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Research Article

Development and Characterization of a Composite "Extra-Superdisintegrant" from Sodium Starch Glycolate and Croscarmellose Sodium and its Evaluation in Rapid Disintegrating Ciprofloxacin Tablets

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ABSTRACT

Orally disintegrating/ rapid dissolving tablets are an emerging trend in novel drug delivery system. This can be attained by addition of different excipients, from which disintegrant is the key adjuvant. In the present work, an attempt has been made to develop rapid disintegrating tablets of Ciprofloxacin by fabricating an extra-superdisintegrant and incorporates as a tablet buster. A solvent evaporation method of co processing was used to form a composite extra-super disintegrant from sodium starch glycolate and croscarmellose sodium. Blend of all the formulations showed good flow properties such as angle of repose, bulk density, tapped density. All the formulations were prepared by direct compression method using 8mm punch on single station Carver hydraulic press and evaluated for tablet properties. The co-processed extra-superdisintegrants were also characterized by FTIR Studies. There was no chemical interaction between drug and excipients. The in-vitro disintegration times (DT) of rapid dissolving tablets were found to be 3.03±0.06 to 20.0±2.0seconds. The composite extra superdisintegrant "CSD5" produced RDT "CT_{CSD5}" with crushing strength of 9.40 $\pm$ 0.62, DT of 3.40 $\pm$ 0.06 seconds, this could be a promising approach to enhance tablet breakdown, with subsequent increase in drug dissolution and improved bioavailability. The novel extra-superdisintegrant showed significant reduction in DT when compared with the primary composite ($P<0.05$). The designed and engineering of the novel extra-super disintegrant was excellent, and the utilization in the formulation of rapid disintegrating tablet was a success.

INTRODUCTION

In the recent time, tablet disintegration has received extensive consideration as a basic advance in attainment of quicker medication discharge. Medication discharge from a solid dosage compact can be improved by development of a highly functional disintegrants. In more recent years, attention has been given to formulating orally disintegrating tablets that are intended to disintegrate as well as dissolve quickly in the mouth.

An ideal disintegrant should have poor solubility, poor gel formation, good hydration capacity, excellent compressibility, good flow properties and no tendency to form complexes with the drugs [1].

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For many solid dosage forms, drug dissolution is preceded by disintegration. Therefore, to enhance the rate and extent of tablet breakdown, with subsequent increase in drug dissolution "super-disintegrate" such as croscarmellose sodium, sodium starch glycolate, and crospovidone amongst others are now commonly implored in tablet formulation. As a first-line alternative to conventional tablets and capsules, rapid disintegrating tablets (RDTs) have received significant attention owing to improved patient compliance [2].

RDTs are defined by United State Food and Drug Administration (FDA) as "solid dosage forms containing medicinal substances which disintegrate rapidly, usually in a matter of seconds, when placed on the tongue" [3]. These dosage forms could be of advantage in certain patients who experience issues in gulping (dysphagia) such as pediatric, geriatric,

bedridden and psychiatric patients [4]. Travelers who do not access water can likewise benefit from this formulation.

Co-processing is based on the novel concept of two or more excipients interacting at the sub-particle level, with the aim of providing a synergy of functionality improvement and masking the undesirable properties of individuals with added values related to their functionality / price ratio [5].

In the present research, Consideration will be on the fabrication and assessment of rapidly disintegrating ciprofloxacin tablets using co-processed superdisintegrants (extra-superdisintegrant) comprising sodium starch glycolate and croscamellose sodium. The study is aimed at fabricating a multifunctional excipient with synergy of functionality improvement and to expedite rapid disintegration of tablets and subsequent dissolution of active pharmaceutical ingredient to elicit rapid onset as well as. The motive for choice of croscarmellose sodium are rapid swelling, pronounced hydration capacity and wicking upon contact with water, sodium starch glycolate was selected because of its high swelling capacity. The concept of fabricating orodispersible tablets utilizing co-processed superdisintegrants which enhance the water uptake with shortest wetting time and along these lines decline the breakup time of the tablets by simple and cost-effective direct compression technique will be evaluated.

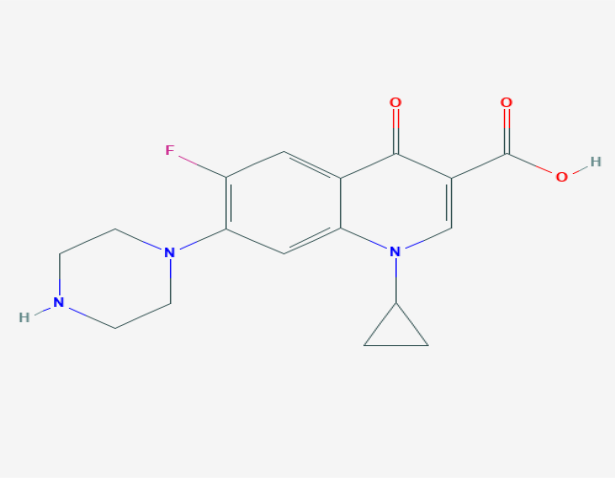

Figure 1: Structure of Ciprofloxacin

Ciprofloxacin a prevalent second-generation fluoroquinolone was chosen for its broad spectrum of activity and diverse therapeutic prospects. It's a mainstay in treatment of serious bacterial infection and depicts several favorable properties such as excellent bioavailability, good tissue penetrability, and a relatively low incidence of adverse and toxic effects. These drugs are possibly used in the treatment of urinary tract infection, prostatitis etc., [6].

MATERIALS AND METHODOLOGY

Materials

Chemicals and Reagents

Ciprofloxacin powder (Shanghai Macklin Biochemicals Co. Ltd China), Sodium starch glycolate (Shanghai Macklin Biochemicals Co. Ltd China), Croscarmellose sodium (Yuhao Chemicals Co. Ltd China), isopropyl alcohol (Merck KGaA, EMD Corporation Germany), Cellactose (Molkerei MEGGLE Wasserburg GmbH & Co.KG), Distilled water (Department of Pharmaceutical Chemistry, Unilorin.)

Method

Preparation and Evaluation of Co-processed Superdisintegrant

Kneading Technique of Solid Dispersion

The kneading technique of solid dispersion was adopted for co-processing superdisintegrants as proposed by Gohel *et al.*, [7]. This involves the preparation of physical mixture of the two primary super disintegrate. A small volume of isopropanol solution was added to the mixture in a clean mortar to form a wet mass/paste. The content of the mortar was kneaded by adding sufficient solvent at three kneading times of 5,8 and 10 min till most of isopropyl alcohol evaporated. The wet coherent mass was granulated through 1.18mm-mesh sieve. The wet granules were dried on a stainless-steel tray at room temperature for 48h. The dried granules were sifted on 710µm-mesh sieve and stored in airtight container till further use.

Table 1: Formula Ratio for Co-processing of Two Super-disintegrate

Batch	Ratio(SSG:CCS)	SSG(g)	CCS(g)
CSD1	1:5	2.5	12.5
CSD2	1:3	3.75	11.25
CSD3	1:2	5.0	10.0
CsD4	1:1	7.5	7.5
CSD5	5:1	12.5	2.5
CSD6	3:1	11.25	3.75
CSD7	2:1	10.0	5.0

SSG (Sodium Starch Glycolate); CCS (Croscarmellose sodium)

Physical and Direct Mixture Method
Direct physical mixtures of the two super-disintegrate were prepared by mixing accurate weight of sodium starch glycolate with croscarmellose sodium. These were evaluated in ciprofloxacin tablets and compared with the co-processed composite binary disintegrate.

Formulation of Ciprofloxacin 100mg Tablet
The fast disintegrating tablets of ciprofloxacin were prepared by direct compression method. All ingredients (except cellactose) were passed through # 50-mesh individually before mixing. The ingredients were weighed and mix in geometrical order, and compressed into tablets weight of 370mg using compression load of 1.5MT, on a carval hydraulicpress machine (Erweka).

Characterization and Evaluation
Preformulation Analysis
Angle of Repose
Angle of repose was determined by using funnel method. The accurately weighed blend is taken in a funnel. The height (h) of the funnel was adjusted in such a way that the tip of the funnel just touches the apex of the heap of blend. The drug-excipient blend was allowed to flow through the funnel freely on to the surface. The diameter (d) of the powder cone was measured and angle of repose was calculated using the following equation.

$\tan \Theta = h/r$

Where, Θ is the angle of repose, h and 'r' are height and radius of cone respectively.

Bulk Density
Apparent bulk density was determined by pouring a weighed quantity of blend into graduated cylinder and measuring the volume and weight. Bulk density was calculated by using the following formula:

Bulk density = Weight of the powder/Volume of the packing

Tapped Density
Tapped density was determined by transferring a known mass of drug-excipient blend into graduated cylinder. The cylinder was allowed to fall under its own weight onto a hard surface from a height of 10 cm at 2 second intervals. The tapping was continued until no further change in volume was noted. Tapped density was calculated by using the following formula:

Tapped density = Weight of the powder/Volume of the tapped packing

Compressibility Index
The compressibility index of the blends was determined by calculation using the following formula:

Compressibility Index (%) = [(TD – BD) x 100/TD]

Table 2: Composition of various Ciprofloxacin Rapid Disintegrating Tablets

	CROPROCESSED_TABLET_BUSTER									
	BATCHES 1-7								CONTROL	
INCREDIENTS		**1**	**2**	**3**	**4**	**5**	**6**	**7**	**A**	**B**
	%	**mg**	**mg**	**mg**	**mg**	**mg**	**mg**	**mg**	**mg**	**mg**
Ciprofloxacin	28.5	100	100	100	100	100	100	100	100	100
Cellactose	63.5	240	240	240	240	224	240	240	240	240
Tablet Buster	8.0	30	—	—	—	—	—	—	—	—
CSD 1										
CSD 2		—	30	—	—	—	—	—	—	—
CSD 3		—	—	30	—	—	—	—	—	—
CSD 4		—	—	—	30	—	—	—	—	—
CSD 5		—	—	—	—	30	—	—	—	—
CSD 6		—	—	—	—	—	30	—	—	—
CSD 7		—	—	—	—	—	—	30	—	—
SSG		—	—	—	—	—	—	—	30	—
CCS		—	—	—	—	—		—	—	30
TOTAL WEIGHT	100	370	370	370	370	370	370	370	370	370

CSD (Composite Superdisintegrant)

Hausner's Ratio
Hausner's ratio also indicates the flow properties of powder/granules. This can be calculated by using the following formula:

Hausner's ratio = (Tapped density x 100) / (pour density)

Fourier Transform Infrared Spectroscopic Studies
IR spectroscopy was performed using FT-IR Spectrophotometer to find the possibility (if any) of chemical interaction between sodium starch glycolate and croscarmellose sodium during co-processing, ciprofloxacin and the composite extra superdisintegrant. Solid admixtures were prepared by mixing the drug with each formulation excipient separately in the ratio of 1:1 and stored in airtight containers at 40^0C/75%RH and 60^0C/75%RH. The solid admixtures were characterized by using Fourier transform infrared spectroscopy (FT-IR).

Surface Microscopy
The surface morphology of the composite superdisintegrant and the blended ciprofloxacin granules was also examined using an optical microscope at magnification of 40 (Douroumis *et al.*, [8].

Evaluation of Tablets
All the formulated FDTs were subjected to the following quality control tests:

Weight Variation
The weight variation test was carried out in order to ensure uniformity in the weight of tablets in a batch. First, the total weight of 20 tablets from each formulation was determined and the average was calculated. The individual weight of each tablet was also determined. The deviation of each tablet from the mean, were calculated, and the USP maximum % difference allowed (5 %) for tablets average weight greater than 324 mg was applied.

Hardness
The hardness of tablet is an indication of its strength. It is measured as the crushing strength, i.e., the force required to break the tablet across its diameter. The force is measured in kg and the hardness of 3 -6 kg/cm^2 is considered to be satisfactory for uncoated tablets. Crushing strength of ten (10) tablets from each batch was determined by Monsanto hardness tester.

Friability Test
Friability test was carried out to access the ability of the tablet to withstand abrasion in packaging, handling and transport. Roche friabilator was employed to determine the friability of the tablet samples from each batch of the formulations. Twenty (20) tablets from each were weighed and transferred into the friabilator. The rotation was set at 25 rpm for 4 minute, after which the tablets were removed collectively, dedusted and weighed. The percentage lost in weight, i.e., friability, was calculated using the formula:

$\%\ \text{Friability} = [(W_1 - W_2) \times 100] / W_1$

Where, W_1 is the weight of tablets before the test; W_2 is the weight of the tablets after the test.

Wetting Time
A 6ml of distilled water containing acridine orange (a water-soluble dye was placed in a petri dish of 10 cm diameter.A piece of tissue paper folded twice was placed in the petri dish. Tablets were carefully placed in the centre of the petri dish and the time required for water to reach the upper surface of the tablet was noted as the wetting time. The test results are presented as mean value of three determinations.

Drug Content Uniformity
Standard Preparation
An accurately weighed amount of pure Ciprofloxacin (100mg) was transferred into 100mLvolumetric flask. It was dissolved and made up to volume with phosphate buffer of PH-6.8 to get 1g/mL or 100ug/mL concentration of the standard stock solution. Various working concentrations (10, 5, 2.5, 1.25ug/mL) were made by further dilution with the same medium and absorbance was measured at 275nm. A standard calibration curve was first established to quantify the drug.

Sample Preparation
Three tablets were weighed individually then placed in a mortar and powdered with a pestle. A 100 mg powdered ciprofloxacin were transferred into buffer solution. The solution was filtered through 0.45µm membrane and absorbance was measured at 275nm after suitable dilution.

Calculation
The amount of ciprofloxacin present in tablet can be calculated using the formula:

AT/AS x SW/100 x 100/St x AV

Where,
AT = Absorbance of sample preparation
AS=Absorbance of standard preparation
SW=Weight of ciprofloxacin working standard (mg)
St =Weight of ciprofloxacin tablet (mg)
AV=Average weight of tablet (mg)

Disintegration

The disintegration times of the tablets were determined in distilled water at 37± 0.5 ^{0}C using the Apex disintegration testing apparatus. Four tablets from each batch were employed for this evaluation. One tablet was placed in each tube and the Basket rack positioned in a 1L beaker of distilled water at 37±0.5 ^{0}C in a manner that the tablet remained 2.5 cm below the surface of liquid on their upward movement and not closer than 2.5 cm from the bottom of the beaker in their downward movement. The basket containing the tablets was then operated at a rate of 30 cycles per Minute. Then the disintegration time for each formulation was determined.

Dissolution

The USP, 2000 dissolution apparatus basket method was adopted. Six tablets were taken for the study of dissolution pattern of the tablets. A 900 ml of the 0.1 N HCL solutions was used as the dissolution medium. The revolution of the basket was maintained at 50 rpm and the temperature of the medium was set at 37$\pm$0.5^{o}C. The dissolution was carried for a period of one hour. After the desired time, 10 mL solution was collected and filtered. The amount of drug dissolved was determined by UV spectrophotometric analysis of the filtrate.

RESULTS

Evaluation of Precompression Characteristics

Particle Morphology

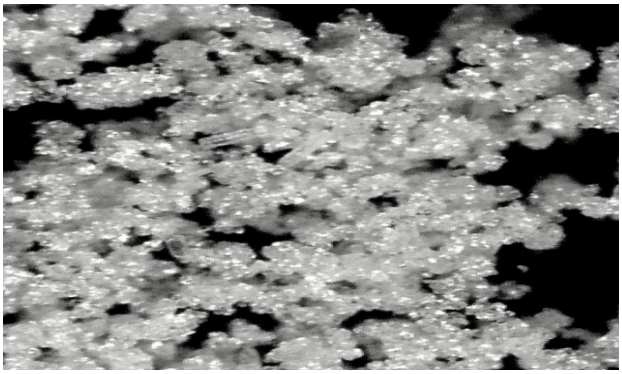

Figure 2: SEM -Sodium Starch Glycolate

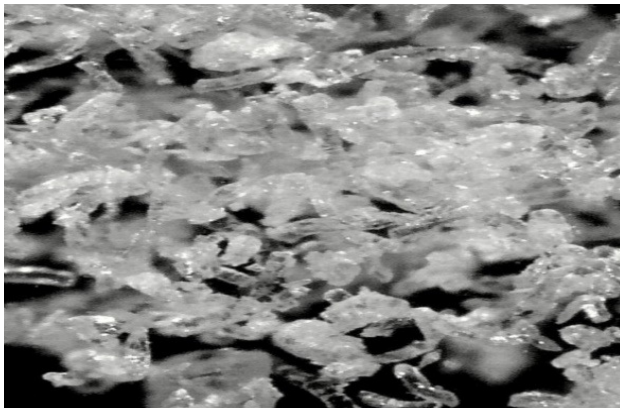

Figure 3: SEM -Croscarmellose Sodium

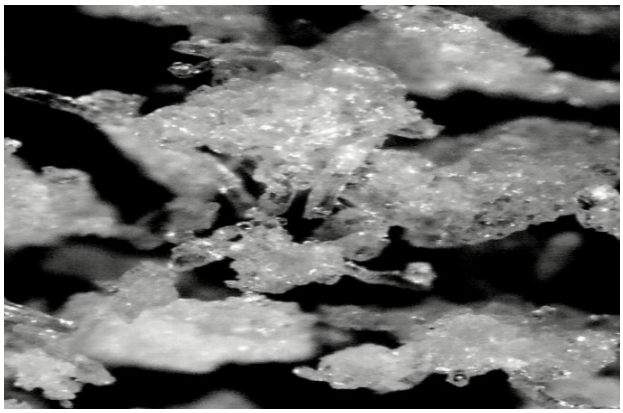

Figure 4: SEM -Co-processed Excipient (CSD1).

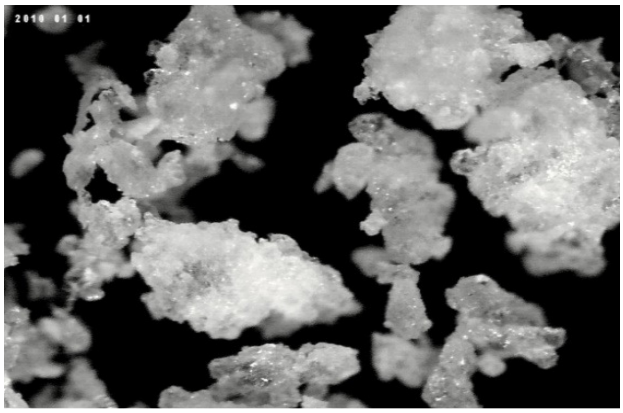

Figure 5: SEM- Co-processed Excipient (CSD4)

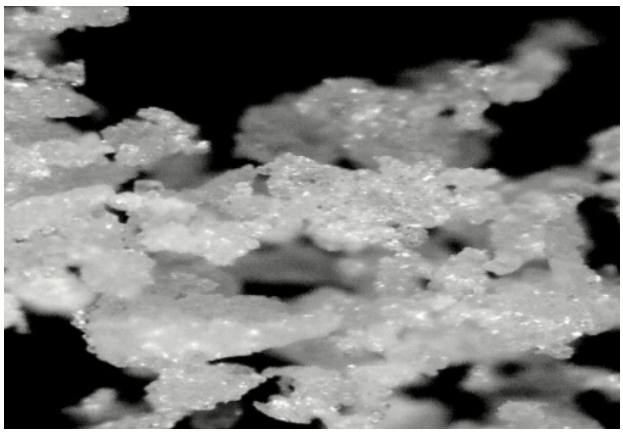

Figure 6: SEM- Co-processed Excipient (CSD5).

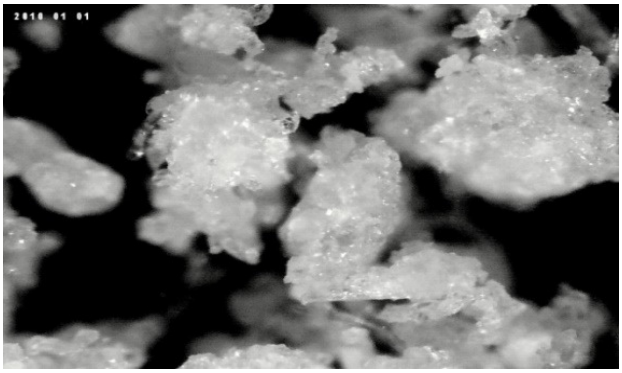

Figure 7: SEM –Co-processed Excipient (CSD3)

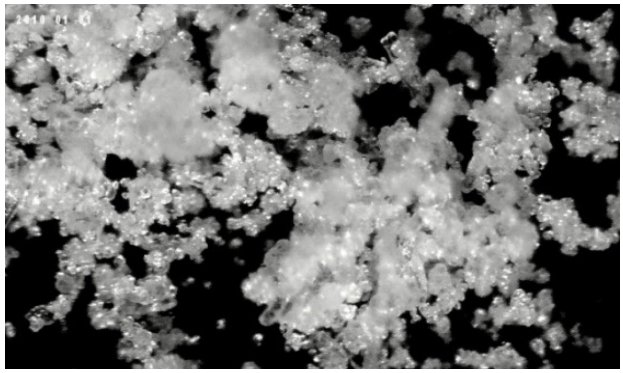

Figure 8: SEM- Physical mixture excipient (CSD2)

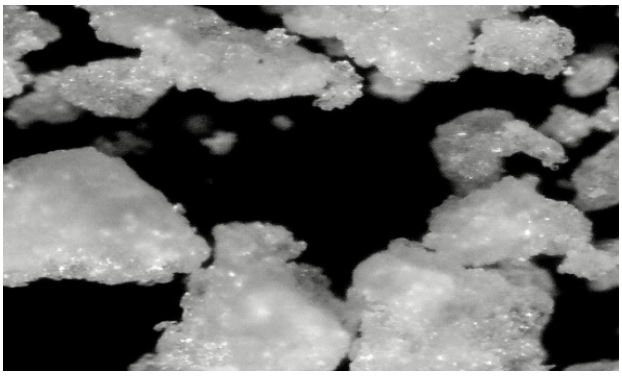

Figure 9: SEM- Co-processed excipient (CSD7)

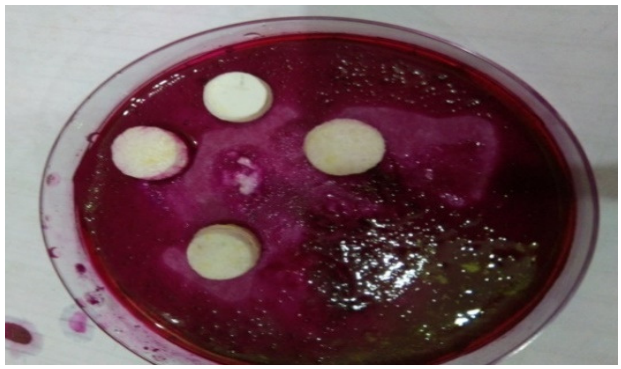

Figure 10: Pictorial representation batches of ciprofloxacin RDTs.

Figure 11: Pictorial representation of tablet water absorption ratio and wetting time.

Table 3: Evaluation of pre compression characteristics

BATCHES (SSG:CCS)	Flow rates (sec^1) ±SD, n=3	Angle of repose (Ø) ±SD, n=3	Bulk density (gm/cm^3) ±SD, n=3	Tapped density (gm/cm^3) ±SD, n=3	Carr's index (%) ±SD, n=3	Hausner's index ±SD, n=3
CSD_1 [1:5]	3.36±0.06	23.17±1.65	0.45±0.01	0.69±0.03	39.6±3.66	1.50±0.10
CSD_2 [1:3]	4.81±0.51	25.47±0.76	0.43±0.02	0.72±0.00	33.9±2.40	1.48±0.12
CSD_3 [1:2]	3.14±0.19	24.17±1.00	0.47±0.02	0.69±0.05	31.9±5.50	1.57±0.07
CSD_4 [1:1]	3.60±0.39	24.13±2.78	0.45±0.01	0.69±0.02	36.9±3.34	1.70±0.03
CSD_5 [5:1]	3.66±0.26	25.77±1.86	0.47±0.02	0.72±0.05	34.8±1.55	1.53±0.04
CSD_6 [3:1]	2.46±0.13	24.43±0.64	0.43±0.02	0.73±0.03	41.3±1.99	1.64±0.11
CSD_7 [2:1]	2.41±0.17	22.70±1.71	0.46±0.01	0.70±0.03	34.3±0.89	1.52±0.02
STD(SSG)	3.34±0.41	24.97±0.81	0.45±0.01	0.72±0.05	38.4±2.95	1.63±0.08
STD(CCS)	3.43±0.13	24.30±2.01	0.45±0.02	0.69±0.03	34.3±0.87	1.53±0.03

SD: standard deviation for n=3 observations, CSD: composite super-disintegrants, STD:standards, SSG: sodium starch glycolate, CCS: Crosscarmellose sodium.

Drug-Excipient Interaction Study (FT-IR) Study

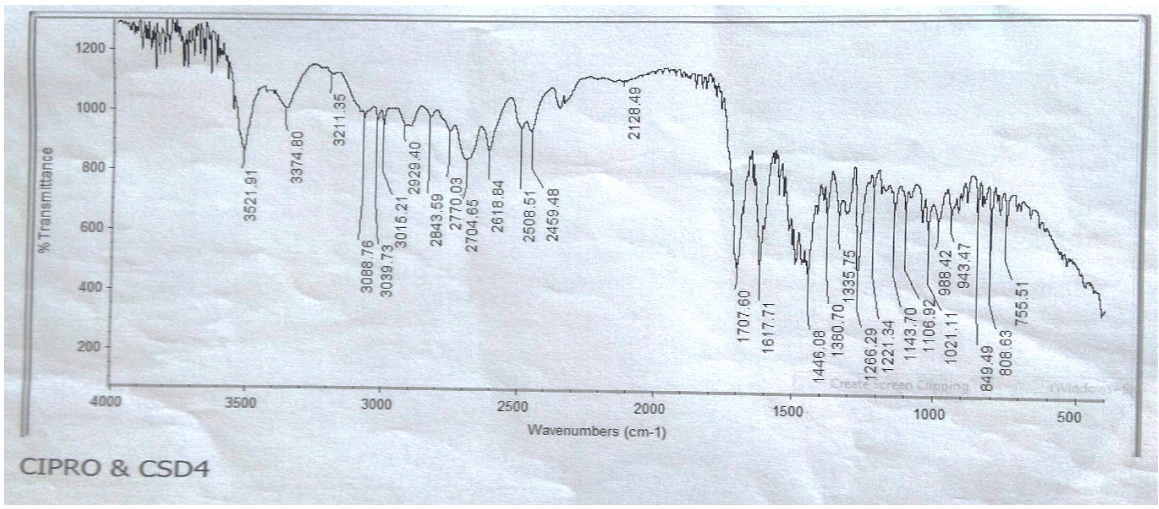

Figure 12: FTIR Analysis of Ciprofloxacin + Composite Super Disintegrant (CSD4)

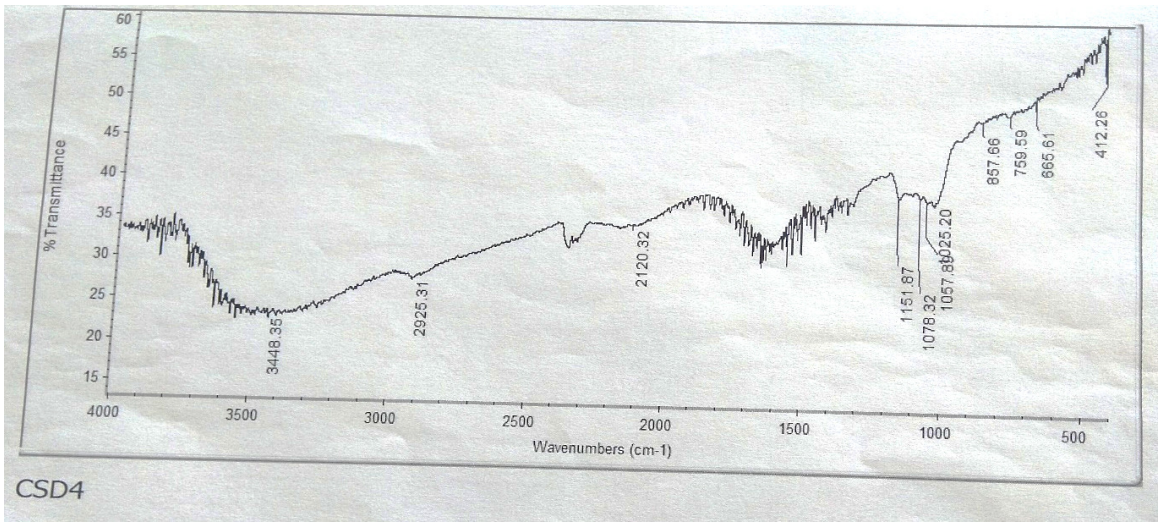

Figure 13: FTIR Analysis of Composite Super Disintegrant (Sodium starch glycolate and croscarmellose sodium) CSD4 (1:1)

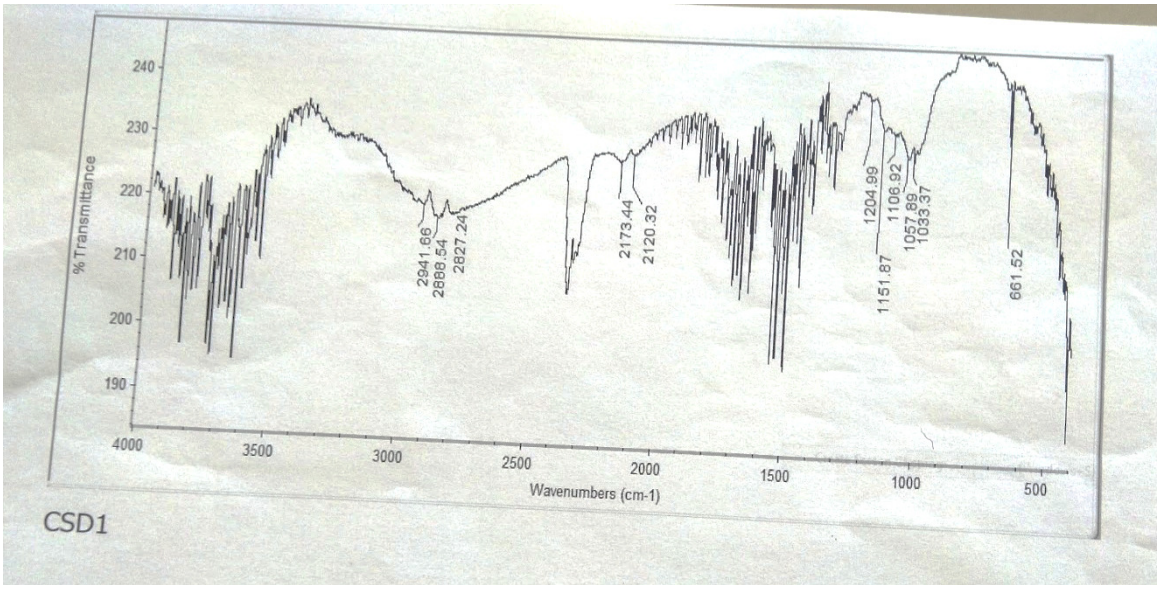

Figure 14: FTIR Analysis of Sodium starch glycolate (SSG+CCS [1:5])

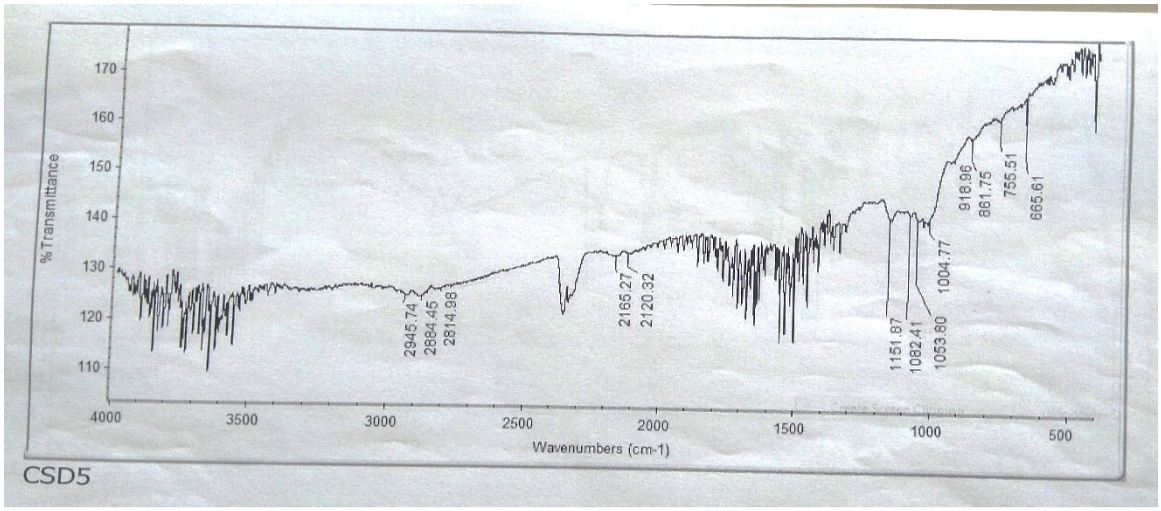

Figure 15: FTIR Analysis of sodium starch glycolate and croscarmellose sodium composite (5:1)

Table 4: Physicochemical parameters of ciprofloxacin tablet.

Batch	Weight variation (mg) ±SD, n=3	Diameter (mm) ±SD, n=3	Thickness (mm) ±SD, n=3	Hardness (kg/cm²) ±SD, n=3	Friability (%) n=10	Wetting time (sec) ±SD, n=3	Disintegration time (sec) ±SD, n=3	Content uniformity (mg)
CT_{CSD1}	373±5.77	11.03±0.02	3.19±0.09	12.90±1.83	0.30	12.33±1.40	10.47±0.42	98.7 %
CT_{CSD2}	363±5.77	11.14±0.36	3.24±0.03	10.77±0.50	0.41	12.50±0.11	10.93±0.12	96.5 %
CT_{CSD3}	356±5.17	11.16±0.07	3.07±0.25	9.20±1.65	0.82	8.00±2.19	6.21±0.18	94.5 %
CT_{CSD4}	370±0.00	10.92±0.16	3.29±0.10	7.80±1.05	0.74	9.40±2.93	7.33±0.22	98.1 %
CT_{CSD5}	376±5.77	10.86±0.13	3.28±0.04	9.40±0.62	0.50	6.67±2. 01	3.40±0.06	99.5 %
CT_{CSD6}	376±5.77	11.07±0.02	3.46±0.04	6.43±1.03	0.74	9.00±1.47	8.00±2.0	99.0 %
CT_{CSD7}	373±5.77	10.82±0.09	3.42±0.11	4.27±0.47	0.75	6.33±3.53	5.33±0.58	98.8 %
SSG	**370±0.00**	**10.93±0.05**	**3.44±0.01**	**5.43±0.21**	**0.49**	**13.67±0.55**	**15.67±4.04**	**98.9 %**
CCS	**380±0.00**	**10.93±0.01**	**3.45±0.14**	**7.20±0.10**	**1.20**	**78.45±0.02**	**260.0±0.90**	**99.8 %**

Coprocessed (SSG) plus (CCS) Cipro Tablets containing CSD ($CT_{CSD\ 1\text{-}5}$)

DISCUSSION

Particle Morphology

From studies on the surface morphology of pure sodium starch glycolate powder, croscarmellose sodium powder, composite excipients (CSD1, CSD4, CSD5, CSD3, CSD7) and their corresponding physical mixtures, it was observed from the image that the modified starch (Croscarmellose sodium) was seen to be crystalline in nature (Fig. 3). While sodium starch glycolate is irregularly crystalline with smooth surfaces (Fig. 2). The crystalline nature of the two modified starches varies due to the differences in their cross linkages (ester and ether respectively). Morphology of the co-processed excipients in various proportion shows a more profound crystalline particle embedded in the clumped compact ether linked starches (Fig. 4 – 9).

The values for angle of repose were found in the range of 23°-27°. Bulk densities and tapped densities of various formulations were found to be in the range of 0.43±0.02 to 0.47±0.02 (g/cm^3) and 0.69±0.02 to0.73±0.03 (gm/cm^3) respectively. The compressibility indexes were in the range of 31.9±5.50% to 41.3±1.99%. The Hausner's ratios are in the range of 1.48±0.12 to 1.70±0.03. The results showed that the powder blends had good flow properties and these can be used for tablet manufacture.

The hardness of RDT in this study was relatively higher with blends containing CCS than blends with SSG as disintegrant. The tablet hardness of blend containing CSD1 is 12.90±1.83 kgf, while that of CSD5 is 9.40± 0.62 kgf. The former consist of SSG:CCS in ratio 1:5 while the latter contains SSG:CCS in ratio 5:1. It is clear from the figure above that, formulations CSD1 – CSD5 are harder and more compact than formulations CSD6 – CSD7. The reason is due to the contributing effect of the co-processed disintegrant on tablet hardness so that, the former sets of formulations

contained the composite superdisintegrate with more of CCS than SSG while the latter sets of formulations contained more of SSG than CCS. This study found that there is correlation between the composite superdisintegrants used with tablet hardness obtained. This finding could be attributed to fact that, CCS is modified cellulose termed carboxymethyl cellulose cross-linked polymer. They also vary in the synthetic procedures used to modify the polymer apart from the variations between the starch and the cellulose polymer backbones. Most importantly, CCS disintegration time is longer as compared to SSG (Table 4). The modification is performed using the ether synthesis of Williamson to yield the carboxymethyl cellulose sodium salt. Cross-linking render the cellulose insoluble, hydrophilic and highly absorbent resulting in ideal swelling properties. It has greater water wicking capacities due to its distinctive fibrous nature. It also offers superior features of drug dissolution and disintegration, enhancing bioavailability. From Table 4, CT_{CSD1} to CT_{CSD5}, tablet hardness and disintegration time range from 7.8±1.05to 12.9±1.83 N and 7.33± 0.22 to 10.47±0.42 s respectively. Tablet hardness was found to decrease with decreased in CCS and increased in SSG content of CSD for all formulations. The reason has been attributed earlier to the cellulose nature of CCS which contributed to the bond summation of the various formulations. More so, the DT features a decreased trend from CSD1 – CSD5, and also, from CSD5 – CSD7, in all these formulations, the reason is due to decrease in the amount of CCS across which means that the disintegrating effect of SSG manifest its faster action. But the overall effect is synergistic between SSG and CCS, this can be seen when you compare the results of CT_{CSD1} – CT_{CSD7} with CT_{SSG} and CT_{CCS} (Table 4). The extra superdisintegrant (CSDs) rapidly absorbed water when RDT was completely submerged in the medium. Croscarmellose sodium shows a longer wetting time. This is due to the capillarity nature and good gel formation properties attributed to it. Thus, making it difficult to soak in water compared to the properties of sodium starch glycolate which is very hydrophilic.

The choice of CSD can now be streamlined to CSD3 – CSD5 based on good compact formation and lower disintegration time. Moreover, the selected batches of composite superdisintegrants (CSD3 – CSD5extra superdisintegrant) possessed better disintegration time (6.21 ± 0.18, 7.33 ± 0.22 and 3.40 ± 0.62 s) than SSG (15 s) and far much better than CCS (260 s).

All the batches of ciprofloxacin showed0.3-1.20% (Table 4) loss of weight after the friability test. Table 4 shows that the batches of composite superdisintegrants at different level were able to affect the hardness of the formulations positively. Based on friability results (Table 4), CSD1 and CSD2 with relatively higher CCS than SSG formed stronger compact tablets than SSG alone and even far more compact than CCS alone. This reflects the direct relationship between hardness and friability. In this situation, creation of large surface area that favours multiple bonding coupled with modified cellulose and starch materials that constitute the structure of the CSDs could be attributed to the novel results.

Stability Studies:

Infrared studies reveal that both characteristic bands were present in all spectra. While no new bands or shift in characteristic peaks appeared. Thus, confirming that no interaction of drug occurred with the components of the formulations.

The FT-IR spectrum of drug sample was coherent with reference spectra as given in Clarke analysis of drug and poison. The IR spectra studies of drug- excipients and excipients are shown in Fig. 11 - 14, respectively. The FT-IR spectra verified the authenticity of the procured sample as the characteristic peaks of the drug. The absorption maxima of Ciprofloxacin were observed at 275 nm in phosphate buffer (pH 6.8). The spectrum of ciprofloxacin showed an intense well-defined infrared band at around 3521.91 cm^{-1}(O-Hstretching vibration, intermolecular H-bonded), another peak at around 1707.60 cm^{-1} represented the carbonyl C=O stretching. A peak at 1617.71cm^{-1} is a representative of the quinolines (δN-H bending vibration).

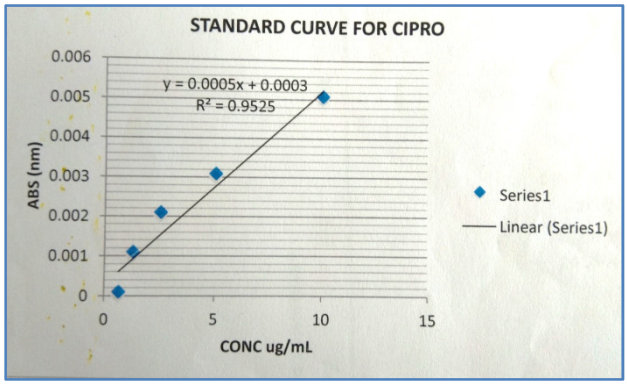

Figure 5: A calibration curve of ciprofloxacin in phosphate buffer (pH 6.8) at 275 nm

Uniformity of Actives

Analysis of the percentage content uniformity of the active in each batch as calculated was found to be almost 100% per formulation. The uniformity of content was determined and the results shown in Table 4.

CONCLUSION AND RECOMMENDATION

CONCLUSION

In the present study the disintegrating properties of the co-processed crosscarmellose sodium, and Sodium starch glycolate had been studied. The results from this research suggests that the fabrication of a superior composite ''extra superdisintegrant'' and it utilization in rapid disintegrating ciprofloxacin tablets yielded a novel extra superdisintegrants (Tablet burster) consisting of SSG: CCS (CSD3, CSD4 and CSD5) in ratio of 33 % of SSG and 67 % of CCS; 50 % of SSG and 50 % CCS;83 % SSG and 17 % CCS respectively. This work produced rapid disintegration of ciprofloxacin, which is required for faster drug dissolution and improved bioavailability. In summary, the composite extra superdisintegrant "CSD5" produced FDT "CT_{CSD5}" with crushing strength of 9.40$\pm$ 0.62, DT of 3.40 $\pm$0.06,this could be a promising approach to enhance tablet breakdown, with subsequent increase in drug dissolution and improved bioavailability, also will address drug compliance challenges associated with dysphagia.

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