RESEARCH ARTICLE

Investigation of tablettability and drug release properties of ethyl cellulose

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The purpose of the present research is to investigate systematically the tablettability and drug release properties of ethyl cellulose (EC) in compact form. A total of nine batches of compacts containing metformin hydrochloride (MTF) as model drug and ECs with varying viscosity grades (7, 10, and 100 cps) at 10, 20 and 30% w/w contents were prepared. Profound effect of viscosity grades and content of EC on compression behavior of granules and drug release from compacted matrices was observed. An increase in EC 7 cps content resulted improvement in tensile strength and compactibility. However, compression susceptibility gets inversely affected. EC 7 cps has shown MTF release, which is extended upto 10 hours ($t_{90\%}$), attributed to high interparticulate interactions. Similar trend was observed with both EC 10 cps ($t_{90\%}$; upto 13 hours) and 100 cps ($t_{90\%}$; upto 10 hours). Surprising results were observed for matrices of EC 10 cps at 20% w/w, which showed moderate compactibility and tensile strength, but extended the MTF release for maximum time among all compact formulations ($t_{90\%}$; 13 hours; peppas model). These results show the use of EC 10 cps in formulations desired for extended drug release at its optimum content. Matrices containing EC 100 cps have shown better compressibility and compactibility among all batches. The anomalous behavior of high viscosity EC (at 20% w/w content) matrices releasing drug in shorter time ($t_{90\%}$, 8 hours; zero order) can be ascribed to poor matrixing of MTF in EC network due to high molecular weight of EC 100 cps.

Key words: *Compactibility, compressibility, ethyl cellulose, extended release, metformin hydrochloride*

INTRODUCTION

Ethyl cellulose (EC) has been widely used in design of controlled drug delivery systems, alone, or in combination with other hydrophilic polymers. Mainly, it has been used as a film former in the form of organic or aqueous coating, polymer to design microcapsules, and beads, and matrix former in compaction/tabletting technology.[1-3] The main attractive feature of EC is its inert, compressible and non-toxic nature, hydrophobicity, stability and little affinity for water.[4] As a consequence, it has been exhaustively researched by formulators in the preparation of extended release dosage forms, especially for water soluble drugs. It has been reported that the geometry and structure of the pore network of porous, hydrophobic polymers are responsible for deciding drug dissolution and release process from tablets. In this process drug comes into contact with dissolution medium, where it dissolves and diffuses through media-filled pores.[5,6]

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Previous researchers have studied the compaction characteristics of EC in the presence of some channeling agents,[7] and the effect of various additives on release properties.[8] Additionally, various size fractions (420-840, 250-420, 177-250, 149-177, and 105-149 μm) of EC 10 cps have been studied for compression confirming plastic deformation as the predominant consolidation mechanism.[9] Tablets of pseudoephedrine hydrochloride and lower viscosity grade EC prepared by direct compression have shown sustained drug release attributed to high compressibility of EC and formation of harder tablets.[10] Even solid dispersions of dimenhydrinate with EC in different proportions have shown extended drug delivery tending to zero order release with increase in EC content.[11] Reports state that EC can be considered as a polymer transforming crystalline drug to amorphous form by solid dispersion technique, and simultaneously controlling the release

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of drug. Additionally, several researchers have demonstrated the ability of EC to sustain the drug release.[12-14]

However, effect of different viscosity grades of EC and its quantity on compressibility, compactibility, tensile strength, and drug release have not been systematically investigated till now. Hence, the present study involves preparation of compacts containing varying viscosity grades of EC such as 7, 10, and 100 cps at different contents (10, 20, 30% w/w) and metformin hydrochloride (MTF) as a water-soluble model drug. Prepared EC compacts have been evaluated for pressure-relative density relationship, pressure-tensile strength relationship, Leuenberger equation (compression susceptibility and compactibility) study, and same data was correlated with drug release kinetics from compacts.

MATERIALS AND METHODS

Materials

Colorcon Asia Pvt. Ltd. (Mumbai, Maharashtra, India) supplied EC with % ethoxyl content of 48.0-49.5% (Ethocel Standard 7, 10 and 100 premium grades) as a gift sample. MTF was a kind gift sample from Cipla Pharmaceuticals Ltd. (Mumbai, Maharashtra, India). Magnesium stearate (Research Labs, Mumbai, India); Fumed silica (Aerosil, Research Labs, Mumbai, India); and Lactose (Research Labs, Mumbai, India) were purchased.

Methods

Preparation of MTF-EC granules

Different batches of EC granules (E1 to E9) were prepared as per composition given in [Table 1]. Water was used as a granulating liquid to obtain wet mass, which was further screened through mesh size 600 microns (ASTM #30) and dried at 60°C for 1 hour in a hot air oven. Lactose, magnesium stearate, and aerosil (fumed silica) were added as diluent, lubricant and glidant, respectively.

Pressure-relative density relationship (Heckel Plot)

Dried granules (500±5 mg) of all batches (E1 to E9) were compressed separately using a hydraulic press (Technosearch Instruments, Mumbai, Maharashtra, India) having a 13-mm flat-faced punch and die set at pressures of 1, 2, 3, 4, 5, 6, and 7 tons for 1 min of dwell time. Die and punches were lubricated by 1% w/v homogenous dispersion of magnesium stearate in acetone. After ejection, compacts were allowed to relax for 24 hours at ambient conditions for hardening and elastic recovery to occur.[15]

Pressure–relative density data were subject to Heckel Equation,[16,17]

$$\ln\left(1-\rho_r\right) = KP + A \quad (1)$$

Where, 'ρ_r' is relative density; 'P' is applied pressure in tons; and 'K' is Heckel constant; equal to $1/3s_0$. Where, 's_0' is yield strength; and $3s_0$ as a mean yield pressure (MyP). Constant 'A' expresses densification at low pressure.

Pressure-tensile strength (st) relationship

Input data of Heckel plot was also used for pressure-tensile strength relationship studies. Monsanto-type of hardness tester was used to determine crushing force (F) required to break the compacts. Following equation was used to study the pressure-tensile strength relationship.[18]

$$\sigma_t = \left(2F/\pi Dt\right) \quad (2)$$

Where, 'D' is diameter in mm, 't' is thickness of compacts in mm, and 'F' is force in kg/cm^2 required to break the compacts.

Leuenberger equation

Pressure-tensile strength relationship data was further analyzed by Leuenberger equation[19,20] as given below.

$$\sigma_t = \sigma_{t\max}\left[1-e^{\left(\gamma P \rho_r\right)}\right] \quad (3)$$

Where, σ_t is tensile strength; σ_{tmax}, compactibility; γ, compression susceptibility; *P*, pressure; and ρ_r, relative density.

In vitro drug release kinetics of compacts

Granules (500±5 mg) from all batches (E1 to E9) were compressed separately by using a hydraulic press (Technosearch Instruments, Mumbai, Maharashtra, India) having a 13-mm flat-faced punch and die set at a pressure

Table 1: Formulation composition of EC compacts*

Batch code	Ingredients						Total weight of compact (mg)
	EC 7 cps	EC 10 cps	EC 100 cps	Magnesium stearate	Aerosil	Lactose	
E1	10	-	-	5	5	30	500±5
E2	20	-	-	5	5	20	
E3	30	-	-	5	5	10	
E4	-	10	-	5	5	30	
E5	-	20	-	5	5	20	
E6	-	30	-	5	5	10	
E7	-	-	10	5	5	30	
E8	-	-	20	5	5	20	
E9	-	-	30	5	5	10	

*Each compact contains 250 mg of MTF. Quantities of ingredients are given in %w/w, with respect to total weight (500 mg) of compact

of 2 ton for 1 min of dwell time. Dissolution study was performed in triplicate for every batch (E1-E9) in United States Pharmacopoeia (USP) Type-II dissolution test apparatus (Electrolab, TDT 08L, Mumbai, India). Dissolution medium used was 900 ml of 0.1N HCl for initial 2 hours, followed by phosphate buffer IP (Indian Pharmacopoeia), pH 6.8 at 37.5±0.5°C. Paddle speed was kept constant at 100 rpm.[21] Each time, aliquots of 5 ml were withdrawn at different time intervals and analyzed by UV-Vis Spectrophotometer at 236 nm.[22] Same amount of fresh 0.1N HCl and phosphate buffer IP, pH 6.8 was used to replace the amount withdrawn from respective dissolution media.

RESULTS AND DISCUSSION

Pressure-relative density relationship

MyP shows inverse relationship with ability of a material to deform plastically under pressure. In present study, a higher value of MyP indicates requirement of higher pressure for plastic deformation to occur for compacts containing 7 cps EC in order of E1 > E3 > E2 [Table 2]. Higher resistance offered by batch E1 might be related to augmented inter-particulate interaction.

Furthermore, batches E4 and E5 containing EC 10 cps have shown negligible difference in consolidation ability. However, batch E6 showed higher MyP indicating more resistance for compaction attributed to increased inter-particulate interaction at higher content of EC.

However, linear increase in MyP with 100 cps EC content (E7 < E8 < E9) has been observed, which indicates lower consolidation ability for higher EC content. Table 2 clearly indicates that a higher viscosity EC at maximum content offered highest resistance for compaction among all the batches (E1-E9) attributed to strong inter-particulate interaction and molecular weight (MW).

EC at 10% w/w content showed a linear increase in deformability with EC viscosity attributed to MW of EC. It has been observed that batch E7 have shown highest deformability among all the batches (E1-E9). However, compacts containing 20% w/w of EC have shown greater deformability with intermediate viscosity EC (batch E5) than extreme ones. In case of compacts containing 30% w/w of EC, batch E9 has shown lowest deformability amongst all the batches (E1-E9). However, batches E3 and E6 have shown negligible difference in deformability. It has been revealed that higher viscosity EC have majorly contributed in deciding deformability of EC granules at both lower and higher contents. This indicates that both viscosity and content of EC have profound effect on consolidation ability of compacts [Table 2].

Pressure-tensile strength relationship

It has been observed that tensile strength of 7 cps EC increases linearly with its content as E1 < E2 < E3 [Table 3]. Batch E3 has shown highest tensile strength among all the batches (E1-E9) attributed to high interparticulate bonding.

However, 10 cps EC have shown non-linear relationship between tensile strength, and EC content [Table 3]. Compacts from batch E5 have shown higher tensile strength than batches E4 and E6 containing extreme contents of EC (20 > 30 > 10% w/w). These results indicate that tensile strength of EC compacts not merely depend on viscosity and content of EC but other factors might also be responsible such as physicochemical properties of drug and other excipients added in formulation.

However, 100 cps EC has shown inverse relationship between tensile strength and EC content (E7 > E8 > E9). Batch E9 has shown lowest tensile strength amongst all the batches (E1-E9) as given in Table 3 attributed to lower physical bonding in particles.

EC at constant content of 10% w/w has shown non-linear relationship between tensile strength and viscosity of EC used (batches E1, E4, and E7). Similarly, analogous results have been observed with compacts containing 20% w/w of EC (batches E2, E5, and E8). However, compacts containing 30% w/w of EC have shown linear decrease in tensile strength with increase in EC viscosity. Batches E9 (100 cps EC) and E3 (7 cps EC) containing higher content of EC have shown lowest and highest tensile

Table 2: Compressibility, compactibility, and dissolution data for EC compacts*

Batch no.	Mean yield pressure (MyP)	Compression susceptibility (γ)	Compactibility (σ_{tmax})	Dissolution study		
				R^2	$t_{90\%}$ (mins)	Model fit
E1	2.459±0.31	1.463±0.23	13.65±0.34	0.839±0.11	506.7±2.02	Peppas
E2	1.893±0.23	1.243±0.27	13.36±0.53	0.958±0.02	569.1±4.81	Peppas
E3	2.173±0.23	1.233±0.21	17.30±0.52	0.984±0.01	598.2±2.66	Peppas
E4	1.472±0.20	1.202±0.18	11.42±0.31	0.975±0.01	514.0±5.26	Peppas
E5	1.431±0.18	0.968±0.22	16.09±0.77	0.964±0.01	790.5±4.84	Peppas
E6	2.101±0.29	1.326±0.20	14.14±0.46	0.960±0.03	603.7±6.54	Hixson-crowell
E7	1.040±0.21	0.956±0.23	22.48±1.17	0.946±0.01	519.1±3.49	Zero
E8	2.014±0.19	2.102±1.09	10.61±0.59	0.993±0.00	490.1±4.67	Hixson-crowell
E9	3.639±0.22	3.988±7.16	5.41±0.30	0.963±0.02	596.3±2.98	Peppas

*indicates Average±Standard Deviation (*n* = 3).

Table 3: Tensile strength and porosity data for EC compacts*

Batch no.	Tensile strength (kg/cm²) [Pressure in tons]							Porosity [Pressure in tons]						
	1	2	3	4	5	6	7	1	2	3	4	5	6	7
E1	15.12± 0.21	16.29± 0.51	16.79± 0.62	16.75± 0.22	16.61± 0.62	18.03± 0.85	17.93± 0.44	0.06	4.02	2.24	2.00	1.14	0.64	-
E2	14.27± 0.56	15.54± 0.91	16.23± 0.66	16.96± 0.39	16.93± 0.95	19.18± 0.22	19.74± 0.98	0.04	2.48	1.86	1.59	1.31	0.92	-
E3	19.36± 0.15	20.81± 0.50	22.36± 0.99	24.73± 0.19	24.50± 0.19	25.25± 0.61	25.19± 0.16	0.02	1.58	1.38	1.23	0.34	0.22	-
E4	11.75± 0.95	12.34± 0.78	14.51± 0.91	14.50± 0.46	14.21± 0.48	14.92± 0.53	14.92± 0.58	0.04	3.45	2.51	2.35	0.24	-	-
E5	15.92± 0.54	16.75± 0.52	17.42± 0.90	18.94± 0.57	21.20± 0.65	21.14± 0.48	22.53± 0.79	0.07	1.53	0.91	1.00	0.98	0.58	-
E6	14.17± 0.65	14.98± 0.62	17.34± 0.46	17.86± 0.92	20.31± 0.95	20.12± 0.94	20.10± 0.77	0.01	1.90	2.03	0.29	1.11	0.11	-
E7	17.16± 0.85	17.65± 0.89	15.12± 0.53	17.19± 0.79	17.54± 0.81	17.50± 0.59	17.59± 0.96	0.44	20.02	2.82	1.28	0.31	-	-
E8	13.60± 0.25	14.52± 0.48	12.10± 0.72	14.33± 0.61	15.84± 0.66	16.59± 0.51	16.44± 0.49	0.02	3.13	3.02	1.72	1.27	0.93	-
E9	8.38± 0.69	8.20± 0.55	9.55± 0.81	10.25± 0.88	10.86± 0.54	11.04± 0.55	11.04± 0.33	0.07	4.90	1.82	0.13	0.65	0.003	-

*indicates Average±Standard Deviation (n = 3).

strength among all the batches (E1-E9), respectively. From the present study, it may be clearly understood that higher contents of EC (batch E3 and E9) have majorly contributed in deciding tensile strength of compacts at both lower and higher viscosities. Hence, it can be concluded that both viscosity and content of EC have profound effect on tensile strength of compacts [Table 3]. Therefore, at the time of selection major attention should be given to tensile strength, as tensile strength is one of the key factors responsible for extended drug release. Additionally, inverse relationship between tensile strength and porosity has been confirmed by observed results (E1-E9) where increase in tensile strength decreases porosity as given in Table 3.

During compression, all compacts of batch E9 have shown capping problems which limits the use of viscosity and percentage of EC for compression.

Leuenberger equation

Compression susceptibility and compactibility of EC powder have been studied by Leuenberger equation. Compression susceptibility indicates ability to get compressed, while ability to retain compressed form is referred as compactibility.

At lower content, EC (batch E1) has shown higher compression susceptibility (compressibility) than higher contents [Table 2]. However, 10 cps EC has shown non-linear relationship between content and compressibility (30 > 10 > 20% w/w). Conversely, 100 cps EC has shown a linear increase in compressibility with its content. It has been observed that compacts containing lower (E7) and higher (E9) content of 100 cps EC have shown lowest and highest compressibility amongst all the batches (E1-E9).

Compacts containing EC at constant content of 10% w/w have shown a linear decrease in compressibility with increase in EC viscosity (E1 > E4 > E7). However, EC at 20% w/w content has shown non-linear relationship between compressibility and EC viscosity. Conversely, EC at 30% w/w content has shown linear increase in compressibility with EC viscosity, where highest compressibility amongst all the batches (E1-E9) has been observed with batch E9. These results indicate major contribution of extreme contents in deciding compressibility. Hence, from the present study it can be concluded that both viscosity and content of EC have profound effect on compressibility of granules.

Compactibility of powder material is the ability to remain compressed. In present study, both 7 and 10 cps EC have shown non-linear increase in compactibility with EC content [Table 2]. However, a linear decrease in compactibility with increase in 100 cps EC content has been observed (E7 > E8 > E9). Additionally, 100 cps EC at lower (E7) and higher (E9) content has shown highest and lowest compactibility amongst all the batches (E1-E9), respectively [Table 2]. This highest compactibility of batch E7 might be attributed to high physical bonding between EC particles.

Compacts containing EC at constant content of 10% w/w (batches E1, E4, and E7) have shown non-linear relationship between compactibility and EC viscosity (10 < 7 < 100 cps). Similarly, compacts containing EC at 20% w/w (batch E2, E5 and E8) have shown non-linear increase in compactibility with EC viscosity (100 < 7 < 10 cps). However, compacts containing 30% w/w of EC (batches E3, E6, and E9) have shown a linear decrease in compactibility with increase in EC viscosity (7 > 10 > 100 cps). It has been revealed that higher

viscosity EC (100 cps) has majorly contributed in deciding compactibility of powder, and hence, drug release properties at both lower and higher contents of EC. Therefore, from the present study it can be concluded that both viscosity and content of EC have profound effect on compactibility [Table 2].

Compacts prepared using EC 100 cps at its lower content (E7) has shown lowest resistance for compaction with highest compactibility amongst all the batches (E1-E9) and vice versa for batch E9. Consequently, highest tensile strength and extended drug release was expected from batch E7 but it was shown by batches E3 and E5, respectively.

In vitro drug release kinetics of ec compacts

Previous researchers have reported that the drug release extended upto 24 hours upon increasing the content of EC in tablet coating solution.[23] Additionally, Katikaneni *et al.*[10] have studied EC as the sole direct compression matrix-forming material to deliver a water soluble drug pseudoephedrine hydrochloride. In the present study, viscosity and content of EC, both have shown profound effect on drug release from compacts. The dissolution data obtained were further analyzed by plotting the cumulative % drug release as a function of time to describe MTF release kinetics from EC compacts [Figures 1-3]. It has been observed that viscosity and content of EC have affected drug release greatly in 0.1 N HCl (initial 2 hours). However, in phosphate buffer, MTF release was independent of viscosity and content of EC used. Compacts from batch E7 have shown poor yield strength (MyP, 1.04±0.21), poor compressibility (0.956±0.23), highest compactibility (22.48±1.17), and tensile strength (17.59±0.96 kg/cm^2) as given in Tables 2 and 3. Ideally, maximum extended drug release was anticipated from same batch. However, surprisingly, compacts from batch E5 having lower compactibility (16.09±0.77) and higher tensile strength (22.53±0.79 kg/cm^2) than E7 [Tables 2 and 3] have extended MTF release for maximum time ($t_{90\%}$ > 13 hours) amongst all the batches fitting Peppas model [Figure 2]. Ahmed *et al.*[24] have studied the effect of viscosity grades of EC on indomethacin release and observed that drug release increases with increase in viscosity of EC. From the present study, it can be concluded, that EC at both intermediate viscosity and content can be preferred to obtain compacts with extended drug release for maximum time instead of using higher viscosity EC. However, higher viscosity EC can be preferred to obtain compacts with better compressibility and compactibility. Anomalous behavior of EC compacts containing higher viscosity EC that releases drug in shorter time ($t_{90\%}$ < 10 hours; Peppas model) can be ascribed to poor matrixing of MTF within EC network due to its high MW. The drug release mechanism from EC matrices for all batches was found to be diffusion, erosion and polymer relaxation.

In 0.1 N HCl, a linear decrease in drug release with increase in viscosity and content of EC has been observed. Increasing the content of EC increases number of EC particles and theoretical contact points for interparticulate bonding in

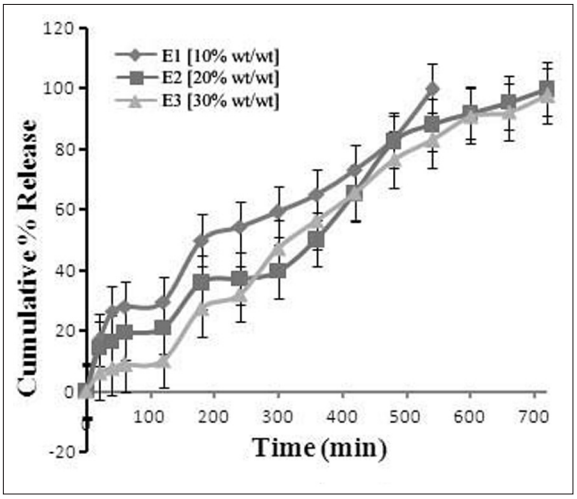

Figure 1: Plot of cumulative % drug release versus time (mins) for EC 7 cps

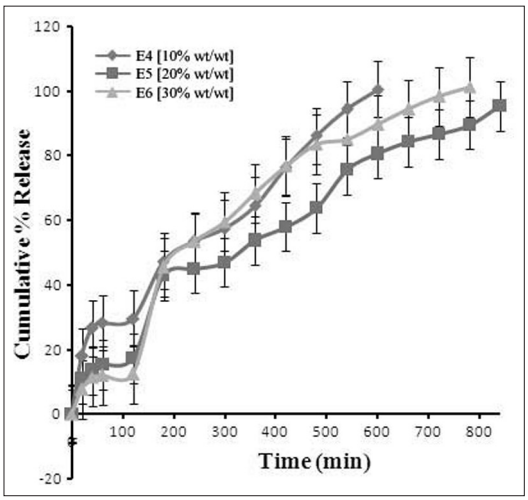

Figure 2: Plot of cumulative % drug release versus time (mins) for EC 10 cps

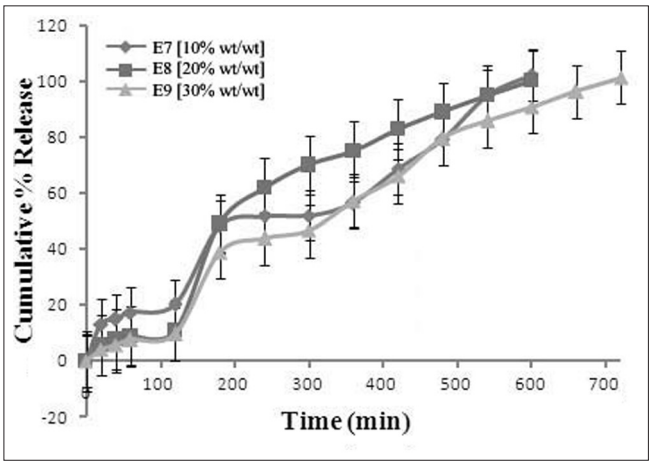

Figure 3: Plot of cumulative % drug release versus time (mins) for EC 100 cps

between EC particles have been observed. This results into increased density and slower initial drug release as seen in the case of batches E3, E6, and E9. Slower initial drug release was attributed to time required for dissolution media to wet the hydrophobic EC matrix and reach the interior of the tablet to diffuse out the drug. It has been observed that as the amount of any viscosity grade EC increased, the rate of drug release decreased respectively due to a greater reduction in drug diffusion into the dissolution media representing greater controlled drug release. According to previous results, highest $t_{90\%}$ value was expected from compacts of batches E7 to E9 containing higher viscosity EC at varying contents.[24] However, amongst all the batches (E1-E9), compacts from batches E8 and E5 have shown lowest (8 hours) and highest (13 hours) $t_{90\%}$ values, respectively [Table 2 and Figure 2 and 3]. This indicates that along with EC viscosity and content, several other physicochemical factors related to drug and other excipients added were also responsible for deciding drug release kinetics.

Dissolution study of 7 cps EC (batches E1, E2, and E3) shows a linear relationship between compactibility and $t_{90\%}$, where increase in compactibility also increases $t_{90\%}$ value and slows down initial rate of drug release [Table 2]. Similarly, linear relationships between compactibility and $t_{90\%}$ have been observed with 10 cps EC (batches E4, E5, and E6), where increase in compactibility also increases $t_{90\%}$ value [Table 2]. However, 100 cps EC has shown nonlinear relationship between compactibility and $t_{90\%}$, where surprisingly batch with lowest compactibility (E9) have shown higher $t_{90\%}$ amongst 100 cps EC batches (E7-E9). This lowest compactibility was found to be responsible for initial drug release at faster rate. However, subsequently it has extended drug release for maximum time amongst 100 cps EC matrices related to improved entrapment of MTF at higher EC content [Table 2]. Like compactibility, tensile strength also shows similar effect on $t_{90\%}$ value [Table 3].

From dissolution study, it has been observed that at lower content 100 cps EC has shown higher $t_{90\%}$ value (E7 > E4 > E1). However, at both intermediate and higher EC contents, 10 cps EC has shown highest $t_{90\%}$ value (10 > 7 > 100 cps). Higher tensile strength, MyP, compactibility, compressibility and hardness of tablets resulted in reduced porosity and slower drug release. Therefore, from the present study it can be concluded that compactibility and tensile strength have majorly contributed in deciding drug release kinetics from EC compacts.

While performing dissolution study it has been observed that compacts containing 10% w/w of any viscosity grade EC disintegrated much faster than those containing higher contents (10 > 20 > 30% w/w) of EC, indicating faster rate of drug release in the initial 2 hours [Figures 1-3]. This could be explained by decreased content of EC, decreases number of EC particles and theoretical contact points for interparticulate bonding in between EC particles. This results in reduced density, tablet hardness and in increased porosity. This will increase the initial drug release rate as observed in case of batches E1, E4 and E7.

However, compacts containing 30% w/w of any viscosity grade EC have shown extended drug release over a longer period of time compared to tablets containing EC at lower content. This was explained by Crowley *et al.*[25] As time proceeds, the pore network increases due to the interconnecting clusters. Interior drug clusters are able to diffuse through this formed pore network. Increasing EC content increases total number of EC particles that leads to reduced formation of drug clusters. This results in development of less extensive pore network, with slower drug release.[25]

CONCLUSION

Present study investigated the effect of viscosity and content of EC on tablettability and drug release kinetics from EC matrix tablets for a water soluble drug MTH. The extent and nature of the effect is dependent on the viscosity and content of EC incorporated in the formulation. The Peppas model was found to be in good agreement with the drug release profiles from EC matrices. It can be concluded that EC at both intermediate viscosity and content can be preferred to extend the drug release over a period of more than 13 hours. Higher viscosity grade EC can be preferred to obtain compacts with better compressibility at higher content and better compactibility and tensile strength at its lower content. The release of MTF from EC tablets followed a matrix-controlled diffusion mechanism. Thus, different release rates can be achieved by modifying the viscosity and content of EC as considered in this study.

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