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Preparation and Characterization of Starch-Metal Silicate Co-Precipitates – Evaluation as Tablet Superdisintegrant

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A – research concept and design; **B** – collection and/or assembly of data; **C** – data analysis and interpretation; **D** – writing the article; **E** – critical revision of the article; **F** – final approval of the article

Abstract

Background. Starch is a potential biomaterial used for various pharmaceutical applications because of its unique physico-chemical and functional characteristics. A number of modification techniques, such as physical, chemical, enzymatic and genetic or a combination of any of these methods have been reported with the aim of enhancing the positive attributes and eliminating the shortcomings of the native starches.
Objectives. The present studies deal with the development of co-precipitates of corn starch with different silicates (Mg, Ca, Al) with an aim of using it as a tablet superdisintegrant. Co-precipitates of starch with different silicates were prepared and FTIR-ATR, XRD and SEM techniques were used for the characterization of conjugates.
Material and Methods. The conjugate were analyzed for various powder evaluation test like angle of repose, bulk density, tapped density, Hausner's ratio, Carr's index, swelling index and effective pore radius.
Results. The prepared co-precipitates were found to possess good powder flow properties. The swelling and effective pore radius of all co-precipitates (SMgC, SAlC and SCaC) was found in the range between 30–100% and 15.89–21.71 μm respectively. Different ratios of the prepared co-precipitates were used to formulate fast disintegrating tablets. Fast disintegrated tablets formulated using starch silicate conjugates as superdisintegrant were evaluated for diameter, thickness, hardness, friability, tensile strength, *in vitro* tablet disintegration, water absorption ratio, wetting time and *in vitro* dissolution studies. The effective pore radius and swelling of the co-precipitates were correlated with the *in vitro* disintegration, water absorption ratio and wetting time of the tablets.
Conclusions. It was concluded that silicated co-precipitates of starch could be used as superdisintegrants in pharmaceutical tablet formulations (**Polim. Med. 2014, 44, 3, 157–166**).

Key words: starch, starch-silicate co-precipitate, superdisintegrant, disintegration time.

The oral route being the safest, most convenient, non-invasive and economical method of drug delivery with the highest patient compliance is the preferred route for systemic delivery of drugs. Solid dosage forms are widely preferred as a drug delivery system due to the advantages afforded both to the manufacturer and to the patient. Fast disintegrating tablets (FDTs) have overcome the swallowing or chewing problems associated with conventional tablets. Improved pre-gastric absorption associated with fast disintegrating tablets may result in improved bioavailability and clinical performance of bioactives, by reducing side-effects. Conventional tablet superdisintegrants like cross linked carboxymethyl cellulose (croscarmellose), sodium starch glycolate (primogel, explotab), polyvinylpyrollidone (polyplasdone), etc. are used in the formulation of FDTs on a commercial scale. The efficacy of these superdisintergrant depends upon type, concentration, method of incorporation, step used for preparation and/or physicochemical characteristics of the formulations. Some commonly used technologies for the manufacturing of fast-disintegrating tablets include freeze-drying, spray-drying, tablet moulding, sublimation, tablet compression [1, 2].

Starch is a readily available biopolymer and is commercially extracted from various botanic sources such

as potato, maize, wheat, and rice. It is a polysaccharide comprising of glucose monomers joined in 1, 4 linkages. Starch has been explored as a potential biomaterial for various pharmaceutical applications because of its unique physicochemical and functional characteristics. Modification of starch involves the alteration of its physicochemical properties with an aim to enhance its use for desired applications. A number of modification techniques, such as physical, chemical, enzymatic and genetic or a combination of any of these methods have been reported with an aim of enhancing the positive attributes and to eliminate the shortcomings of the native starches [3]. Various modifications (physical and chemical) of starches improve its functionality and compaction properties [4]. Staroszczyk performed silication of potato starch by microwave irradiation and reported that the silicated starch is thermally more stable [5].

Natural and synthetic silicates are used as polymer fillers and selective adsorbents in various pharmaceutical formulations [6]. Rashid et al. (2009) prepared rapidly disintegrating tablets of chitin-metal silicate co-precipitates with 3 different model drugs using direct compression and wet granulation methods and studied the compressional properties of formulations. From their study it was concluded that chitin metal silicate co-precipitates can be used as a filler, binder and superdisintegrant, in tablet formulations [7]. Rashid et al. (2011) developed a directly compressible excipient by co-processing starch with magnesium silicate. The permeability of both maize and partially pregelatinized starch was found to increase, resulting in an increase in the mechanical strength, short disintegration time and low lubricant sensitivity of the compacts [8].

Domperidone is a dopamine receptor antagonist used for the treatment of upper gastrointestinal motility disorders. It is absorbed from the stomach and the upper part of the gastrointestinal tract. It is a weak base that has good solubility in acidic pH but reduced solubility in alkaline medium. The bioavailability of domperidone is about 90% through intramuscular and 13 to 17% through oral route. The low systemic bioavailability of the oral form of domperidone is likely due to first pass hepatic metabolism and gut wall metabolism [9].

The aim of the present research is to prepare co-precipitates of starch with different silicates viz. Ca (Calcium) silicate, Mg (Magnesium) silicate and Al (Aluminium) silicate and to explore their potential as tablet superdisintergrant. The prepared co-precipitate powders were evaluated for various powder properties, such as bulk density, tapped density, angle of repose, Carr's compressibility index, Hausner ratio, pH, swelling index, loss on drying (LOD) and effective pore radius. Fast disintegrating tablets were formulated and evaluated for hardness, friability, tensile strength, water absorption ratio, wetting time, porosity, tablet packing fraction, *in vitro* dissolution study, disintegration time, drug content and stability testing.

Material and Methods

Corn starch was supplied as a gift sample by IPZHA Pharmaceuticals, Patiala, Punjab, India. Magnesium silicate and aluminium silicate were procured from Loba Chemie, Mumbai, India. Calcium silicate and Avicel 102 were purchased from Sigma-Aldrich, USA. HCl and NaOH were procured from Merck Specialities Pvt. Ltd., Mumbai, India. Talc and Magnesium stearate were procured from S.D. Fine Chemicals Ltd. Mumbai, India. Marketed tablet of domperidone (Domstal® Manufactured by Torrent Pharmaceuticals Ltd. Baddi, India, Batch No. C2359015, Expiry date: Dec 2014) was procured from Mohali, Punjab, India. All reagents used were of analytical grade.

Preparation of Starch Silicate Co-Precipitates

Co-precipitates were prepared by taking equal proportions (w/w) of starch and different silicates (Mg, Al and Ca). Dispersion of starch was prepared in distilled water. Solution of different silicates employed in the study was prepared by dissolving in 2 M NaOH solution (25 mL). Silicate solution was then added drop wise to starch dispersion under continuous stirring (300 rpm). Additional water (50 mL) was added and stirring speed was increased to 500 rpm to aid the formation of co-precipitate of starch with silicates. pH of the above reaction mixture was adjusted to 8 for precipitating the starch-silicate co-precipitate. The precipitated starch--silicate co-precipitate was filtered using whatman filter paper (GE Healthcare UK Limited) having a pore size of 125 μm and dried in oven (Perfit, India) at a temperature NMT 50 ± 2 °C. The dried starch-silicate co-precipitate were passed through a sieve with meshes no. 35 (pore size 595 μm) and stored in desiccators until further use.

Evaluation of Powder Properties of Co-Precipitates

Starch-Magnesium silicate co-precipitate (SMgC), Starch-aluminium silicate co-precipitate (SAlC) and Starch-calcium silicate co-precipitate (SCaC) were evaluated for various powder flow property, including bulk density, tapped density, angle of repose, Carr's compressibility index, Hausner ratio.

Swelling Index

Initial bulk volume of the powder was evaluated with the use 100 mL stoppered graduated cylinder. After a sufficient quantity of water had been added, sediment volume of the swollen mass was measured after 24 hours.

Table 1. Powder evaluation of different starch-silicate co-precipitates

S. No.	Property	Observation		
		SMgC	SAlC	SCaC
1.	bulk density (g/cm^3)	0.72 ± 0.04	0.69 ± 0.05	0.78 ± 0.08
2.	tapped density(g/cm^3)	1.15 ± 0.09	0.92 ± 0.02	1.14 ± 0.07
3.	Carr's index (%)	37.52 ± 0.12	25.09 ± 0.18	30.71 ± 0.10
4.	Hausner ratio	1.65 ± 0.05	1.33 ± 0.08	1.47 ± 0.04
5.	angle of repose (°)	25.39 ± 1.04	26.88 ± 0.95	26.45 ± 1.82
6.	swelling index (%)	90	30	45
7.	pH	8	8	8
8.	LOD (%)	4.72 ± 0.18	6.27 ± 0.28	7.16 ± 0.25
9.	effective pore radius (μm)	21.71 ± 0.22	15.89 ± 0.36	17.48 ± 0.25

The swelling index was calculated from equation 1:

$$\text{Swelling indes} = \frac{V_1 - V_2}{V_1} \times 100 \quad (1)$$

where, V_1 and V_2 are initial volume of the powder before and after hydration respectively. The study was repeated in triplicate for SMgC, SAlC and SCaC powder samples.

pH

1% dispersion (w/v) of the sample (SMgC, SAlC and SCaC) was prepared in distilled water and the pH was determined individually using digital pH meter at 37 ± 2°C. The pH of the samples was determined in triplicates and the mean and standard deviations were recorded.

Loss on Drying (LOD)

LOD depicts the amount of moisture and/or other solvents present in the sample. For calculating LOD, the powder sample was weighed (W_1) followed by heating it in an oven at 100 ± 5°C for 2 hrs. The sample was then cooled in a desiccator and was then reweighed (W_2). % LOD was calculated using equation 2:

$$\%\text{LOD} = \frac{W_1 - W_2}{W_1} \times 100 \quad (2)$$

Effective Pore Radius ($R_{eff.P}$)

Effective pore radius of the powder was determined employing method reported by Goel et al. [10]. A transparent micropipette tip (2 mL) was filled with powder and weighed (W_i). N-hexane (surface tension (γ); 18.4 mN/m) was then added drop wise on powder bed top till it came out from the bottom of the tip. The tip was reweighed (W_f) and effective pore radius was calculated employing equation 3:

$$R_{effP} = \frac{W_f - W_i}{2\pi\gamma} \times 100 \quad (3)$$

Characterization of Co-Precipitates

Attenuated Total Reflectance-Fourier Transform Infrared Spectroscopy (ATR-FTIR)

The samples of polymer and optimized formulation were scanned in the spectral region of 4000 cm^{-1} to 400 cm^{-1}. ATR-FTIR spectrophotometer (Alpha, Bruker, Japan) was employed for Fourier transform infrared (FTIR) spectral analysis of the samples. KBr pellet of the samples were prepared for ATR-FTIR analysis.

X-Ray Powder Diffractograms (XRPD)

The X-ray powder diffractrograms were registered in X-Pert Pro (USA) in Bragg-Brentano geometry, using glass tubing with a Cu anode and graphite monochromator. The intensity and voltage applied were 30 mA and 40 kV respectively.

Scanning Electron Microscopy (SEM)

Surface morphology of the samples was studied employing scanning electron microscope (Hitachi S 4300 SE/N) equipped with a secondary electron at an accelerating voltage of 10 kV. A double-sided sticking carbon tape of 200 nm thickness was used for placing the sample on SEM sample stub. A 0.001 mm Hg of reduced pressure was used for sample analysis.

Formulation of Fast Disintegration Tablets

Different batches of fast disintegrating tablets containing 10 mg of domperidone were prepared according to the formula given in Table 2. The powders of domperidone, Avicel 102 and starch-silicate co-precipitates (SMgC, SAlC and SCaC) were passed separately through 60 mesh sieve (250 μm opening size) and mixed for 20 min by tumbling the powder in a sealable

Table 2. Formulation chart for the preparation of FDT

Tablet constituent	SMgC				SAlC							
	M1	M2	M3	M4	A1	A2	A3	A4	C1	C2	C3	C4
Domperidone	10	10	10	10	10	10	10	10	10	10	10	10
Starch Co-precipitate	2.5	5	7.5	10	2.5	5	7.5	10	2.5	5	7.5	10
Avicel 102	85.5	83	80.5	78	85.5	83	80.5	78	85.5	83	80.5	78
Mg Stearate	1	1	1	1	1	1	1	1	1	1	1	1
Talc	1	1	1	1	1	1	1	1	1	1	1	1
Total Weight	100 mg											

The formula is for single tablet and all the quantities are in mg.

polybag with sufficient headspace for adequate mixing of the powders. The powder blend was lubricated using talc and magnesium stearate and directly compressed into tablets of an average weight of 100 mg using single stroke multipunch tableting machine (AK Industries, Nakodar, Punjab, India) fitted with 6.75 mm biconcave round die-punch tooling.

The formulated tablets were evaluated for thickness and diameter using digital vernier calliper (M/s Mitutoyo Corp., Japan n = 10), friability using Roche friabilator (Model 902, EI, India) (n = 10) and hardness using hardness tester (Perfit, India) (n = 10). Tablet tensile strength (T) is a measure of the stress required to cause diametric fracture of the tablet and was calculated from equation 4:

$$T = \frac{2P}{\pi dt} \tag{4}$$

where P is the crushing load and d and t denote the diameter and thickness of the tablet, respectively.

Content Uniformity

For the assessment of content uniformity, ten tablets were pulverized and the quantity of powder equivalent to 10 mg of domperidone was shaken with 100 mL of 0.1 N HCl for 30 min. The contents were filtered through a 0.45 μm membrane filter and were diluted suitably for analysis at 284 nm using UV/VIS double beam spectrophotometer (2202, Systronics, India).

Wetting Time

A piece of tissue paper (10.75 × 12 mm) folded twice was placed in a glass petri plate (6.5 cm diameter) containing eosin dye solution (6 mL). A tablet was placed on the surface of tissue paper and the wetting time was noted as the time required for colored dye water to reach the upper surface of the tablet [11].

Water Absorption Ratio

Experimental procedure was the same as that of wetting time. The weight of the tablet before and after complete wetting was measured and the water absorption ratio (R) was determined using equation 5:

$$R = \frac{W_b - W_a}{W_b} \times 100 \tag{5}$$

W_a and W_b are the tablet weight before and after water absorption respectively [12].

Porosity

Porosity is a measure of the void spaces in a material and ranges between 0-1, or as a percentage between 0–100%. The porosity of the tablets was calculated using equation 6:

$$\varepsilon = \frac{1 - m}{\rho_{trus}} \times V \tag{6}$$

m and V are the weight and volume of the tablet, respectively and ρ_{true} is the true density of the mixture, detrmined using true density meter (SMART PYCNO 30).

Tablet Packing Fraction (P_f)

Tablet packing fraction (P_f) is a measure of the degree of compactness of the tablet. Tablet packing fraction was determined from the following equation:

$$\text{Packaging fraction } (P_f) = \frac{w}{\pi r 2 t \rho} \tag{7}$$

where w is weight, r is radius and t is thickness of the tablet measured using a vernier calliper. ρ is the apparent particle density of the powder and was determined using liquid paraffin displacement method [13].

In Vitro Disintegration Time

In vitro disintegration time for the formulated batches of fast disintegrating tablets was determined us-

ing USP disintegration apparatus (EI Product, Panchkula, India) and using 0.1N HCl (pH 1.2) as the disintegrating medium.

In Vitro Dissolution Studies

All the formulated FDT batches were evaluated for *in vitro* dissolution study using 6 station paddle type dissolution test apparatuses (DS 8000, Lab India) employing a stirring speed of 50 rpm at 37 ± 0.5°C using 900 mL of 0.1 N HCl (pH 1.2) as a dissolution medium. 5 mL samples were withdrawn at predetermined time intervals, filtered through a 0.45 μm membrane filter and diluted suitably for analysis at 284 nm using a UV/ /VIS double beam spectrophotometer (2202, Systronics, India). The equation obtained from the calibration curve was used for calculating cumulative percent drug release from the formulation.

Results and Discussion

The aim of the present investigation was to develop FDT employing starch silicate co-precipitates (SMgC, SAlC and SCaC) as a tablet superdisintegrant. Starch silicate co-precipitates were used in different concentrations in formulating FDT. The results of various powder characteristic test and tablet parametric tests are here presented.

Powder Properties

Powder properties, bulk density, tapped density, Carr's compressibility index, Hausner's ratio and angle of repose, swelling behavior, pH, effective pore radius, porosity and loss on drying of SMgC, SAlC and SCaC were studied and the results are listed in Table 1. The findings of powder flow properties indicate good flow characteristics of the different starch-silicate co-precipitate (SMgC, SAlC and SCaC). Swelling index of SMgC powder was found to be 90%, which was far better than SAlC and SCaC powder. Effective pore radius of SMgC was 21.71 ± 0.22 μm, whereas that of SAlC and SCaC was 15.89 ± 0.36 and 17.48 ± 0.25 μm respectively. The results of both swelling and effective pore radius point out towards more wicking action capability and hence disintegration potential of SMgC compared to SAlC and SCaC.

FTIR Analysis

Starch-silicate co-precipitate interactions studies were carried out using ATR-FTIR spectrophotometery. FTIR spectra of starch, magnesium silicate, aluminum silicate, calcium silicate and starch-silicates co-precipitates (SMgC, SAlC and SCaC) are shown in Fig. 1. The FTIR spectra of corn starch showed a peak at 3434 cm^{-1} and 2931 cm^{-1} representing O-H and C-H stretching respectively. The absorption band at 1652 cm^{-1} is due to absorbed water in amorphous region of starch. Peak at 1241 cm^{-1} represent CH_2OH group whereas peak at 1159 cm^{-1} represents coupling mode of C-C, C-O stretching vibrations. The band at 1080 cm^{-1} represents C-O-H bending vibration, whereas the peak at 926 cm^{-1} could be ascribed to the skeletal mode vibration of α-1, 4-glycosidic linkage. The spectra of SMgC, SAlC and SCaC feature bands at 674 cm^{-1} and 1026 cm^{-1} which are due to Si-O bending and Si-O-Si symmetrical stretching vibrations respectively. Absorption bands at 3434–3000 cm^{-1} represents hydroxyl stretching, whereas band at 1642 cm^{-1} could be due to C=O stretching. Additional peaks obtained at 458–468 cm^{-1} could be assigned to bending vibration of Si-O-Si bridging group. The silicon atom of different silicates possess a positive charge, which made it an active side for nucleophilic attack from hydroxyl group of D glucose units of starch, resulting in the silication of starch.

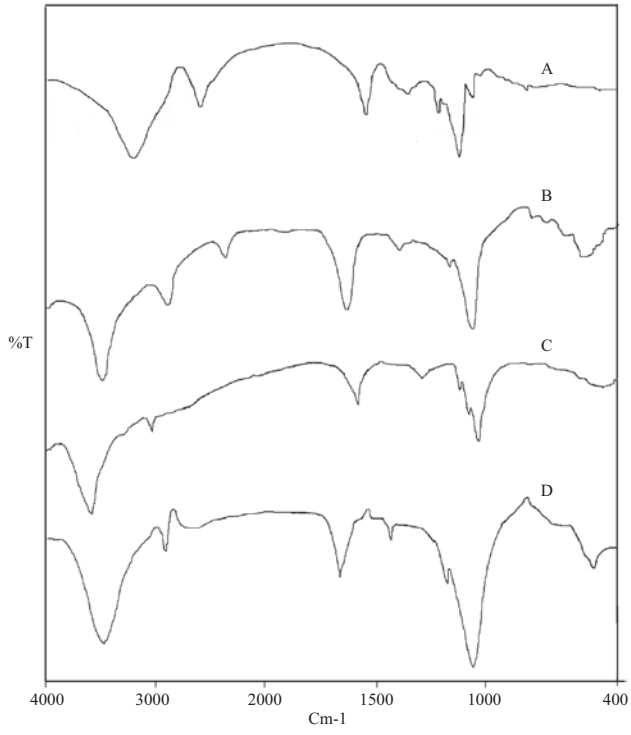

Fig. 1. FTIR Spectra of A – starch, B – SCaC, C – SAlC, D – SMgC

XRPD Analysis

The XRD patterns of the samples are shown in Fig. 2, 3. The structure of corn starch characterized by the presence of peak at 24.56 °2θ angle. XRPD spectra of Al, Ca and Mg silicates depicts their amorphous characteristic with broad peaks throughout the diffraction pattern range. Co-precipitates of starch with the metal silicates were found to alter the amorphous state of both starch and metal silicates. SMgC, SAlC and

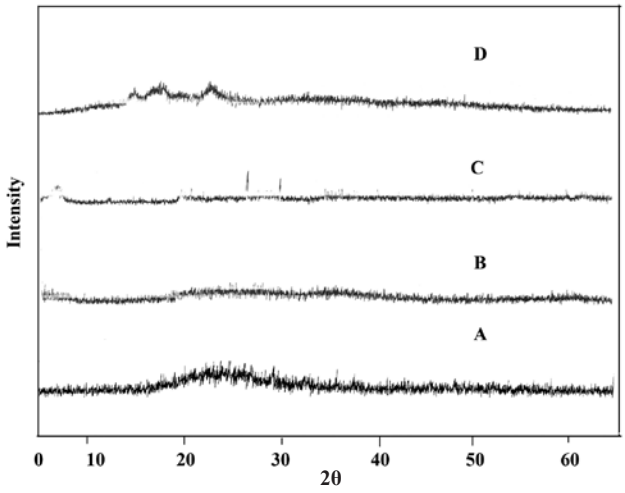

Fig. 2. X-ray powder diffractograms of A – starch, B – magnesium silicate, C – aluminium silicate, D – calcium silicate

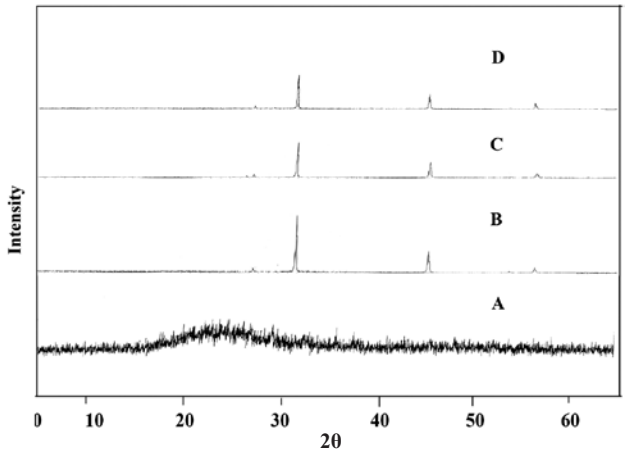

Fig. 3. X-ray powder diffractograms of A – starch, B – SMgC, C – SAlC, D – SCaC

SCaC shows XRPD peaks at 27.38, 31.72, 45.47 °2θ. An increase in crystalline behaviour could probably be the reason for the enhancement of swelling potential of co-precipitate of starch with different silicates.

SEM Analysis

Surface morphology of starch and SMgC were studied by SEM analysis as shown in Fig. 4. Starch undergoes a change in its native structure from thin smooth, flat surface structure, with folded edges, to 3-dimensional compacts upon conjugation with metal silicate. SEM micrograph of SMgC shows the presence of interparticulate voids and channels that are responsible for the increase in water absorption and swelling capacity of the silicated starch as compared to the pure starch. Furthermore, these voids/channels contributed towards the wicking behavior responsible for the tablet superdisintegrant property of the starch silicate co-precipitate.

FDT Parametric Tests

All the batches of fast disintegrating tablets were formulated under similar conditions to avoid processing variables. The prepared tablets were evaluated for various tablet parametric tests in Table 3. Tablets require a certain amount of strength and resistance to friability in order to withstand the mechanical shock of handling during manufacturing, shipping and packaging. Tablet friability and hardness were found to be ranging between 0.24 ± 0.04 to 0.75 ± 0.04 % and 3.0 ± 0.18 to 4.75 ± 0.21 kg/cm^2 respectively. Tensile strength, a measure of inherent strength of the compacted material, characterizes the ability of a formulation to undergo good particle bending, producing good tablets with optimal disintegration and dissolution. Tensile strength of different batches of FDT formulated using different concentration of SMgC, SAlC and SCaC as tablet superdisintegrants are depicted in Table 3, Fig. 5. Tensile strength was found to increase in the concentration of starch silicate co-precipitates in FDT formulation.

The result of water absorption ratio (WAR), wetting time (WT), disintegration time (DT) of the formulated batches of FDTs are shown in Fig. 6. WAR was found to be inversely related to WT, DT of the tablets. Tablets

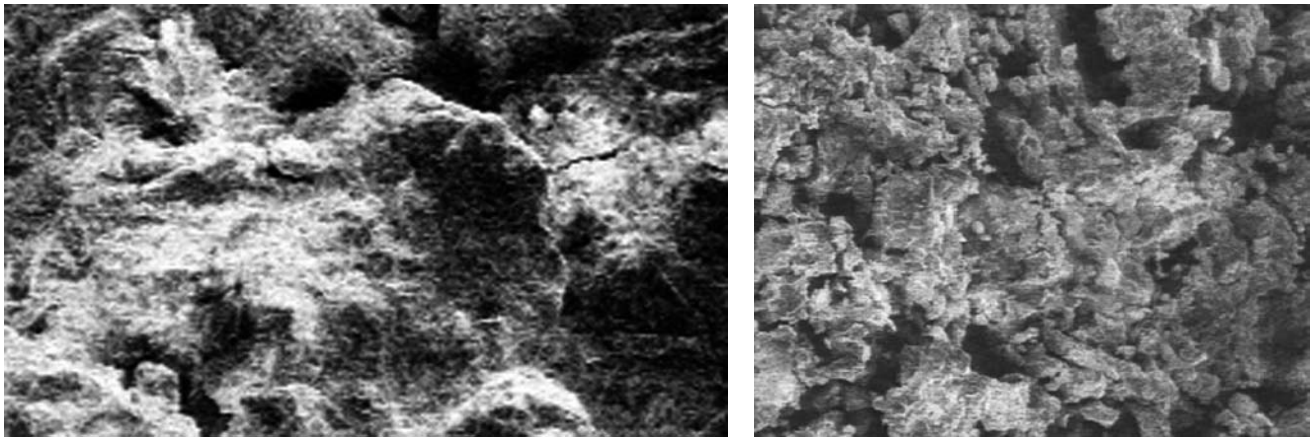

Fig. 4. SEM photomicrograph of A – starch, B – SMgC

formulated using SMgC showed maximum WAR and minimum WT, DT compared to SAlC and SCaC formulated batches of FDTs. The results are in line with the powder evaluation results where SMgC powder was showing better swelling, effective pore radius compared to SAlC and SCaC. The rapid disintegration of tablets due to presence of pores results in faster penetration of the dissolution media leads to swelling and wicking of superdisintegrant which creating hydrodynamic pressure inside the tablets responsible for quick and complete disintegration of tablets. Tablet packing fraction was found to be ranging between 0.90 to 0.99 for all formulated batches of FDT, indicating the tablet superdisintegrant property of different starch-silicate co-precipitates. The results of *in vitro* drug release from the formulated batches of FDT are shown in Fig. 7, 9.

The similarity factor (f_2) is a logarithmic transformation of the sum-squared error of differences between the test Tj and reference Rj products over all time points. It is a useful tool for comparison of dissolution profiles when more than 3 or 4 dissolution time points are available.

$$f2 = 50 \times \log\left\{\left[1 + \left(\frac{1}{n}\right) \Sigma_{j=1}^{n} W_j \mid R_j - T_j \mid 2\right] - \right.$$
$$\left. - 0.5 \times 100\right\}$$

Wj is an optional weight factor. The similarity factor fits result between 0 and 100. It is 100 when the test and reference profiles are identical and tends towards 0 as the dissimilarity increases. In order to consider similar dissolution profiles, f2 values should be close to 100. Result of f_2 values indicates better resemblance *in vitro* dissolution results of SMgC formulated tablets compared to SAlC and SCaC. Moreover, increasing the concentration of the starch silicates co-precipitate with that of the tablet was not showing much effect on the drug release from FDT. Hence, from the commercial point of view, the lowest concentration of superdisintegrant showing optimum tableting results should be recommended.

Starch silicate co-precipitates developed using magnesium silicate, aluminium silicate and calcium

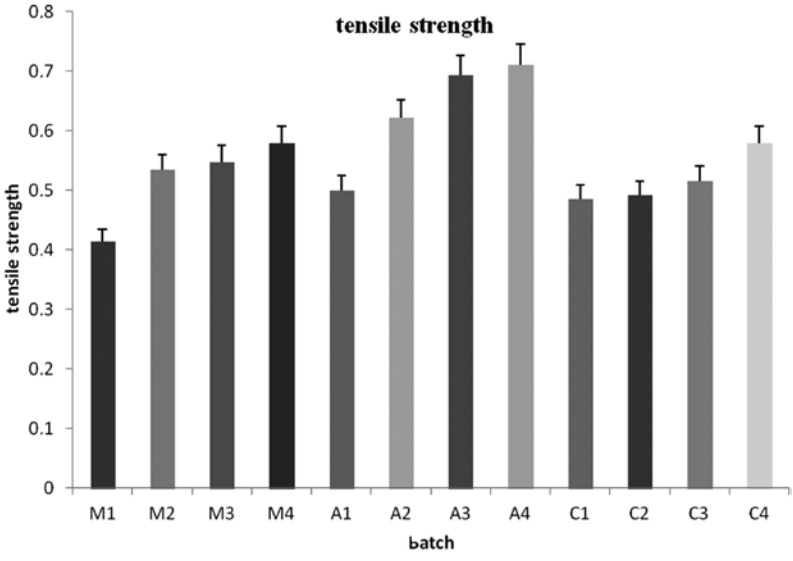

Fig. 5. Tensile strength (MN/m^2) of the formulated batches of FDT

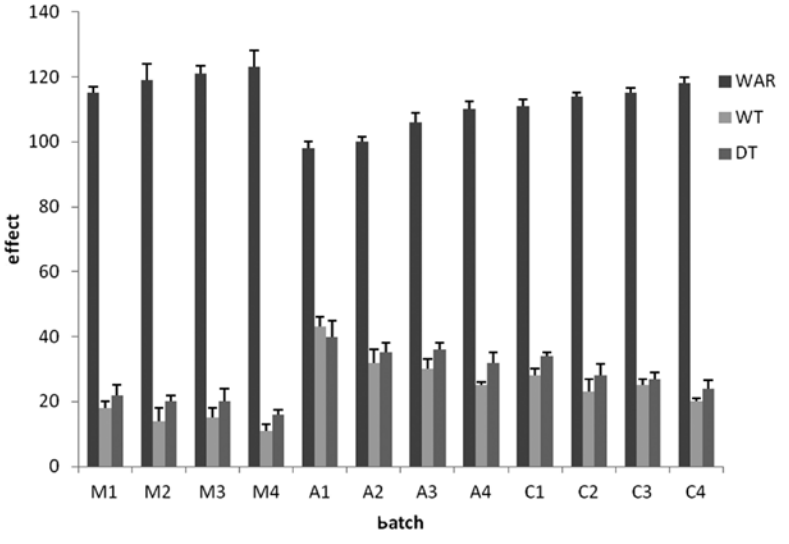

Fig. 6. Water absorption ratio (%), wetting time (sec.), and disintegration time (sec.) of formulated batches of FDT

Table 3. Results of Various Tablet Evaluation Tests

S.No.	Property	SMgC				SAlCSCaC				SCaC			
		M1	M2	M3	M4	A1	A2	A3	A4	C1	C2	C3	C4
1.	diameter (mm)	6.75 ± 0.01	6.73 ± 0.02	6.74 ± 0.01	6.74 ± 0.03	6.72 ± 0.04	6.74 ± 0.05	6.75 ± 0.03	6.75 ± 0.02	6.71 ± 0.03	6.75 ± 0.01	6.72 ± 0.03	6.75 ± 0.01
2.	thickness (mm)	3.21 ± 0.05	3.56 ± 0.04	3.45 ± 0.05	3.55 ± 0.03	3.65 ± 0.02	3.28 ± 0.07	3.43 ± 0.04	3.48 ± 0.03	3.55 ± 0.04	3.21 ± 0.04	3.45 ± 0.06	3.59 ± 0.05
3.	friability (%)	0.75 ± 0.04	0.64 ± 0.05	0.61 ± 0.02	0.55 ± 0.03	0.29 ± 0.01	0.25 ± 0.05	0.25 ± 0.03	0.24 ± 0.04	0.66 ± 0.07	0.62 ± 0.02	0.64 ± 0.04	0.57 ± 0.07
4.	hardness (Kg/cm^2)	3.0 ± 0.18	3.5 ± 0.15	3.7 ± 0.17	3.8 ± 0.2	3.2 ± 0.11	4.2 ± 0.05	4.7 ± 0.11	4.75 ± 0.21	3.20 ± 0.27	3.25 ± 0.2	3.5 ± 0.10	3.75 ± 0.45
5.	tensile strength (MN/m^2)	0.41 ± 0.05	0.53 ± 0.01	0.54 ± 0.18	0.57 ± 0.08	0.49 ± 0.19	0.62 ± 0.06	0.69 ± 0.11	0.71 ± 0.15	0.48 ± 0.08	0.49 ± 0.20	0.51 ± 0.18	0.57 ± 0.19
6.	wetting time (sec)	18 ± 1.14	14 ± 1.67	15 ± 1.10	11 ± 1.40	43 ± 1.34	32 ± 1.25	30 ± 1.05	25 ± 1.38	28 ± 1.52	23 ± 1.26	25 ± 1.15	20 ± 1.40
7.	water absorption ratio (%)	115 ± 0.04	119 ± 0.04	121 ± 0.05	123 ± 0.02	98 ± 0.03	100 ± 0.02	106 ± 0.01	110 ± 0.04	111 ± 0.08	114 ± 0.07	115 ± 0.03	118 ± 0.05
8.	D T (sec)	22 ± 2	20 ± 3	20 ± 1	16 ± 2	40 ± 6	35 ± 3	36 ± 2	32 ± 7	34 ± 2	28 ± 5	27 ± 3	24 ± 4
9.	content uniformity	96.50 ± 0.3	99.1 ± 015	98.35 ± 0.2	99.23 ± 0.5	99.12 ± 0.4	98.92 ± 0.7	97.27 ± 0.9	96.59 ± 0.5	99.15 ± 0.1	98.99 ± 0.2	95.75 ± 1.0	99.12 ± 0.3
10.	tablet packing fraction	0.90	0.95	0.98	0.95	0.93	0.98	0.99	0.97	0.96	0.96	0.99	0.94
11.	porosity (%)	9.256	4.24	1.340	4.048	6.469	1.34	0.91	2.33	3.69	3.44	0.90	5.32
12.	f_2	63	50	60	54	25	35	29	24	39	34	49	59

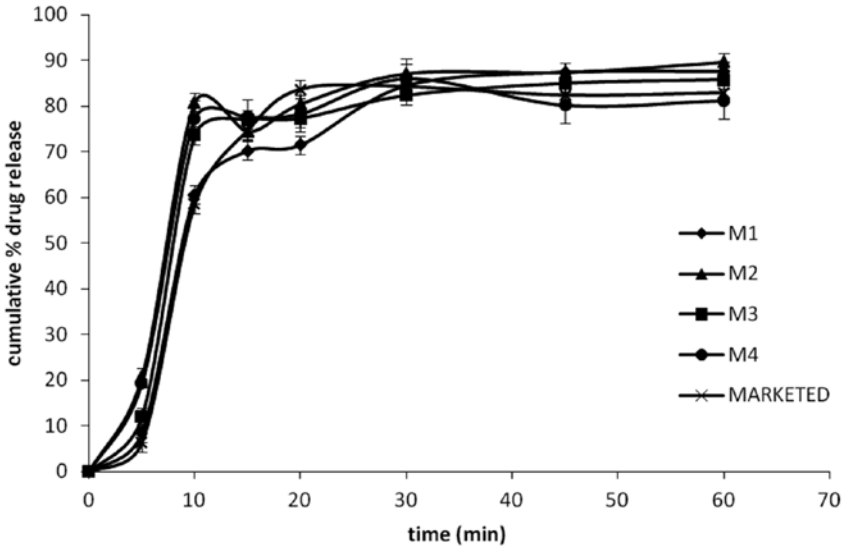

Fig. 7. *In vitro* dissolution profile of domperidone from prepared batches (M1 to M4) of FDT

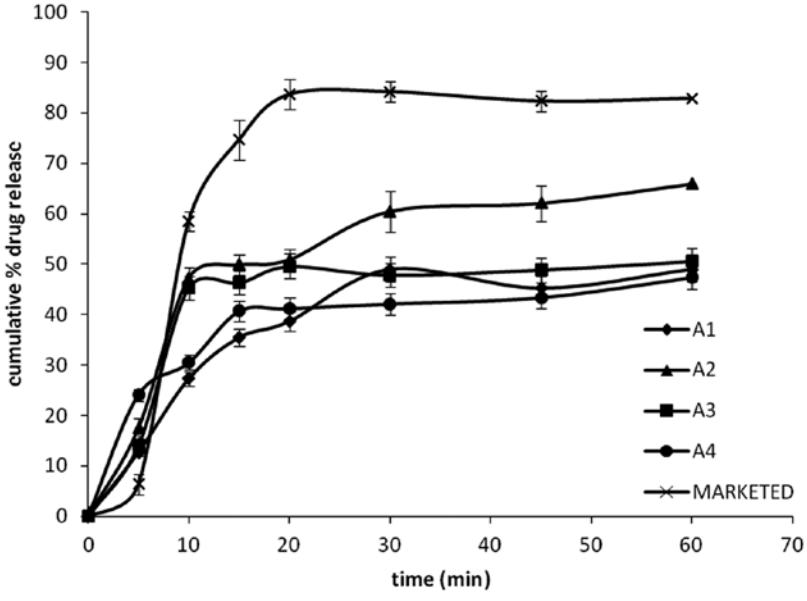

Fig. 8. *In vitro* dissolution profile of Domperidone from prepared batches (A1 to A4) of FDT

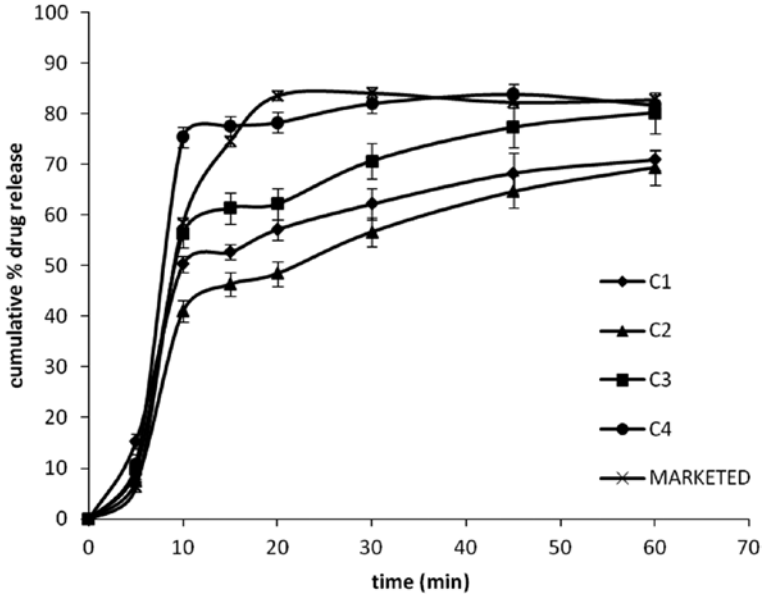

Fig. 9. *In vitro* dissolution profile of Domperidone from prepared batches (C1 to C4) of FDT

silicate were found to possess excellent disintegrating properties. Swelling and wicking were the postulated mechanism responsible for the superdisintegrant property of the developed co-precipitates. It can, thus, be concluded that starch silicate co-precipitates can be evaluated as superdisintegrants in pharmaceutical formulation. After assessing the economical viability of the starch silicate co-precipitates, these are proposed as an effective adjunct to existing tablet superdisintegrant.

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