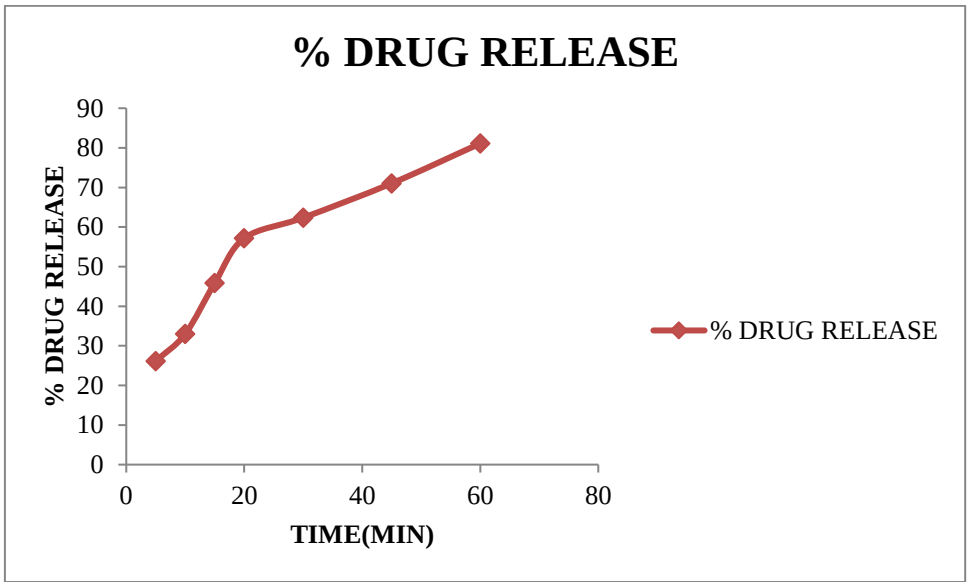

Fig. 2: Dissolution profile of Diclofenac tablet incorporating Pregelatinized Starch as disintegrant

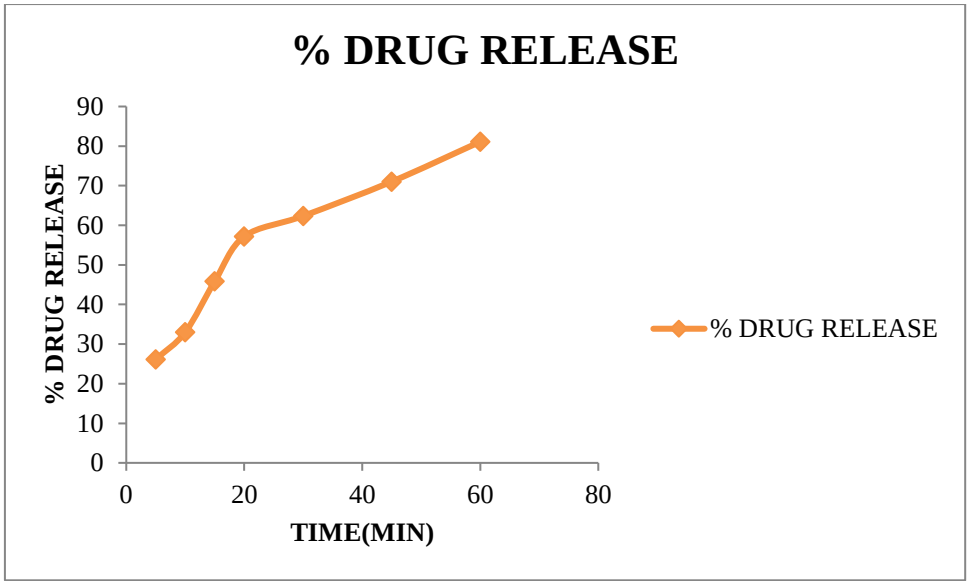

Fig.3: Dissolution profile of Paracetamol tablet incorporating Sodium Starch Glycolate as disintegrant

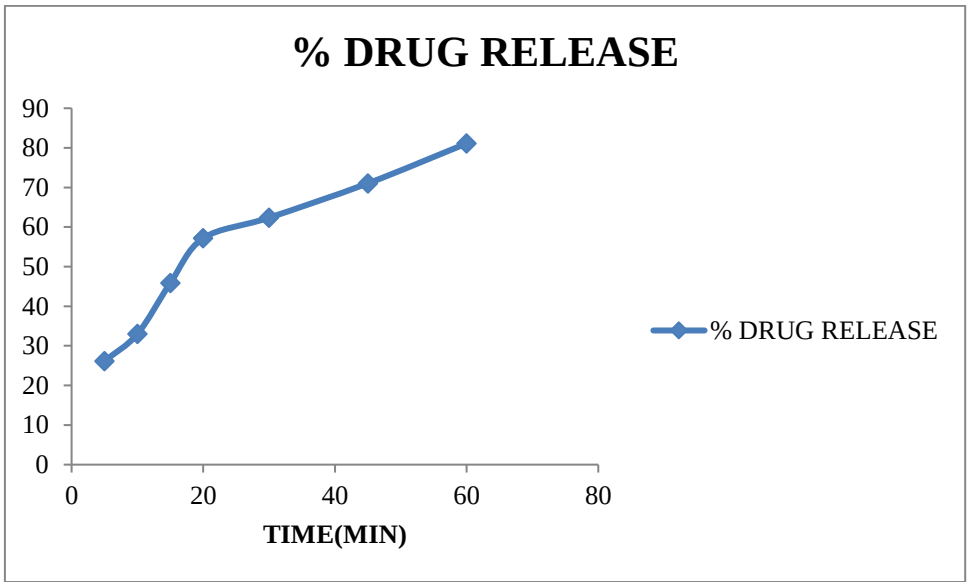

Fig. 4: Dissolution profile of Paracetamol tablet incorporating Pregelatinized Starch as disintegrant

As per the data obtained by various formulated formulation evaluation it concluded that, the values of the Hausner's ratio and Carr's index obtained in this study showed that the Paracetamol and Diclofenac powder mixture possessed good flow ability. However, Angle of repose of Paracetamol and Diclofenac powder mixture do not exceed >30.14, confirms the good flow ability of the powder mixture.

The prepared tablets were evaluated for post compression parameters such as weight variation, hardness, friability, disintegration, and in vitro release characteristics. Weight variation among all tablets related to Diclofenac tablet ranged between 196 (±0.49) mg to 203 (±2.48) mg and for Paracetamol it ranged from 168 (±0.58) mg to 173 (±2.33) mg. Hardness values, which were obtained within limits ranged from 3.42 to 4.82 in case of Diclofenac and 4.34 to 5.84 in case for Paracetamol. Friability for Diclofenac and Paracetamol was found not to be exceeded >1.09. Similarly, the disintegration time which reveal the actual result of the experiment showed that the disintegration time in Diclofenac tablet containing pregelatinized starch was found to be not >80 sec and for Paracetamol tablet disintegration time was found to be not >68 sec this proves that pregelatinized starch is equal as effective as a disintegrant compare with the superdisintegrant i.e. Sodium Starch Glycolate. Maximum drug release in one hour was found to be 80.88% in case of Diclofenac tablet, which is greater than the

release of drug interference batch (approximately 79.79%) and for Paracetamol the release of drug in one hour was found to be 81.11% which is greater than reference batch (approximately 77.41%).

CONCLUSION

In present study the disintegrating properties of pregelatinized starch had been studied in comparison with commercially available sodium starch glycolate. Comparative evaluation studies proved that the modified starches exhibit similar disintegration and dissolution properties like sodium starch glycolate. Hence the pregelatinized starch can be as an alternative disintegrant in tablet formulation. They can be used when faster disintegration is desired and can be an economical and better choice for commercial uses.

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