

Formulation of carbamazepine fast dissolving tablets employing guar gum and croscarmellose sodium as disintegrants

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Abstract

Aim: The aim of this investigation was to formulate and evaluate fast dissolving tablets (FDT) of carbamazepine (CBZ) employing guar gum as the disintegrating agent and compared with synthetic superdisintegrant croscarmellose sodium (CCS). **Materials and Methods:** CBZ was characterized by melting point, Fourier Transform Infrared (FTIR) spectroscopy and ultraviolet UV Spectroscopy. GG and CCS were studied for particle size and shape, bulk densities, settling volume and bed hydrophilicity. CBZ has been incorporated in the FDTs as its solid dispersion using mannitol as carrier. FDT powder blends were evaluated for precompressional parameters. The solid dispersion of drug was incorporated into tablets. Tablets were prepared by direct compression. FDT of CBZ were evaluated for weight variation, thickness, hardness, friability, drug content, wetting time, in vitro disintegration time and in vitro drug dissolution. **Results and Discussion:** IR spectroscopy showed that there is no interaction of drug with excipients. Precompression blends exhibited good flowability and compressibility. All the formulations disintegrated within 1-2 minutes. Thus GG is comparable to synthetic superdisintegrants for formulation of FDT. Selected formulation was F8 with hardness of 3.5 ± 0.18 kg/cm², wetting time of 42 ± 2.28 s, disintegration time of 10.56 ± 1 s, drug content of 99.78 ± 0.8 % and gave 96.82 ± 0.42 % cumulative drug dissolution in 25 minutes and stability study on F8 at $40 \pm 2^\circ\text{C}$ / $75 \pm 5\%$ RH for two months revealed that there was very mild change in disintegration time and in vitro drug release needing further study to ascertain the physical stability and storage conditions. **Conclusion:** FDT of CBZ could be formulated using GG as the disintegrating agent which was comparable to CCS for tablet disintegration. A combination of natural and synthetic superdisintegrants yielded FDT of CBZ with shortest disintegration time.

Key words: Carbamazepine, Fast dissolving tablet, guar gum, croscarmellose sodium, superdisintegrants, solid dispersion

INTRODUCTION

Fast dissolving tablets (FDTs) are solid dosage forms that dissolve or disintegrate rapidly within a few seconds in the mouth without the need for consuming water.^[1] Superdisintegrants have been known since the 1980s and earlier. Sodium starch glycolate was the first followed by croscarmellose sodium (CCS) and crospovidone. These have been very popular yet have their limitations like incompatibilities with certain Application Programming Interfaces. Hence, there is a need for new excipients to be used as superdisintegrants. In modern era, natural superdisintegrants are widely used in pharmaceutical industries as

thickeners, suspending agents, and superdisintegrants.^[2] The natural superdisintegrants are guar gum,^[3] gellan gum, gum karaya,^[4] *Plantago ovata* seed mucilage,^[5] *Lepidium sativum* mucilage,^[6] Fenugreek seed mucilage,^[7] Mango peel pectin,^[8] Agar and treated agar,^[9] Chitin and chitosan,^[10] and Cucurbita maxima pulp powder.^[11] Natural materials

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have been reported for suitability as superdisintegrants. Natural gums and mucilages are preferred over synthetic superdisintegrants in the field of drug delivery because they are cheap and easily available, have soothing action and nonirritant nature. Further, they are ecofriendly, capable of multitude of chemical modifications, potentially degradable, and compatible due to their natural origin.^[12] Guar gum has been reported to function as tablet disintegrant.^[13] In the present work, guar gum is being tried for superdisintegrant action in comparison with synthetic superdisintegrant CCS. A combination of natural and synthetic superdisintegrants has been employed to prepare FDT of Carbamazepine (CBZ).^[14]

MATERIALS

CBZ and CCS were obtained from Yarrow Chemical Limited, Bengaluru, India, Guar gum from Karnataka Fine Chemicals. All other excipients used in this study are of pharmacopoeia grade and procured from commercial sources.

METHODS

Determination of Melting Point

The melting point was determined by Thiele tube method ($n = 3$).

Construction of Calibration Curve of CBZ

CBZ 100 mg was weighed accurately and dissolved in phosphate buffer pH 6.8 in a 100 ml volumetric flask. Further dilutions were made to yield solutions of 2, 4, 6, 8, 10, 12, and 14 $\mu\text{g/ml}$. The absorbance was measured UV–Spectrophotometrically at 285 nm (Agilent Cary 60 UV spectrophotometer).^[15]

Drug-Excipient Compatibility

Studies of compatibility were conducted to know the possible interactions between the drugs and polymers used in the formulations. Studies of compatibility with drug-polymers were performed using Fourier Transform Infrared (FTIR) spectroscopy (Tensor 27, Bruker Optics, Japan). Spectra of pure samples (drug and excipients) and physical mixture polymers were seen recorded in the range of 400–4000 cm^{-1} .^[16]

Studies on Disintegrating Agent

For comparative assessment of guar gum, as a natural superdisintegrant against the established synthetic superdisintegrant croscarmellose certain physical properties

of the materials was studied.^[17] They include particle size, bulk, and tapped densities and powder bed hydrophilicity study.

Particle size and shape

These parameters were observed by optical microscopy (Labovision). GG and CCS powder samples were made to a very dilute suspension using a nonsolvent. The size was measured using stage and eye piece micrometers. Hundred particles were measured and average particle size was determined.

Bulk and tapped density

Electrolab bulk and tapped density test apparatus was used to determine the property of GG and CCS.

Settling volume

Disintegrant powder 0.5 g was suspended in 100ml of distilled water and taken in stoppered measuring cylinder. After 4 h, the volume of the settled mass was noted.^[17]

Powder bed hydrophilicity

An in-house method based on principle discussed by Rizk *et al.*^[17] was performed to estimate the powder bed hydrophilicity. Powder bed of known weight and height is placed on a dry tissue paper. Dye powder (patent blue v) was sprinkled on the powder bed. The tissue with powder bed is placed on the wet sponge (2 cm height) taken in a Petri plate filled with water. Time taken for the rise of the water through the powder bed is noted. This time is obtained based on the time taken for dissolution of the dye powder and spreading of color due to contact of dye with water. The test was initially tried with dye alone to ascertain the spreading of color due to absorption of water.

Preparation of Solid Dispersion of CBZ

Solid dispersion of CBZ was prepared by solvent evaporation method. The carriers employed were mannitol and polyethylene glycol (PEG) 4000 and solvent employed was ethanol. Drug: carrier ratio tried was 1:1 and 1:2. The solvent was evaporated by constant kneading at room temperature. The solid mass was collected and passed through the sieve no.60. It was stored in a desiccator until further studies.^[18] The solid dispersions prepared are given in Table 1.

Table 1: Solid dispersions of carbamazepine

Code	Carrier	Drug:carrier
SD1	Mannitol	1:1
SD2	Mannitol	1:2
SD3	PEG 6000	1:1
SD4	PEG 6000	1:2

Evaluation of Solid Dispersion^[19]

Percentage of yield

It is calculated to identify the efficiency of the method of preparation. The percentage practical yield of solid dispersion (SD) of CBZ prepared with solvent evaporation method was determined using the following equation.

$$\text{Percentage yield} = \frac{\text{Practical weight of solid dispersion}}{\text{Theoretical mass (drug + carrier)}} \times 100$$

Percentage drug content

SD equivalent to 10 mg of CBZ was weighed and dissolved in methanol and volume was made up to mark with phosphate buffer pH 6.8. The solution was then filtered, diluted suitably, and scanned in UV visible spectrometer at 285 nm to determine the percentage drug content using following equation.

$$\text{Percentage drug content} = \frac{\text{Practical drug content}}{\text{Theoretical drug content}} \times 100$$

Determination of solubility

SDPs equivalent to 10 mg of CBZ was added to 10 ml each of distilled water and phosphate buffer pH 6.8. The dispersion were shaken well and kept aside for 24 h. The solution was filtered and analyzed at wavelength after appropriate dilutions.

Preparation of Fast Dissolving Tablets of CBZ

Direct compression method was employed for tablet preparation. The formulation chart for FDT of CBZ is given in Table 2. Solid dispersion equivalent to 100 mg of CBZ was taken and blended with superdisintegrant such as guar gum and CCS,

diluents mannitol, and microcrystalline cellulose. Aspartame was the sweetener. Then lubricant and glidant, namely, magnesium stearate and talc were passed through sieve no.60 mixed and blended with initial mixture. The blend was compressed on Rimek rotary tablet compression machine using 8 mm punches.^[20]

Evaluation of Pre-compression Parameters of Powder Blend

The precompression parameters, namely, angle of repose, bulk density, tapped density, Carr's Index, and Hausner's Ratio were evaluated. Angle of repose (θ) was determined by fixed funnel method by recording the height (h) and radius (r) of the heap where $\theta = \tan^{-1}(h/r)$. Bulk and tapped density were determined using the Electrolab tapped density test apparatus. % Carr's compressibility index (%) and Hausner's ratio were calculated as given below.

$$\% \text{ Carr's Index} = \left[\frac{D_t - D_b}{D_t} \right] \times 100 \text{ and Hausner's Ratio} = \frac{D_t}{D_b}$$

Where, D_t is the tapped density and D_b is the bulk density of the powder.

Evaluation of Fast Dissolving Tablets^[21-24]

Tablet diameter and thickness

Using screw gauge, the diameter and thickness of the fast dissolving tablets were determined. ($n = 10$).

Hardness

The hardness of FDT was tested using Monsanto hardness tester ($n = 10$).

Friability

Roche friabilator was used to determine % friability. Twenty tablets have been used for the test. The apparatus was run for 4 min. The tablets were dusted and reweighed and % weight loss was calculated.

Table 2: Composition of CBZ fast dissolving tablets

Ingredients (mg)	Formulations								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
SD1 equivalent to 100 mg CBZ	200	200	200	200	200	200	200	200	200
Guar gum	15	20	25	-	-	-	7.5	10	12.5
Croscarmellose sodium	-	-	-	15	20	25	7.5	10	12.5
Microcrystalline cellulose	50	50	50	50	50	50	50	50	50
Mannitol	25	20	15	25	20	15	25	20	15
Aspartame	6	6	6	6	6	6	6	6	6
Magnesium stearate	2	2	2	2	2	2	2	2	2
Talc	2	2	2	2	2	2	2	2	2
Total weight	300	300	300	300	300	300	300	300	300

Weight variation

Twenty tablets were weighed individually and the average weight was determined and checked for weight variation.

Drug content estimation

Five tablets were precisely measured and powdered. A amount of the powder comparable to 10 mg of CBZ was weighed precisely and dispersed in methanol and made up to 100 ml phosphate buffer pH 6.8. Samples were analyzed UV Spectrophotometrically at 285 nm.

Wetting time

Five circular 10 cm diameter, tissue papers are mounted in Petri dish with an internal diameter of 9.8 cm. In the Petri dish about 10 ml of water was added. A tablet is placed on the tissue paper surface carefully. The time needed to absorb water and hit the top surface of the tablet was noted as wetting time.

In vitro dissolution study

Dissolution test was carried out by using USP type II apparatus. The paddle was rotated at 50 rpm. Phosphate buffer pH 6.8 was used as dissolution medium (900ml) and was maintained at $37 \pm 0.5^\circ \text{C}$. Samples of 5 ml were withdrawn at predetermined intervals of time (5, 10, 15, 20, and 25 min), filtered and replaced with 5 ml of fresh dissolution medium. The collected samples were suitably diluted with dissolution fluid, wherever necessary and were analyzed for the drug at 285 nm using ultraviolet spectrophotometer. ($n = 3$)

Drug release kinetics

To describe the kinetics of drug dissolution and release process of drug from different formulations, the data were studied by different kinetic models - zero-order kinetics, first-order kinetics, and Hixson Crowell equation.^[25,26]

Stability study

For the most suitable formulation, the stability tests were performed. The selected formulation was sealed in aluminum package and kept at $40 \pm 2^\circ \text{C}$ and $75 \pm 5\% \text{ RH}$ for 2 months in

Stability chamber (Thermo scientific). After 30 days, 60 days, the samples were analyzed for hardness, wetting time, disintegration time, drug content, and *in vitro* dissolution.^[27]

RESULTS AND DISCUSSION

Melting Point Determination

The melting point as determined by Thieles tube method was found to be 190°C which is in agreement with the reported value of $189\text{--}192^\circ \text{C}$.

Construction of Calibration Curve of CBZ

The calibration curve for CBZ has been constructed in phosphate buffer pH 6.8 at 285 nm and the correlation coefficient was found to be 0.997 indicating linearity in the concentration range of $2\text{--}14 \mu\text{g/ml}$. This method has been employed in further studies. The % coefficient of variation values ranged from 0.3 to 3.8% and was $<5\%$ indicating the method to be precise and accurate. The standard curve is given in Figure 1.

Drug Excipients Compatibility Study by FTIR

FTIR spectra have been determined for pure drug and excipients and for the physical blends of drug with various

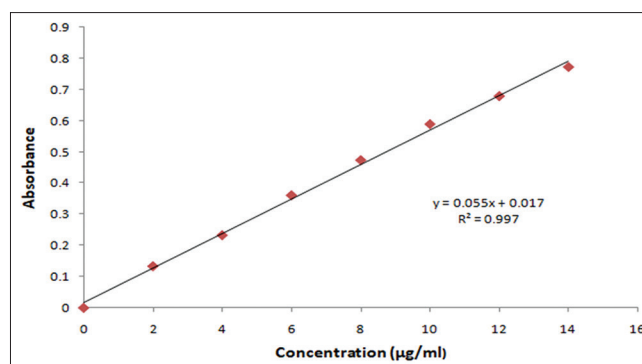


Figure 1: Calibration curve of carbamazepine

Table 3: Characteristics peaks of pure drug, excipients and superdisintegrants

Wavenumber (cm ⁻¹)	C-H (Ar)	C-H (Al)	C=O	C=C	C-N	N-H	C-O	O-H
Carbamazepine (CBZ)	3022.55	-	1670.41	1462.09	1244.13	3281.02	-	-
Croscarmellose sodium (CCS)	3176.87	2928.04	-	1413.87	-	-	1018.45	3464.27
Guar gum	3205.80	2935.76	-	1438.94	-	-	1014.59	3483.56
Mannitol	-	2947.33	-	-	-	-	1020.38	3635.94
CBZ +CCS	3022.55	2926.11	1674.27	1489.10	1244.1	3464.27	1037.74	3684.16
CBZ+Guar gum	3024.48	2926.11	1674.27	1452.45	1242.20	3282.95	1033.88	3462.34
CBZ+Mannitol	2976.26	2864.39	1662.69	1485.24	1244.13	3284.88	1018.45	3462.34
CCS+Guar gum	-	2924.18	-	1435.09	-	-	1020.38	3670.66
CBZ+CCS+Guar gum	3020.63	-	1676.20	1489.10	1244.13	3464.27	1037.74	3684.16

excipients. The data are given in Figures 2 and 3 and Table 3.

The pure drug CBZ shows peak at 3022.55 cm^{-1} due to aromatic C-H stretching, 1670.41 cm^{-1} due to C-O stretching, 1462.09 cm^{-1} due to C=C stretching, 1244.13 cm^{-1} due to C-N stretching, and 3281.02 cm^{-1} due to N-H stretching. It was observed that there were no marked shift in the peaks corresponding to the drug, indicating no interaction between drug and excipients.

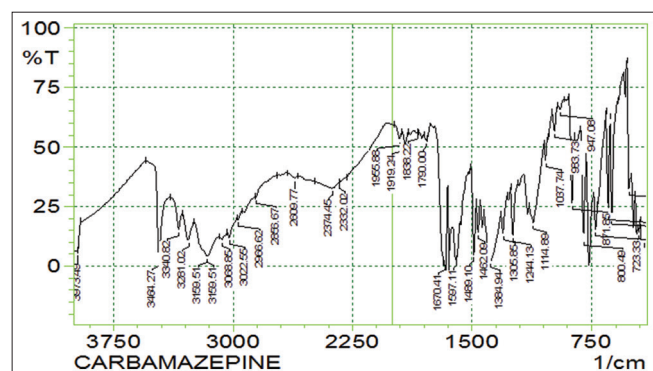


Figure 2: Fourier-transform infrared spectrum of carbamazepine

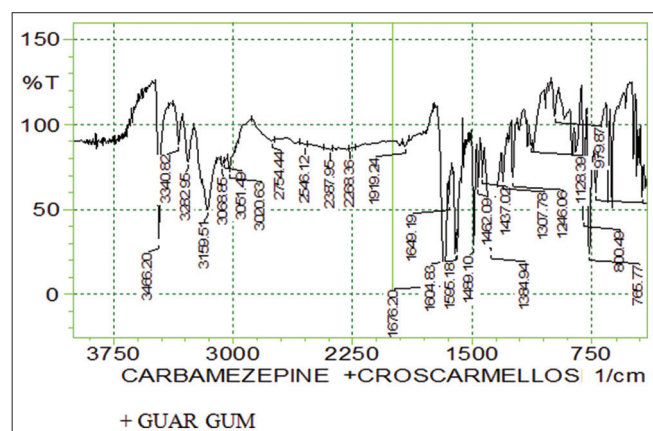


Figure 3: Fourier-transform infrared spectrum of Carbamazepine + Guar gum + croscarmellose sodium

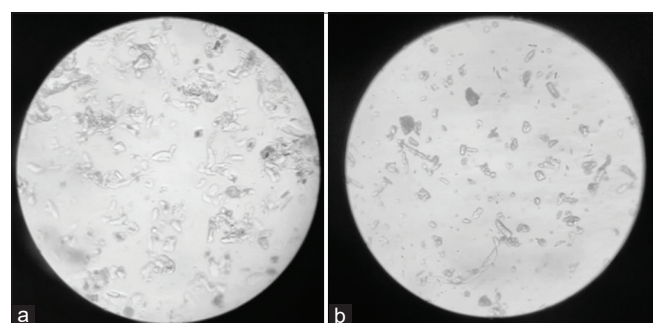


Figure 4: Optical microscopic photograph 10x (a). Guar gum; (b). Croscarmellose sodium

Studies on Disintegrating Agent

GG and CCS have been studied for various physical properties. The results are presented in Figures 4-6 and Table 4.

Evaluation of Solid Dispersion

Solid dispersion of CBZ was prepared using solvent evaporation method. The carriers used were mannitol and PEG 6000. Drug: carrier ratio employed was 1:1 and 1:2. It showed that mannitol 1:1 have higher solubility in phosphate buffer pH 6.8 compared to other ratio and have 97.38% practical yield and % drug content was found to be $98.58 \pm 0.76\%$. Therefore, 1:1 ratio of drug: mannitol was incorporated in the formulation. The properties of solid dispersion are given in Table 5.

Table 4: Characteristics of Disintegrating agents

S. No.	Property	Guar gum	Croscarmellose sodium
1.	Particle size	16.54 μm	20.78 μm
2.	Particle shape : Figure 4	Angular to tabular	Angular to tabular
3.	Bulk Density	0.37g/ml	0.48g/ml
5.	Settling volume Figure 5	12 ml	5 ml
6.	Powder bed hydrophilicity -200 mg		
	Color appearance	> 1 hr	1.5 min
	Complete wetness		10 min
	Powder bed hyrdophilicity	1:1 ratio of GG and CCS	
	Color appearance	10 min	
	Complete wetness	4 h	

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Table 5: Evaluation characteristics of solid dispersions of CBZ

Code	% Practical yield Mean \pm SD*	% Drug Content Mean \pm SD*	Solubility (mg/ ml) Mean \pm SD*
SD1	97.38 \pm 1.16	98.58 \pm 0.76	0.293 \pm 0.014
SD2	92.45 \pm 1.37	98.27 \pm 0.68	0.216 \pm 0.012
SD3	87.25 \pm 1.29	88.38 \pm 0.42	0.165 \pm 0.017
SD4	90.63 \pm 1.53	89.74 \pm 0.17	0.192 \pm 0.015

*n=3

Formulation and FDT of CBZ

FDT have been formulated employing natural disintegrant guar gum and the synthetic superdisintegrant CCS. The disintegrants have been employed individually and in combination with each other. They have been incorporated at low medium and high levels in the formulation F1-F3 has only GG, F4-F6 has only CCS while F7-F9 have a 1:1 combination of GG and CCS. The precompression parameters of blends are given in Table 6. The angle of repose of all formulations was found in the range of 20.54–26.38. The bulk density of all formulations was found in the range of 0.46–0.52 g/ml and tapped density was in range of 0.55–0.61 g/ml. All the blends show good to reasonable flow and compressibility characteristics.

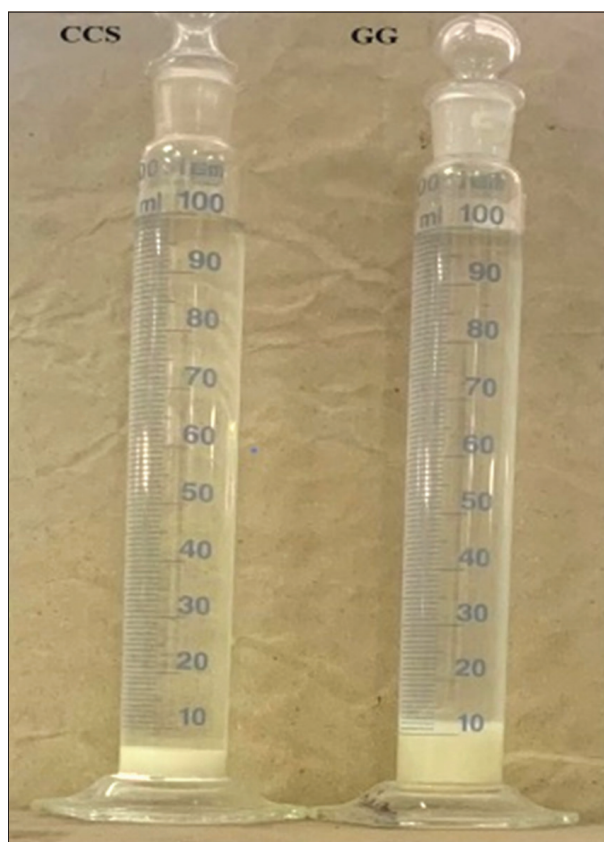


Figure 5: Settling volume of croscarmellose sodium and Guar gum

FDT Evaluation

FDT were evaluated for various parameters as given in Tables 7 and 8. Tablet diameter measured a mean of 8.1 mm, mean thickness ranged from 4 to 4.06 mm, mean tablet weight was 300 mg in the acceptable ranges and with low standard deviation indicating reproducibility of the processing method and formulation. The average hardness for all the formulations was found to be between 3.1 and 3.5 Kg/cm². The mean % friability ranged from 0.67 to 0.9%, which is within the official limits. Lesser hardness compared to normal tablets may have led to higher limit of the % friability. The assay values for the formulations were found to be in the range of 94–99%

Wetting Time and *In Vitro* Disintegration Time

The wetting time for the FDT formulations was found to be in the range of 22–63 s. It can be observed that wetting time was higher for FDT containing GG when compared to CCS while their combination showed a faster wetting

The *in vitro* disintegration time ranged from 10.56 ± 1 to 26.66 ± 1.5 s. It can be observed that there is a reasonable correlation between the wetting time and the disintegration times. Shorter the wetting time quicker was the tablet disintegration. A combination of natural and synthetic superdisintegrants gave the fastest tablet disintegration. The formulation F8 is the most satisfactory formulation, as it showed rapid disintegration within 10 s compared to other formulations.

From the study of the physical properties of GG and CCS [Table 4], it can be seen they do not show a wide variation from each other with respect to particle size and density. Scanning electron microscopy would give a better estimate of the particle shape and structure. The settling volume of CCS is similar to the reported information.^[28] The swelling of individual particles possibly led to higher settling volume for GG compared to that of CCS because GG is a high-molecular-weight hydrocolloid polysaccharide and thus in water it forms a viscous solution. CCS is insoluble in water it does swell upon contact with water. CCS structure

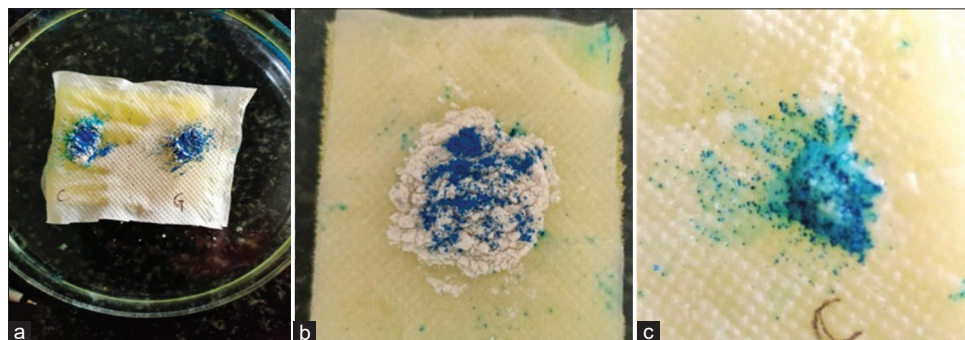


Figure 6: Powder bed hydrophilicity study. (a) Study set up; (b) powder bed at time zero; (c) powder bed after study

Table 6: Precompression properties of formulation blends

Formulations	Parameter				
	Angle of repose Mean±SD* (°)	Bulk density Mean±SD* (g/ml)	Tapped density Mean±SD* (g/ml)	Hausner's ratio Mean±SD* (%)	%Compressibility Mean±SD*
F1	22.52±0.66	0.52±0.00	0.61±0.00	1.22±0.01	14.75±0.79
F2	25.14±0.69	0.47±0.01	0.56±0.00	1.19±0.07	16.09±0.68
F3	23.83±0.68	0.46±0.00	0.55±0.01	1.19±0.02	16.56±1.70
F4	23.19±0.54	0.51±0.008	0.57±0.002	1.14±0.01	10.72±0.14
F5	24.31±1.12	0.52±0.02	0.58±0.03	1.15±0.04	10.64±0.54
F6	26.38±1.32	0.49±0.06	0.57±0.01	1.18±0.02	14.08±1.18
F7	21.61±0.56	0.47±0.01	0.55±0.04	1.18±0.01	14.42±0.94
F8	20.54±0.12	0.51±0.03	0.58±0.005	1.13±0.03	12.14±0.76
F9	21.37±0.24	0.47±0.01	0.56±0.02	1.19±0.01	12.58±0.24

*n=3

Table 7: Properties of FDT of Carbamazepine

Formulation	Evaluation parameters				
	Thickness Mean±SD* (mm)	DiameterMean±SD* (mm)	Hardness Mean±SD* (Kg/cm ²)	Tablet weight Mean±SD* (mg)	Friability Mean±SD* (%)
F1	4±0.00	8.1±0.1	3.3±0.05	300±0.42	0.87±0.01
F2	4.03±0.05	8.03±0.57	3.4±0.11	300±0.49	0.75±0.022
F3	4.06±0.11	8.1±0.57	3.4±0.05	300.85±0.54	0.90±0.018
F4	4.02±0.06	8.1±0.57	3.1±0.06	300±0.48	0.74±0.023
F5	4.02±0.05	8.1±0.1	3.3±0.08	300±0.37	0.88±0.024
F6	4.01±0.02	8.1±0.57	3.5±0.14	300±0.44	0.72±0.025
F7	4±0.00	8.1±0.01	3.4±0.07	300±0.42	0.69±0.019
F8	4±0.01	8.1±0.01	3.5±0.18	300±0.54	0.67±0.021
F9	4.02±0.02	8.1±0.1	3.5±0.14	300±0.32	0.78±0.014

*n=3

Table 8: Evaluation of FDT of Carbamazepine

Formulation	Evaluation parameters		
	Drug content Mean±SD* (%)	Wetting time Mean±SD* (s)	Disintegration time Mean±SD* (s)
F1	94.44±0.15	63.33±2.51	26.66±1.5
F2	95.87±0.04	52±2	24±1.1
F3	95.24±0.04	48±2.51	25.33±0.57
F4	96.12±0.67	41±1	18.66±1.15
F5	97.37±0.5	37±2.23	16.44±1.5
F6	97.81±0.7	35±2	15.70±0.4
F7	98.56±0.6	24±1	14.75±0.8
F8	99.78±0.8	22±2.28	10.56±1
F9	99.17±0.5	23±1.2	12.27±0.35

*n=3

is fiber like and it shows wicking action also. When it came to powder bed hydrophilicity study, CCS clearly

demonstrated quicker uptake of water compared to GG. Additional study about the viscosity of the solutions would be helpful in understanding the behavior of GG against CCS. These studies are related to the disintegrant powders. For the tablet disintegration time, effect of intrinsic as well as bulk swelling is important and during the compressed state. Wetting times for tablets containing CCS were less than that containing GG. A combination of GG and CCS gave quicker wetting and disintegration possibly due to the combined interplay of the wicking action as well as swell ability. Higher % of disintegrant in tablets led to slowing down of disintegration times because of increasing viscosity that would impede water uptake and subsequent disintegration.

In Vitro Dissolution Study and Kinetics

The dissolution profile of CBZ model drug from FDTs is given Figure 7. The % cumulative drug released (%CDR) varied from 81.06 ± 0.75% to 96.82 ± 0.42%. Formulation F8 gave the highest % CDR. The release data were treated

Table 9: Kinetics of drug dissolution from FDT

Formulation	Zero order		First order		Hixson-crowell	
	R ²	K ₀ (mg/min)	R ²	K ₁ (min ⁻¹)	R ²	K (mg/min)
F1	0.980	3.24	0.999	0.360	0.997	0.079
F2	0.964	3.40	0.994	0.369	0.942	0.085
F3	0.989	3.34	0.979	0.365	0.995	0.082
F4	0.954	3.30	0.992	0.363	0.991	0.077
F5	0.972	3.69	0.999	0.372	0.998	0.079
F6	0.996	3.71	0.932	0.384	0.975	0.080
F7	0.900	3.53	0.924	0.385	0.924	0.091
F8	0.990	3.87	0.995	0.393	0.958	0.120
F9	0.998	3.72	0.915	0.375	0.965	0.11

Table 10: Stability study of F8 at 40±2°C, 75±5% RH for

Days	Hardness Mean±SD* (Kg/cm ²)	Wetting time Mean±SD* (s)	Disintegration time Mean±SD* (s)	Drug content Mean±SD* (%)
Initial	3.5±0.18	22±2.28	10.56±1	99.78±0.8
30 th	3.4±0.26	24±3.35	11.43±1	99.37±0.6
60 th	3.4±0.12	25±1.17	12.32±1	97.24±0.14

*n=3

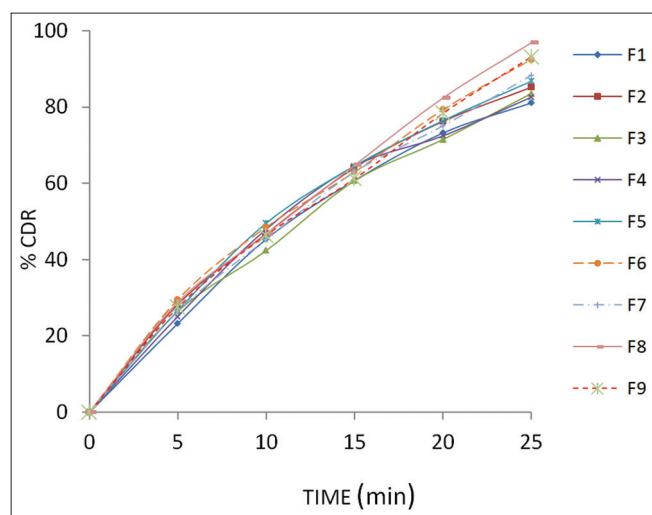


Figure 7: Dissolution profiles of fast dissolving tablets of Carbamazepine

by zero-order, first-order, and Hixson Crowell equation. The data are given in Table 9. From the values of “r²” the coefficient of determination, it can be seen that close for zero as well as first-order release. This may be because of the fast release formulation behavior. The release rate also accordingly is highest for F8 for zero as well as first-order and the R² value is 0.99 for both release kinetics. Based on the R² value, the dissolution method is in agreement with Hixson Crowell model indicated drug dissolution by surface reduction from the disintegrated particles.

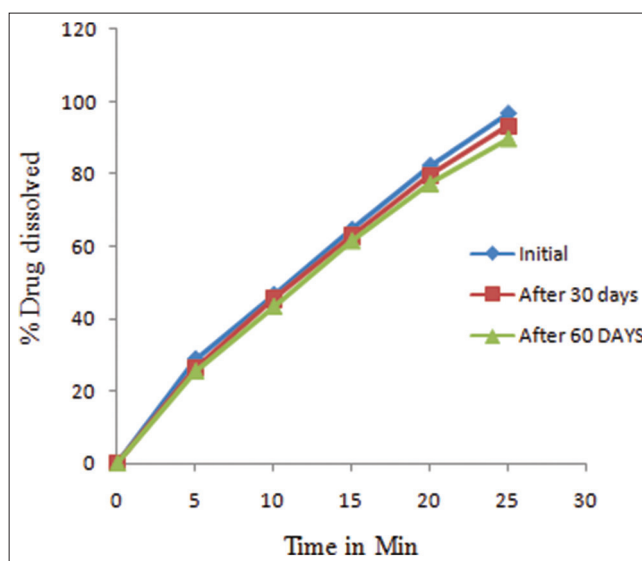


Figure 8: In vitro dissolution profile of F8 after 2 months of stability study

Stability Study

The data from stability study are given in Table 10 and Figure 8. Study was carried out on the selected formulation F8 which showed quickest disintegration and highest drug dissolution. The wetting time and disintegration time increased in 2 months. This change in tablet characteristics also is reflected in the dissolution profile with a mild reduction in the % CDR.

Further study is to be conducted to ascertain the physical stability of the FDT and recommend the storage conditions.

CONCLUSION

CBZ is an agent used in the treatment of epilepsy, trigeminal neuralgia, and acute manic and mixed episode in bipolar disorder. Formulation of FDT for CBZ is a suitable way to improve patient compliance and achieve therapeutic outcome. In the present work, guar gum was explored as a superdisintegrant in comparison with CCS. FDT containing GG were comparable to CCS in providing tablet disintegration within 1–2 min. Combination of natural and synthetic superdisintegrant gave a better disintegration and dissolution of the drug from its FDT.

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CONFLICTS OF INTEREST

The authors declare that they have no conflicts of interest.

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