Pegylated Conjugates Of Microcrystalline Cellulose For Use As Tablet Super-Disintegrants: Development And Evaluation

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Abstract:
In the current study, superdisintegrants for fast-dissolving tablets (FDTs) have been examined using microcrystalline cellulose - polyethylene glycol conjugates. MCC was combined with polyethylene glycol (PEG) 200 and heated in the presence of a catalyst to create the PEGylated conjugate of microcrystalline cellulose (MCC). MCC-PEG conjugates were created, and the powdered conjugates were characterised using micromeritic investigations, FTIR, SEM, and powder XRD techniques. By using FT-IR, the conjugation of MCC and PEG was verified. Conjugate's physical and chemical characteristics were contrasted with MCC. The conjugate was evaluated for water vapour uptake isotherms, maximum water saturation, water penetration rate, disintegration duration, superdisintegration power, and dissolution studies. Through direct compression, the conjugates were employed to create Lurasidone hydrochloride FDTs, and the *in vitro* drug release was assessed. After comparing its results with that of commercial superdisintegrants, it can be concluded that MCC–PEG conjugate can prove to be an excellent superdisintegrant.

Introduction:
Fast disintegrating tablets (FDTs) have gained popularity recently as popular dosage forms because of their quick disintegration in the mouth and quick commencement of action. Pre-gastric FDT absorption in the mouth and oesophagus reduces the amount of medication undergoing first-pass metabolism, improving bioavailability [1, 2]. These dosage forms also provide a number of additional benefits, including accurate dosing, simple mobility, chemical and physical stability, and high patient convenience for elderly, young patients, bedridden patients, psychiatric patients and uncooperative patients [3]. They are frequently described as quick melt, orally disintegrating, melt in mouth, quick dissolve, rapid melt, oro-dispersible, fast dissolve and mouth dissolving tablets. Disintegrants are added to solid oral dosage forms to speed up the compacted mass breakdown and boost medication absorption.
Superdisintegrants, more advanced disintegrants, are currently being researched. Compared to other disintegrants, these substances are used in low concentrations, typically 1–10% of the dosage form's overall weight. Standard super disintegrants like croscarmellose sodium, crospovidone, and sodium starch glycolate are used in a number of formulations [4]. The demand for a shorter disintegration time encouraged ongoing efforts to find new, more effective disintegrating agents. Superdisintegrants are substances that achieve disintegration far more quickly than the commonly used standard disintegrants. The basic modes of action for tablet disintegrants were discovered to be wicking and swelling, while other mechanisms, including deformation recovery, particle repulsion theory, heat of wetting, generation of a gas, etc., may also be involved in specific instances of tablet disintegration [5]. The water uptake induced by capillary forces is one of the most important variables in the disintegration processes of many formulations [6]. Effective tablet disintegration depends on particle's capacity to suck water into the porous network of the material [7].
The exceptional excipients microcrystalline cellulose (MCC) and carboxy methyl cellulose (CMC), which are utilised often as disintegrants in tablet formulations, have undergone numerous alterations to enhance their capabilities as tablet super disintegrants. Another study used the Plackett-Burman design to create improved mouth-dissolving tablets utilising glycine, carboxy methyl cellulose, and sodium alginate. It was discovered that the formulation increased porosity and the ratio of water absorption while reducing disintegration and wetting times [8]. As novel tablet super-disintegrants, chitosan-silicon dioxide [9], starch-silicon dioxide [10], and chitin-metal silicates [11] have been described. Moreover, MCC-SiO_2 and CMC-SiO_2 conjugates were created and utilised in the creation of domperidone FDTs. Microcrystalline cellulose (MCC) is a pure, partially depolymerized form of cellulose that is a white, crystalline powder with no taste or smell and is made up of porous particles. It is offered commercially in a variety of particle sizes and moisture grades with various qualities and uses. The majority of tablet dosage formulations use microcrystalline as a disintegrant. By codrying a suspension of MCC particles and colloidal silicon dioxide, silicified MCC (SMCC) is created, and the dried end product includes 2% colloidal silicon dioxide [12]. According to tableting research, SMCC is

more compactible than ordinary grade MCC, even after wet granulation, and disintegrates more quickly. PEGylation is the word used to describe the process of attaching PEG to any medication, peptide, polymer, or chemical component. In recent experiments, the hydrophilic portions of the resultant moieties were increased by copolymerizing rosin and the hydrophobic polymer polylactide with PEG [13, 14].

In light of MCC's widespread use as a disintegrant and PEG's propensity to increase water intake, MCC was PEGylated in the present investigation. Micro Crystalline Cellulose (MCC) – Polyethylene glycol (PEG) conjugates were prepared and utilized in the preparation of Lurasidone hydrochloride tablets. The micrometric tests were carried out to investigate the flowability of the conjugates and the conjugates were examined using SEM, FTIR, and XRD techniques. Furthermore assessed were the mechanical and drug release properties of Lurasidone hydrochloride FDTs.

Materials:

Signet Excipients Pvt. Ltd, Mumbai, India provided MCC PH 101. Merck Speciality Products supplied the polyethylene glycol-200 (PEG). Hetero Drugs Limited was gracious enough to provide Lurasidone hydrochloride. The remaining components were all of pharmaceutical quality.

Preparation of Microcrystalline Cellulose (MCC) – Polyethylene Glycol (PEG) Conjugate:

Step 1:

8 g of Polyethylene glycol 200 (PEG 200) was introduced to a glass reactor along with a tiny portion of zinc chloride as a catalyst and equivalent moles of strong hydrochloric acid. The mixture was heated for two hours on a water bath at 70°C. The taken PEG 200 quantity in the reactor is half the quantity of microcrystalline cellulose [15].

Step 2:

Preparation of 30% w/v aqueous sodium hydroxide solution:

30 grams of the sodium hydroxide was added to water, stirred well and made up to100 ml of the solution.

Step 3:

Separately, 16 g of microcrystalline cellulose was added to a 30% w/v aqueous sodium hydroxide solution and allowed to swell overnight to reach to its maximum size.

Step 4:

The resultant materials of steps 1 and 3 were slowly combined using a magnetic stirrer assembly with a heater for 10 hours while it was continuously heated to 70°C.The obtained product was added to 100 millilitre of hot water maintained at 70°C. Then it was neutralized to pH 7 by using glacial acetic acid solution. A thorough wash in hot water (70°C) was performed on the product to eliminate any extra acid. Lastly, the product was dried for two hours in an oven set to 80°C.

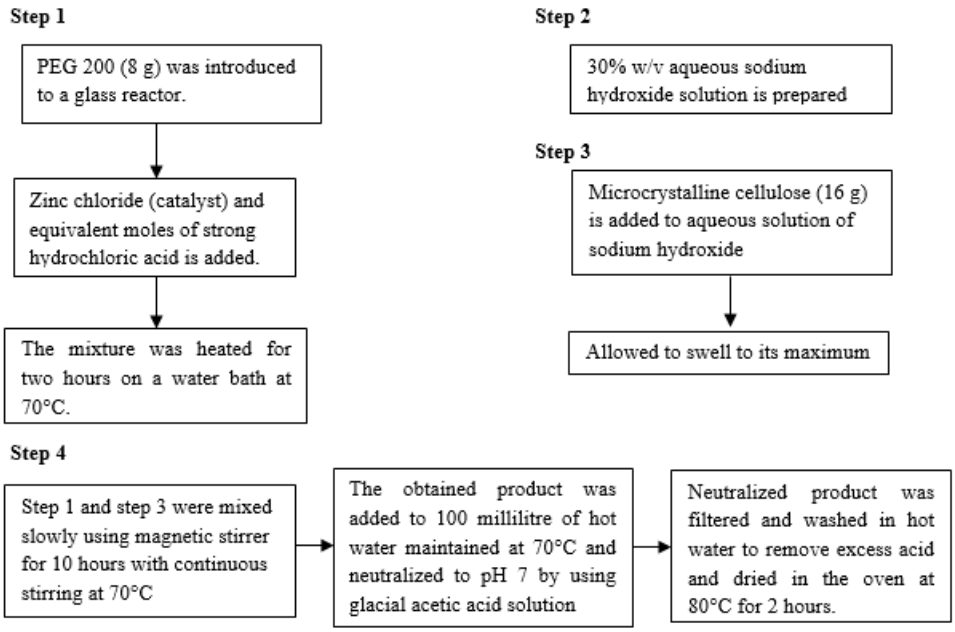


Figure 1: Scheme for synthesis of MCC-PEG Conjugate

Characterization of Microcrystalline cellulose–PEG Conjugate:
Using Fourier transform infrared spectroscopy (FTIR), structural alterations of the MCC-PEG conjugate were identified. Flow properties of the prepared conjugate were studied by determining bulk density, tapped density, angle of repose and compressibility index.

Fourier Transform Infrared Spectroscopy (FTIR):
A Perkin Elmer 2000 FTIR system (Perkin-Elmer, Norwalk, CT) was used to collect the sample's Fourier transform infrared spectroscopy (FTIR) spectra using the KBr disc technique (2 mg sample in 200 mg KBr). The resolution was 1 cm^{-1}, and the scanning range was between 450 and 4000 cm^{-1}. In this method individual samples were ground mixed thoroughly with potassium bromide (1:100) for 3 - 5 mins in a mortar and compressed into disc by applying pressure of 5 tons for 5 min in KBR pellet press. The pellet was kept in the sample holder of FTIR spectrophotometer and scanned. Then the characteristics peaks were obtained of all samples.

Micromeritic Properties:
Angle of repose:
The US Pharmacopoeia provides clear illustrations of this method. 10 g of conjugate were poured down a glass funnel that was 1 inch high from tip to level bench top. The angle of repose was measured as the angle formed by a conical heap and a horizontal plane. The arithmetic mean of three determinations was calculated. Angles of repose values under 30 suggest excellent flow [16].
Angle of repose (θ) = $\tan^{-1}(h/r)$
Where h is height of the heap in cm and r is radius of the heap in cm.
Bulk density and Tapped density:
By pouring around 20 g of the powder into 100 ml glass cylinder, the bulk density was calculated. The powder's mass was then divided by the volume measured to determine its density. The cylinder was tapped 20 times from a distance of 10 cm to determine tap density. Similar to how bulk density was determined, tap density was also determined. The average of three readings was used to calculate densities [17].
Compressibility Index (Carr's Index):
The Carr's index, also known as Carr's Compressibility Index, measures a powder's ability to be compressed. Below mentioned equation was used to compute the compressibility index [18, 19].
% Compressibility Index = (Tapped density - Bulk density) × 100 / Tapped density
The bulk density and tapped density in a free-flowing powder would be close in value, resulting in a low Carr index. On the other hand, the discrepancy between the measured bulk and tapped densities would be greater in a poorly flowing powder where there are more interparticle interactions, leading to a bigger Carr index. A Carr index above 25 is seen as a sign of poor flowability and one below 15 as a sign of high flowability.
Hausner Ratio:
The Hausner ratio is an indirect indicator of a bulk material's capacity to contract under mechanical pressure. Moreover, it measures the interaction between the particles and their capacity for compression. The tapped density divided by the bulk density is how the Hausner ratio is represented.
Hausners ratio = Tapped density / Bulk density
Loss on drying:
Loss on drying (LOD) was used to evaluate whether there were any solvents or moisture in the conjugates. The initial conjugate weight is noted as W1. After heating the conjugate to a temperature of over 100°C for two hours, the cool sample's weight (W2) was noted [20].
As shown in following equation, the percentage loss was calculated:
% Loss on drying = (W1-W2) × 100 / W1

Compaction Studies:
Tablets preparation and Heckle plot:
A single punch tableting machine (KBR pellet press, Karnavati Engineering, India) was used to compress the microcrystalline cellulose and produced MCC - PEG conjugate samples (300 mg) using 13-mm circular punch at compression forces from 10 to 120 kg/cm^2. The following equation was used to calculate the relative densities (R) of the tablets:
Relative density $R = m \div (V_r \times P_s)$
Where P_s is the particle density of solid substance (g/cm^3), Vr is the tablet's volume (cm^3), and m is the mass.
At each stage of compression, compacts were created. The flat-faced punches and the die were treated with magnesium stearate prior to compression. Compact's weight, size, and hardness were all determined. The ratio between the apparent density of the compact and the actual density of the powder was used to calculate the relative density. The data generated using this "ejected tablet approach" was utilised to obtain Heckel plots. Tablet hardness was measured using a Monsanto hardness tester. From this, tensile strength was calculated according to following equation.
Tensile strength $\sigma_t = 2F / \pi Dh$
Where D is the diameter of the tablet, h is its thickness, and F is its hardness. We compared the tensile strength and relative densities.

Compact porosity was calculated according to the following equation:
Porosity $\varepsilon = 1 - \rho$
Where ε is porosity and ρ is relative density. To investigate the compressibility and compatibility of MCC-PEG conjugate, the graph of ln $1/\varepsilon$ vs. pressure was constructed.

Heckel Analysis:

The idea behind the Heckel model was that pore reduction occurs during compression. Porosity is directly related to the degree of compact densification with increasing compression pressure as follows:

$$-\ln \varepsilon = \ln 1/1\text{-}D = KP + A$$

Where K (slope; Heckel coefficient), K is the slope of the straight portion of the graph, reflects the reduction in porosity and A (y-intercept) are regression coefficients of the linear portion of the curve. D is the relative density of the compact, P is applied pressure and ε is porosity.

Water uptake study:

Preparation of saturated salt solutions:

To maintain a range of RHs (0 to nearly 75%) at room temperature, saturated solutions made of salts were utilised. This approach is based on the well-known physical characteristic that equilibrium RHs of particular salt solutions exists. A salt was dissolved in distilled water at the necessary temperature within desiccators to produce saturated salt solutions. A glass rod was used to agitate the solution as salt was added, and salt was continued to be added until only a little amount was left undissolved. The prepared solution was then left in the oven for 24 hours to ensure that it was saturated. Saturated solutions of potassium chloride, magnesium chloride hexahydrate, potassium carbonate, sodium nitrite and sodium chloride are used to produce 11.3%, 32.8%, 43.2%, 64.5% and 75.3% relative humidity respectively at 25°C.

Table 1: Equilibrium relative humidity of saturated salt solutions

Saturated Salt Solution	Relative Humidity (in %) at 25°C
KCl	11.3
$MgCl_2.6H_2O$	32.8
K_2CO_3	43.2
$NaNO_2$	64.5
NaCl	75.3

Sorption Isotherm:

Conjugate and the other three super disintegrants namely, sodium starch glycolate, croscarmellose sodium and crospovidone were stored (5 g of each) in a dessicator after being dried in an oven for 1 hour at 105°C to produce their water sorption isotherms. According to ICH recommendations, superdisintegrants were exposed to various % RH (11.3, 32.8, 43.2, 64.5 and 75.3) at room temperature in the dessicator. After reaching equilibrium, the samples were weighed on a Mettler analytical balance to determine the moisture content. The difference between the sample's final and starting weights indicates how much water was absorbed.

% Water uptake = (Final weight- Initial weight) × 100 / Initial weight

Maximum Water Saturation:

To do this, El-Barghouthi et al approach were applied [21]. At room temperature, conjugate powder was gradually added to the 25 ml of water while being stirred with a magnetic stirrer until the end point of saturation was reached, which was indicated by the development of a solid mass of powder and the absence of additional agitation. By dividing the mass of the added powder by a predetermined amount of water, the maximum saturation power of the conjugate was calculated. Sodium starch glycolate (SSG), croscarmellose sodium (CCS), and crospovidone (CP) were also subjected to this test. The average was computed after each set was conducted three times.

Rate of water penetration:

Conjugate powder (0%, 5%, 20%, and 40% w/w) and microcrystalline cellulose were combined to create the samples. Microcrystalline cellulose was chosen since it does not prevent water absorption due to gelling. Individual samples were added to each graduated cylinder of capacity 50 ml to a predetermined volume without applying pressure to the sample column. To the created MCC conjugate powder mixtures, 25 ml of the sunset yellow solution were added. The rate at which water penetrated the mixture columns (in millilitres per minute) was used to calculate the penetration rate. Furthermore, Sodium starch glycolate, croscarmellose sodium, and crospovidone were subjected to this test.

Scanning Electron Microscopy (SEM):

The S-3700N model scanning electron microscopes from Hitachi High-Tech at an accelerating potential of 10 kV was used to analyse the surface morphology of microcrystalline cellulose and MCC-PEG conjugate by using tungsten as light source.

X-ray diffraction study:
On a Philips powder X-ray diffractometer (equipped with a Philips, PW 1140/90 X-ray generator) employing Ni-filtered, CuK radiation, at 45 KV and 25 mA between 5 and 60° 2θ values with 2° /2 cm/2θ chart speed, X-ray diffraction patterns of powdered materials were captured.

Time of Disintegration:
To ascertain the impact of compression pressures on disintegration time, tablets made from conjugate in accordance with compaction test were subjected to a disintegration test.

Evaluation of conjugate's disintegration efficacy in comparison to commercial superdisintegrants:
This was accomplished by making microcrystalline tablets with different ratios of superdisintegrants that had been carefully blended. For this study, tablets having a weight of 200 mg, a hardness of 4-5 kg/cm^2, and a diameter of 8 mm were created. There were different ratios of each superdisintegrant chosen: 1%, 5%, 10%, 20% and 30%.

Dissolution study:
The model drug lurasidone hydrochloride was made into tablets. Lurasidone hydrochloride (40 mg), microcrystalline cellulose PH-101 (83 mg), mannitol (22.5 mg), sodium saccharin (1.5 mg), disintegrant (1.5 mg), talc (0.75 mg) and magnesium stearate (0.75 mg) are the ingredients in each 150 mg tablet. Direct compression was accomplished to prepare tablets. Except for magnesium stearate and talcum powder, all excipients were previously sieved through 60 mesh, and they were completely and accurately combined for 15 minutes using a plastic bag. The resulting mixture was combined for up to five minutes with the talc and magnesium stearate combination. The powder mixture was then immediately compressed in a 10 station tablet compression machine utilising 8 mm round tooling.

Results and Discussion:
FTIR study:
The IR spectrum of pure microcrystalline cellulose (Fig. 2) exhibits a strong broad band at approximately 3346.62 cm^{-1} attributed to the stretching of the surface hydroxyls in cellulose; the peak at 2908.04 cm^{-1} is associated with the asymmetrically C-H stretching vibration of –CH_2 groups; and the broad absorption at 1060.30 cm^{-1} is associated with the -C-O-C- of cellulose molecule. The band at 1420 cm^{-1} is a result of CH plane deformation. Absorption peak at 1327.83 cm^{-1} is associated with OH bending vibration. Band found at 1371.57 cm^{-1} is associated with C-O stretching vibration of CH_2-OH groups.

Due to PEG's increased number of C-H bonds, the aliphatic stretching band of C-H is bigger and sharper, measuring 2,885.02 cm^{-1}, while the aliphatic ether linkage, CH_2CH_2O, measures 1,229.09 cm^{-1} of the MCC-PEG conjugate (Fig. 3).

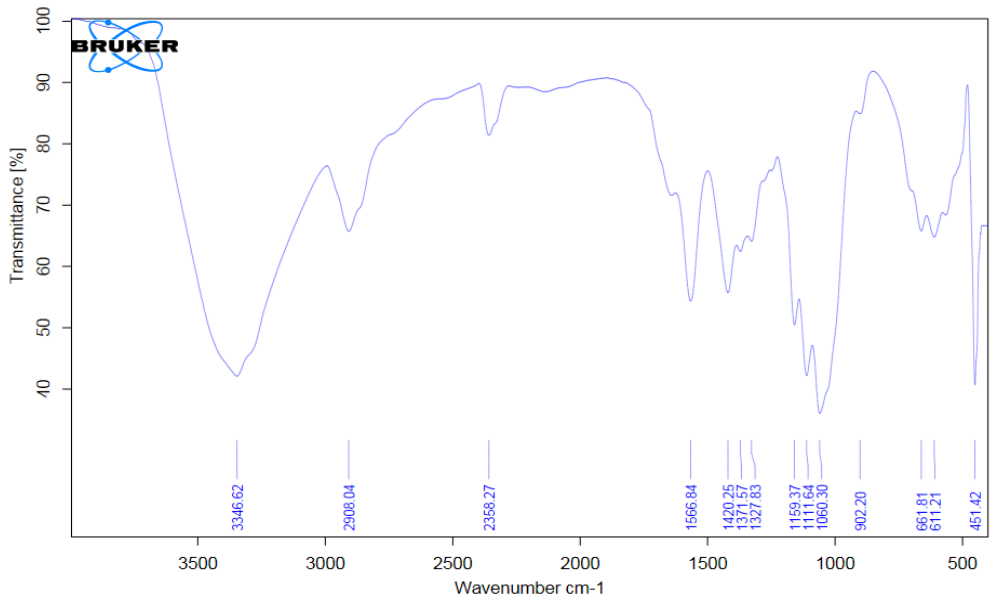


Figure 2: IR spectrum of microcrystalline cellulose (MCC)

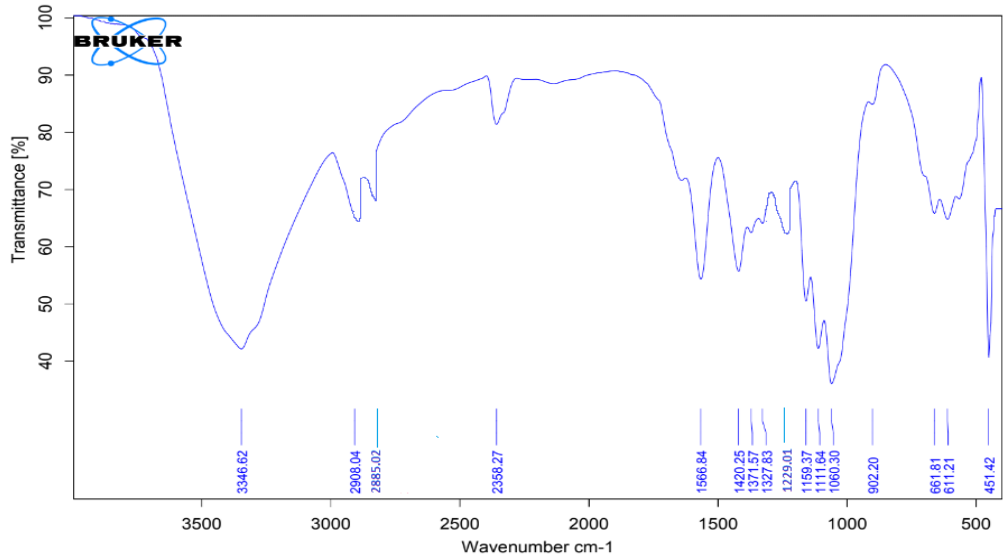


Figure 3: IR spectrum of microcrystalline cellulose – Polyethylene glycol (MCC-PEG) conjugate

Micromeritic properties:

Powder compressibility index was calculated from the measured bulk density of 0.497 g/ml (SD ± 0.0034) and tap density of 0.534 g/ml (SD ± 0.0047). According to the United States Pharmacopeia (USP29 - NF24), the resulting compressibility index was 7.5% (SD ± 0.46), which was classified as an excellent flowable material. The angle of repose measured for MCC-PEG conjugate powder at an average value of 30° (SD ± 0.47) further supported this.

Loss of drying:

MCC-PEG conjugates were found to have a loss on drying of 9.43% ± 0.20.

Compaction study:

Heckles Plot:

Early stages of compression revealed no linearity in the Heckel's plot for MCC or conjugate (Fig. 4). Under lower compression pressure, this was caused by particle rearrangement and fragmentation of bigger aggregates, but as compression pressure increased, the curve seemed to be linear due to plastic deformation. The slope of the Heckel's plot (k) reveals the material's plastic behaviour. A higher slope value denotes a greater degree of flexibility in the substance. The slope of MCC –PEG conjugate was found to be 0.038 (SD±0.0028) is greater than the slope of PEG i.e., 0.0276 (SD±0.03). This shows that microcrystalline cellulose - PEG conjugate can be used as directly compressible material similar to microcrystalline cellulose based on its compressibility and compactability.

Due to the compact's smaller pore size compared to MCC, PEGylation of MCC caused the curve to change to a more compactable form. The superdisintegration activity of the conjugates may be due to the narrow pore size, which encourages quicker disintegration [21].

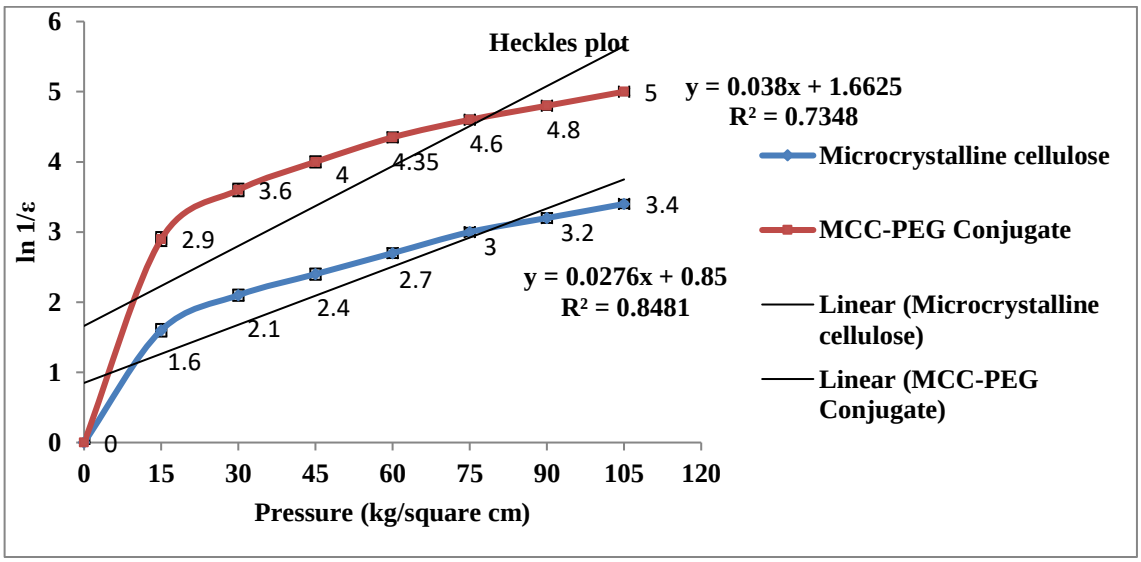


Figure 4: Heckels plot for the tablet incorporating (a) MCC and (b) MCC-PEG Conjugate

Tensile strength:

Fast disintegrating tablet's dimensions, friability, hardness, and tensile strength:

To avoid any variations in the formulation process, all of the rapid dissolving tablets were made under the exact same conditions. The diameter of tablets prepared from MCC and MCC-PEG conjugate ranged from 8.0±0.02 to 8.1±0.03 mm. The thickness ranged between 1.7±0.02 mm and 1.8±0.03 mm for all of the MCC and MCC-PEG conjugate samples. Also, it was discovered that the hardness of MCC and MCC-PEG tablets was in the range of 2.66 Kg/cm^2 and 3.12 Kg/cm^2, respectively. All of the sample's percentage friability was discovered to be less than 1%, indicating sufficient physical characteristics. When compared to pure MCC, the tensile strength of MCC-PEG was shown to be higher. This is because the addition of conjugate during compression causes the particles to move closer to one another, resulting in tighter packing and raising the tensile strength of the tablets. The formulated FDT's diameter, thickness, friability, hardness, and tensile strength are listed in Table 2 along with other characteristics.

Table 2: Size, friability, hardness, and tensile strength values for prepared FDTs containing MCC and MCC-PEG conjugate

Formulation code	Diameter (mm)	Thickness (mm)	Friability (%)	Hardness (Kg/cm^2)	Tensile Strength (MN/m^2)
Conjugate	8.0	1.7 ± 0.02	0.8 ± 0.02	3.12 ± 0.02	1.461
MCC	8.1	1.8 ± 0.03	0.7 ± 0.03	2.66 ± 0.04	1.162

Water vapour sorption isotherm:

Water absorption determines the disintegration power. The moisture sorption isotherms for three super disintegrants and the MCC-PEG conjugate are shown in figure 5. Significant amounts of moisture were sorbed by conjugates as the percentage of relative humidity rose. This is the case with other superdisintegrants, moisture uptake was insignificant at humidity levels below 60%. Due to its ability to prevent humidity from endangering the product's integrity, this attribute makes the material outstanding. At 75% RH however, conjugate absorbed more moisture than the other disintegrants. Conjugate was discovered to be capable of absorbing up to 35% more moisture. Conjugate exhibited its water absorption capacity as a disintegrant under these equilibrium settings.

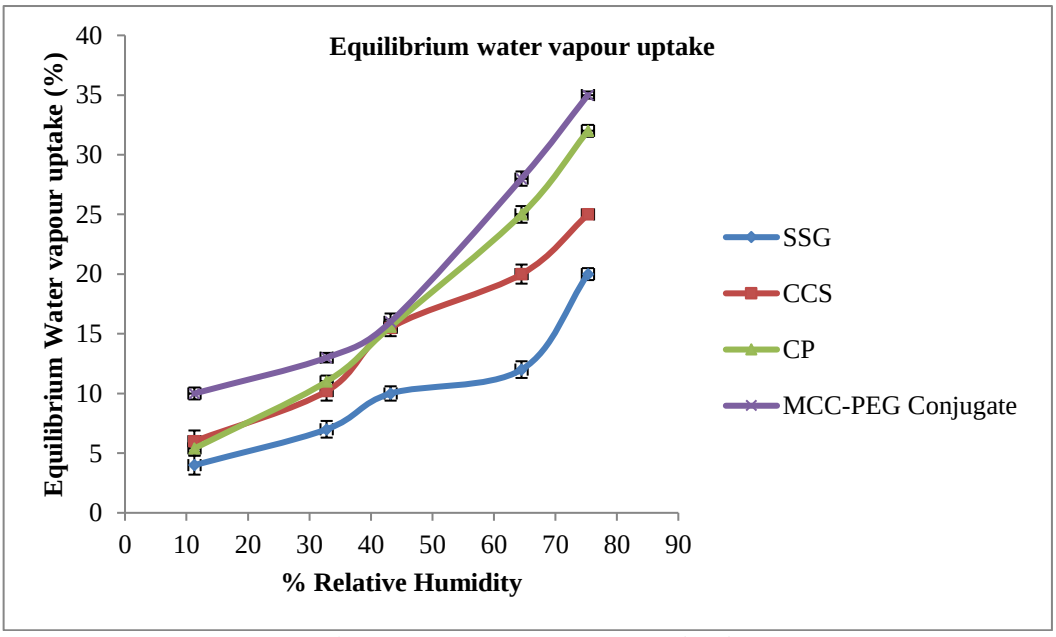


Figure 5: Water vapour sorption (n=3)

Water uptake saturation study:

The entry of water into the tablet matrix becomes inhibited with an increase in the concentration of commercial superdisintegrants i.e., sodium starch glycolate, croscarmellose sodium and crospovidone, which is linked to the production of a gel-like layer that prevents water from moving through the deep layers. In order to create a gel layer, the maximum amount of superdisintegrant that can be added to a specific volume of water must be determined. Figure 6 showed that more water was needed for MCC-PEG conjugate to gel than for other commercial superdisintegrants.

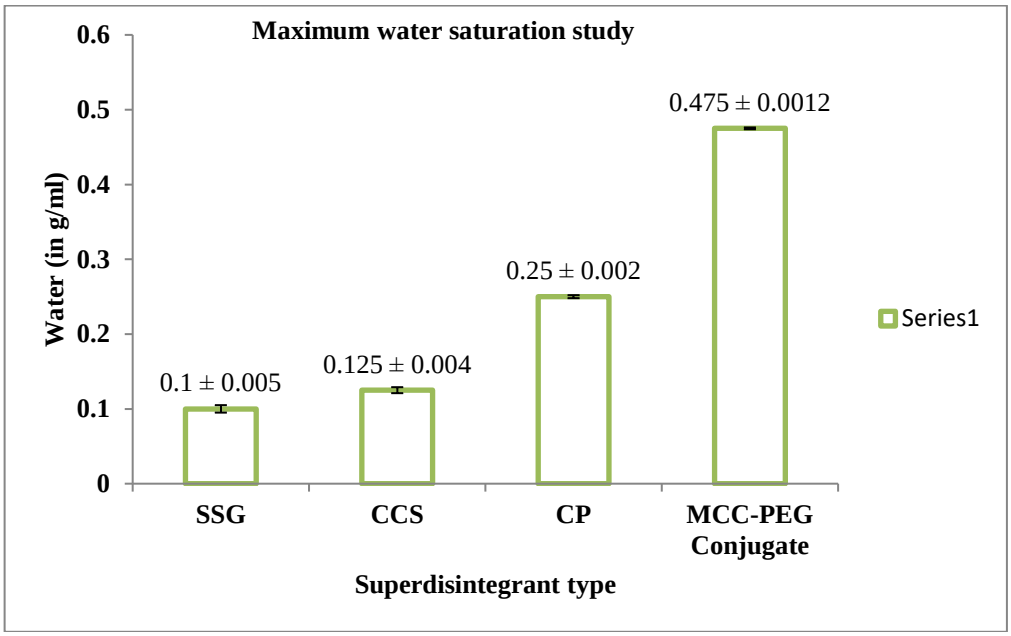


Figure 6: Maximum water required by different superdisintegrants to create a gel layer (n=3)

Rate of water penetration:

This experiment focuses in particular on the way superdisintegrants work. According to Figure 7, Sodium starch glycolate (SSG) and croscarmellose sodium (CCS) demonstrated good penetration within their disintegration limits, but as the amount is increased above that water penetration into the bulk of powder decreases, indicating that the amount of disintegrant in the dosage form affects how well the disintegration action occurs. Crospovidone (CP) shown good water uptake at 5%, but as the concentration was raised, they also demonstrated decreased water uptake. In case of all the three commercial superdisintegrants, as the concentration increases, water penetration rate decreases. Maximum water uptake was demonstrated by MCC-PEG conjugate, and this uptake grew when conjugate concentration was raised. El-Barghouthi et al. reported the same kind of characteristic for the chitosan silica complex [21].

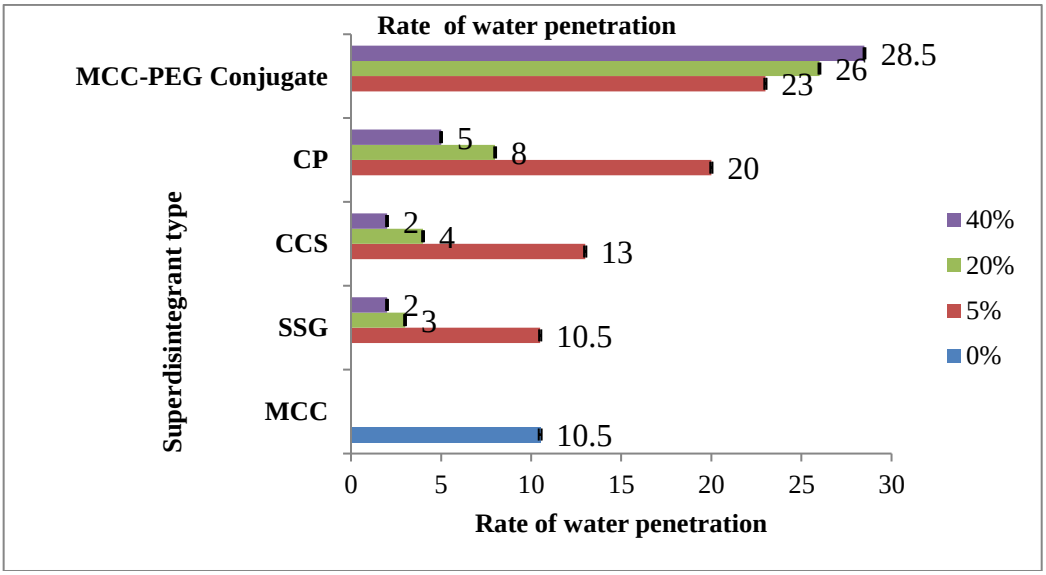
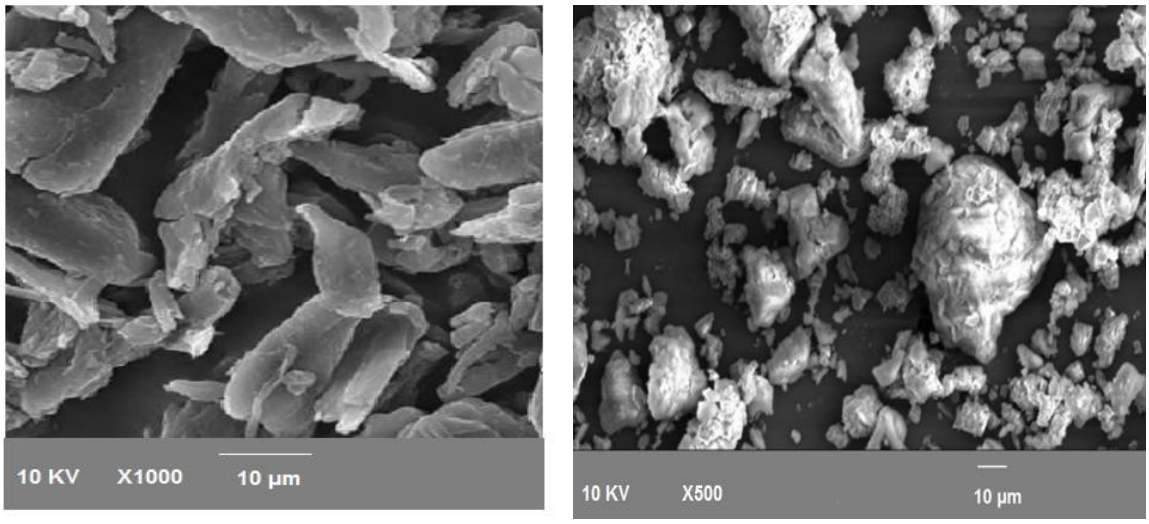


Figure 7: Rate of water penetration (n = 3)

Scanning Electron Microscopy (SEM) Analysis:

MCC's SEM micrographs revealed distinct and unevenly shaped structures. The photos also show unevenly distributed cellulose microfibrils. The microfibrillar structure of the cellulose moiety is broken down into minute fragments during the conjugation of MCC with PEG, increasing the conjugate's overall surface area. When compared to MCC-PEG conjugates, MCC appears to have a non-porous structural appearance. The better tablet super disintegrant property of MCC-PEG conjugates may be attributed to their increased surface area and holes in the surface shape.

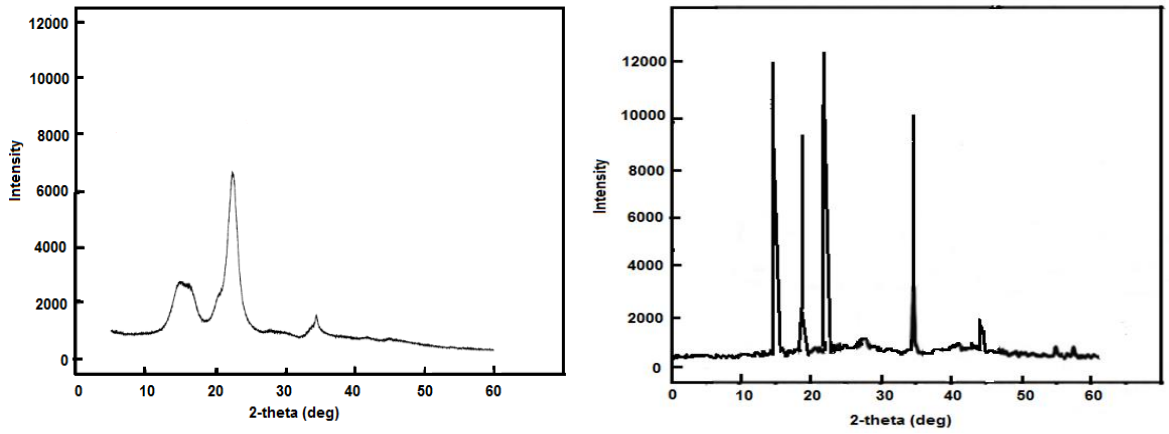


(a) **(b)**

Figure 8: SEM photomicrograph of (a) MCC and (b) MCC-PEG Conjugate

X-ray diffraction:

Figure 9 shows the XRD patterns for MCC and MCC – PEG conjugates. The structure of MCC is shown by the existence of wide peaks at 14.983°2θ, 20.683°2θ, 22.523°2θ and 34.613°2θ. In MCC - PEG conjugates, rather sharp peaks can be seen at 15.602°2θ, 19.312°2θ, 22.412°2θ and 35.123°2θ angles. This corresponds to an increase in crystallinity following modification. The crystallinity of the conjugates is improved by chemically treating MCC with PEG to create the conjugates which shows a rise in the conjugates superdisintegrant activity. This improves the conjugate's ability to hold water, which enhances their effectiveness as tablet super disintegrants.



(a) **(b)**

Figure 9: X-ray diffraction pattern of (a) MCC and (b) MCC-PEG Conjugate

Time of Disintegration:

MCC-PEG Conjugate was as effective as other commercial superdisintegrants at lower levels, but it was more effective at higher levels, which were in compliance with the water saturation and water penetration tests. This was demonstrated by tablets prepared using different proportions of disintegrants. In order to have a fast disintegration, MCC-PEG conjugate has to be used at a concentration greater than 1%.

Dissolution Study:

Studies on tablet dissolution were done on tablets using microcrystalline cellulose as diluent and mannitol for good taste (slightly sweet) and mouth feel. Oral disintegrating tablet containing MCC-PEG conjugate as disintegrant displayed a 90-minute release in full. When compared with formulations containing SSG, CCS, CP as disintegrants, MCC-PEG conjugate containing tablet showed drug release in a fast manner than other super disintegrant containing formulations.
The dissolution rate of orodispersible tablets containing different superdisintegrants followed the order:
MCC - PEG conjugate > Crospovidone > Croscarmellose sodium > Sodium starch glycolate

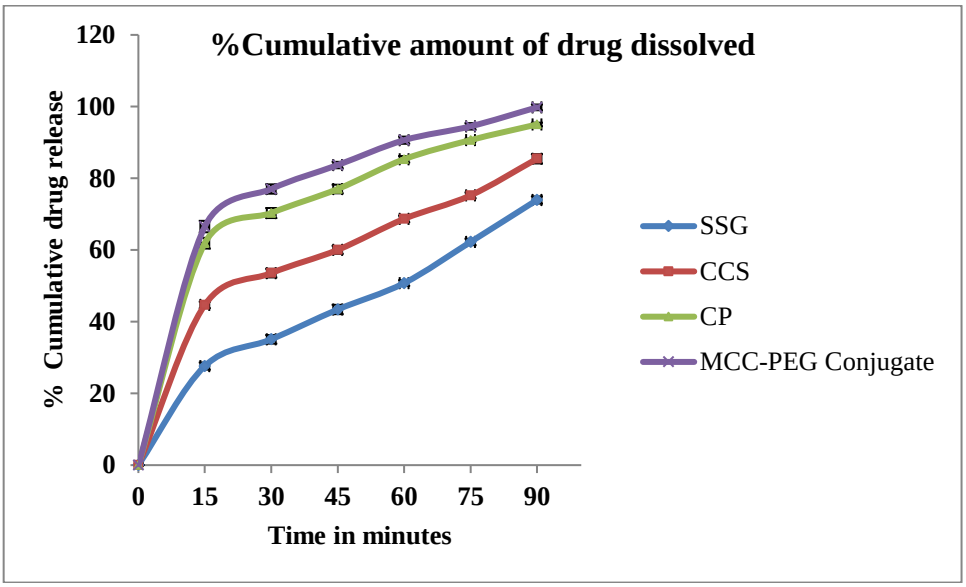


Figure 10: Lurasidone hydrochloride tablets with a 1.0% disintegrant: Dissolution characteristics

Conclusion:

A PEGylated MCC conjugate was created, and MCC's physico-chemical characteristics were contrasted with those of the conjugate. Property differences between conjugate and MCC were found to be substantial. All of the conjugate-containing samples had excellent powder flowability. The conjugates were characterised using FTIR, XRD, and SEM. Intermolecular bridging was visible in the MCC-PEG conjugate's FTIR spectra, which is thought to be a primary factor in the conjugate's quicker disintegration. According to SEM images, the conjugates superdisintegrant and wicking properties were amplified by the fragmentation of cellulose microtubules into minute pieces and the interparticulate gaps. When conjugate was compared with commercial superdisintegrants, all evaluation parameters including water vapour uptake isotherms, maximum water saturation, water penetration rate, disintegration duration, and superdisintegration power showed encouraging results. Over 1% concentration, this conjugate's usefulness as a disintegrant was discovered. MCC-PEG conjugate can therefore be assessed as a superdisintegrant in pharmaceutical formulations, it might be said. We can therefore draw the conclusion that MCC-PEG conjugate can be regarded as a superdisintegrant in pharmaceutical formulations.

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