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Research

Improving Flow and Compression of Natural Polymers for Diclofenac SR Tablets via Co-processing with Microcrystalline Cellulose

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Abstract

The present study aimed to develop and evaluate sustained-release (SR) tablets of Diclofenac Sodium using co-processed excipients via the direct compression technique. To overcome the poor flow properties of natural polymers, three different co-processed excipients were prepared: Guar Gum with Microcrystalline Cellulose (MCC), Sodium Alginate with MCC, and Xanthan Gum with MCC, each in three distinct ratios. Nine formulations (GM1-GM3, SM1-SM3, XM1-XM3) were compressed into 200 mg tablets and evaluated for pre-and post-compression parameters. All formulations exhibited excellent flow properties and produced tablets with acceptable hardness (5.5-6.5 kg/cm²), low friability (<0.31%), and uniform weight. The in-vitro drug release study over 12 hours revealed that the drug release rate was retarded with an increase in polymer concentration and followed the order: Guar Gum > Sodium Alginate > Xanthan Gum. Kinetic modeling indicated that the drug release best fitted the Korsmeyer-Peppas model, with the release mechanism being anomalous transport, a combination of diffusion and polymer erosion. Among all, formulation XM3, containing Xanthan Gum and MCC in a 2:1 ratio, was identified as the optimized formulation. It demonstrated superior tablet hardness (6.5 kg/cm²), the lowest friability (0.22%), and provided a near-ideal zero-order drug release profile (R^2=0.985), achieving 98% drug release in a controlled manner over 12 hours. It was concluded that co-processing Xanthan Gum with MCC produces a robust excipient suitable for directly compressing a highly effective Diclofenac Sodium SR tablet.

Keywords: Sustained release, Co-processed excipients, Direct compression, Drug release, Kinetic study.

INTRODUCTION

Sustained release (SR) drug delivery systems have gained significant attention in modern pharmaceutical research due to their ability to maintain consistent therapeutic levels of drugs over an extended period, thereby improving patient compliance and reducing dosing frequency. Unlike conventional dosage forms, which often require multiple daily administrations, SR tablets release the active pharmaceutical ingredient (API) in a controlled manner, ensuring prolonged pharmacological action and minimizing fluctuations in plasma drug concentration. This approach not only enhances therapeutic efficacy but also reduces side effects associated with peak-trough variations in drug levels. Moreover, SR formulations are particularly beneficial for drugs with short biological half-lives, as they help in achieving a steady-state concentration for optimal therapeutic benefit. Thus, the development of SR tablets remains a vital area in oral controlled drug delivery systems, contributing to improved patient outcomes and better management of chronic conditions[1].

In recent years, the role of excipients in solid dosage formulations has evolved from being inert fillers to functional components that significantly influence the performance and manufacturability of dosage forms. Among these, co-processed excipients have emerged as innovative multifunctional excipients designed to overcome the limitations of individual components. Co-processing involves the physical combination of two or more excipients at the subparticle level without chemical modification, resulting in improved flowability, compressibility, and uniformity of blends. These properties are particularly important in the direct compression technique, which is a preferred method for tablet manufacturing due to its simplicity, cost-effectiveness, and avoidance of moisture or heat exposure. However, the success of direct compression largely depends on the choice of excipients with suitable functional properties. Hence, co-processed excipients offer a promising approach to enhance tablet quality, mechanical strength, and controlled drug release characteristics in SR formulations[2].

Diclofenac sodium[3,4], a non-steroidal anti-inflammatory drug (NSAID), is widely prescribed for the management of pain, inflammation, and rheumatoid arthritis. However, its short biological half-life (approximately 1–2 hours) and frequent dosing requirements often lead to poor patient compliance and gastrointestinal side effects. Therefore, formulating Diclofenac sodium as an SR tablet provides significant therapeutic advantages by maintaining prolonged plasma concentrations, minimizing dosing frequency, and reducing irritation to the gastric mucosa. The direct compression technique, combined with co-processed excipients, serves as an efficient and reliable method for producing high-quality SR tablets of Diclofenac sodium with desirable mechanical and release properties. The present study aims to investigate the influence of co-processed excipients on the formulation and performance characteristics of Diclofenac sodium SR tablets, focusing on optimizing the drug release profile and ensuring robust tablet integrity through direct compression.

METHODOLOGY

Diclofenac sodium (procured from Smithline Beecham), Microcrystalline cellulose, Xanthan gum and Guar gum (purchased from Loba Chemicals, Mumbai).

Fourier Transform Infrared study[5]

FTIR analysis was performed to identify the functional groups present in the drug. The spectrum of the pure drug was recorded using an Agilent CE FTIR spectrophotometer equipped with an Attenuated Total Reflectance (ATR) accessory fitted with a single-bounce diamond crystal at 45°. A small quantity of the solid sample was placed directly on the diamond surface and scanned in the range of 4000–400 cm^{-1} with a resolution of 1 cm^{-1}.

Differential Scanning Calorimetry (DSC)[6]

Thermal analysis of the pure drug, excipients, and formulation mixture was performed using DSC to detect possible drug–excipient interactions. Samples were scanned from 30°C to 300°C at a heating rate of 10°C per minute under a nitrogen purge.

Preparation of co-processed excipients

Table 1: Formulation of Diclofenac sodium tablets

F.Code	GM1	GM2	GM3	SM1	SM2	SM3	XM1	XM2	XM3
Diclofenac	75	75	75	75	75	75	75	75	75
Guar Gum	30	20	40	-	-	-	-	-	-
Sod. Alginate	-	-	-	30	20	40	-	-	-
Xanthan Gum	-	-	-	-	-	-	30	20	40

MCC	30	40	20	30	40	20	30	40	20
Lactose	59	59	59	59	59	59	59	59	59
Mg. Stearate	4	4	4	4	4	4	4	4	4
Talc	2	2	2	2	2	2	2	2	2
Total Wt. (mg)	200	200	200	200	200	200	200	200	200

The preparation of Diclofenac Sodium sustained-release (SR) tablets begins with the creation of co-processed excipients to overcome the poor flow properties of the natural polymers. For this, three distinct types of co-processed mixtures are prepared: Guar Gum with Microcrystalline Cellulose (MCC), Sodium Alginate with MCC, and Xanthan Gum with MCC. Each combination is made in three different ratios, corresponding to the formulations GM1-GM3, SM1-SM3, and XM1-XM3, respectively. The co-processing involves accurately weighing the polymer and MCC, followed by initial geometric mixing and subsequent co-sieving through a #40 mesh sieve. This step is crucial for de-agglomerating the powders and achieving an intimate, homogeneous mixture. The sieved blend is then transferred to a polybag or blender and mixed for an additional 10-15 minutes to ensure uniformity, after which it is stored in an airtight container until ready for use.

Following the preparation of the co-processed excipients, the final tablet blends for each of the nine formulations are manufactured. The process starts with the accurate weighing of all components as per the specified formula: Diclofenac Sodium, the pre-made co-processed excipient, Lactose, Magnesium Stearate, and Talc. The active pharmaceutical ingredient, Diclofenac Sodium, is first mixed with the respective co-processed excipient in a polybag or blender for 10-15 minutes to ensure a uniform distribution of the drug within the polymer matrix. Subsequently, the diluent, Lactose, is added to this mixture, and blending continues for another 10-15 minutes to form a homogeneous powder blend. This initial blend is then passed through a #40 mesh sieve to break any aggregates and ensure a consistent particle size. Finally, the glidant (Talc) and lubricant (Magnesium Stearate) are added to the sieved mixture and blended gently for 2-3 minutes, taking care not to over-mix to prevent negatively affecting the tablet's compressibility and hardness. The final step is the compression of the finished blends into tablets. The lubricated powder blend for each formulation is loaded into the hopper of a tablet compression machine fitted with appropriately sized punches. The machine parameters, such as the filling depth and compression force, are adjusted and set to produce tablets with a consistent target weight of 200 mg and with the desired hardness profile suitable for a sustained-release formulation.

PRE-COMPRESSION EVALUATION[7]

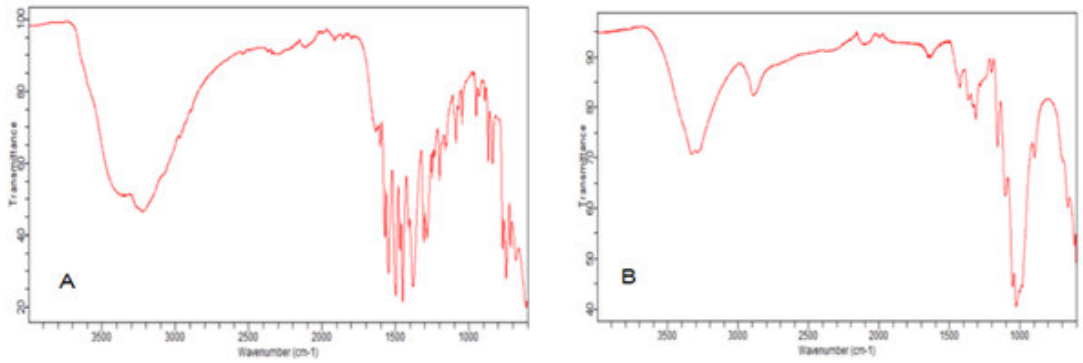
The co-processed excipients were evaluated for Angle of repose, Carr's Index, Hausner's Ratio as per the procedure and the results were compared with the flow properties of individual natural polymers.

POST-COMPRESSION EVALUATION[8.9]

All the prepared tablets were evaluated for Thickness, Diameter, Hardness, Friability and Tensile strength as per the procedure. In addition to the above, the prepared formulations were analyzed for in-vitro dissolution study as follows.

The in vitro dissolution[10] study was performed using a USP Type II (paddle) apparatus containing 900 mL of pH 6.8 phosphate buffer maintained at 37 ± 0.5°C and stirred at 50 rpm. Tablets were placed in the dissolution vessels, and the test was conducted for 8 hours. At 30-minute intervals, 5 mL of the sample was withdrawn and replaced with an equal volume of fresh buffer to maintain sink conditions. The samples were filtered, suitably diluted if necessary, and analyzed using a UV–Visible spectrophotometer at 276 nm.

RESULTS AND DISCUSSION



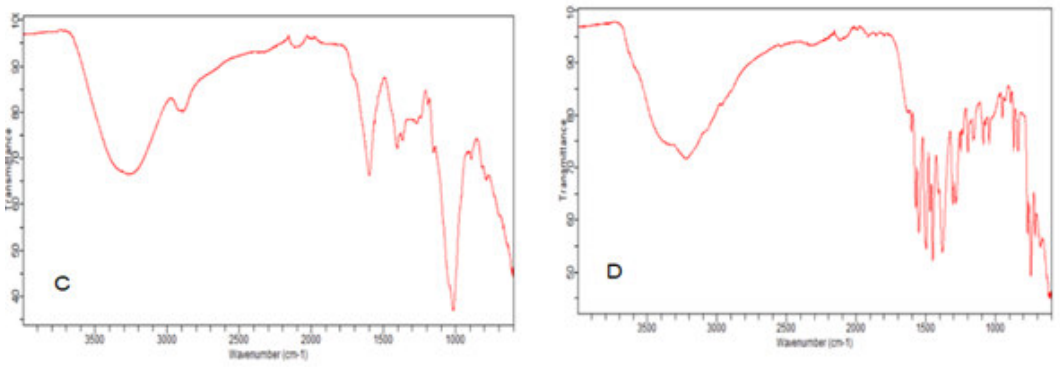


Fig 1: Fourier transform-infrared (FTIR) spectroscopy of (a) Diclofenac sodium (b) Microcrystalline cellulose (c) Xanthan gum (d) Formulation.

The FTIR spectrum of the pure drug Diclofenac sodium confirmed its characteristic functional groups. The spectrum showed a peak at 3386.72 cm^{-1} corresponding to NH stretching of the secondary amine, a peak at 1571.45 cm^{-1} due to C=O stretching of the carboxyl ion, and another peak at 746.90 cm^{-1} indicating C–Cl stretching. The spectrum of Xanthan gum displayed its typical peaks, including an alcoholic O–H stretching peak at 3435.19 cm^{-1}, a peak at 2919.77 cm^{-1} due to symmetric CH_2 stretching, and a peak at 1405.60 cm^{-1} corresponding to CH_2 scissoring. Similarly, the FTIR spectrum of Microcrystalline cellulose (MCC) showed its characteristic peaks at 3333.55 cm^{-1} (O–H stretching), 2893.78 cm^{-1} (C–H stretching), 1051.76 cm^{-1} (C–O stretching), and 659.85 cm^{-1} (O–H out-of-plane bending of the alcoholic group).

From the combined data, it was observed that there were no significant changes in the peaks of the prepared tablet compared to the individual components. This indicates that the drug and excipients were compatible, showing no chemical interaction between them.

Differential Scanning Calorimetry (DSC)

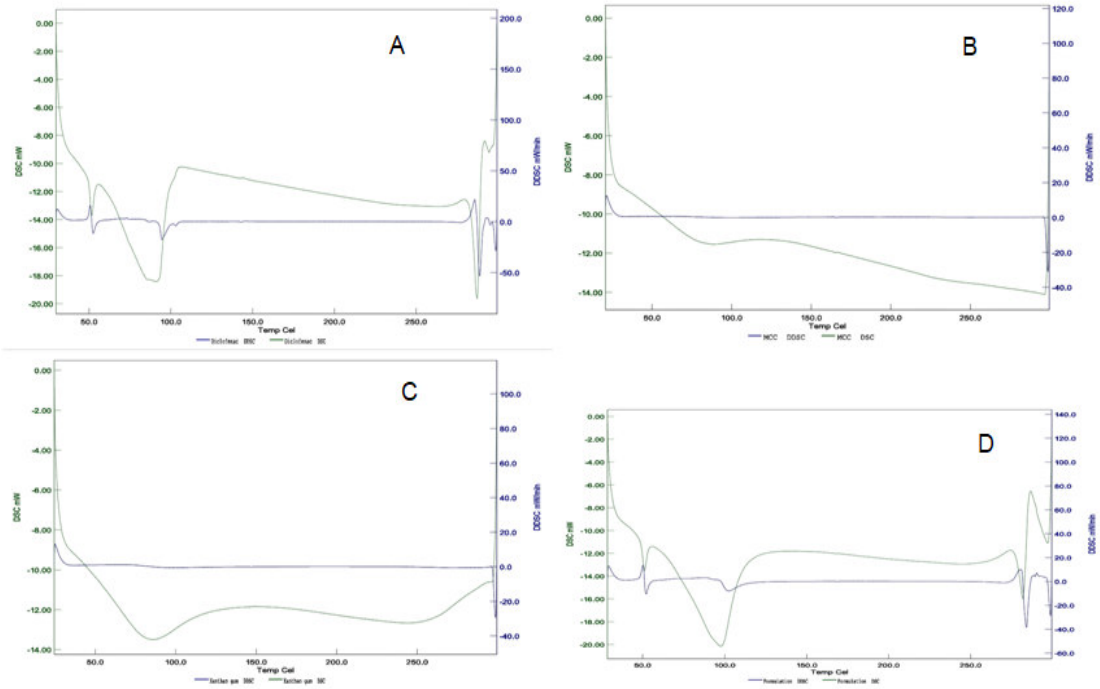


Fig 2: Differential scanning colorimetry of (a) Diclofenac sodium (b) Microcrystalline cellulose (c) Xanthan gum (d) Formulation.

The DSC thermograms of pure Diclofenac sodium, the polymers (Microcrystalline cellulose and Xanthan gum), and the formulated tablet are shown in Figure 2. The pure drug Diclofenac sodium showed a sharp endothermic peak at 287.34°C, corresponding to its melting point. Microcrystalline cellulose exhibited an endothermic peak at 296.51°C, while Xanthan gum showed a peak at 84.81°C. In the formulation, an endothermic peak appeared at 281.90°C, close to the melting point of the pure drug, confirming the presence of Diclofenac sodium. The slight shift in the peak and reduced intensity may be due to the presence of the polymers. This variation suggests a physical interaction between the drug and excipients, rather than any chemical interaction or complex formation.

PRE-COMPRESSION EVALUATION

Flow properties

Flow Properties	Angle of Repose		%Compressibility Index		Hausner's Ratio	
	Value	Inference	Value	Inference	Value	Inference
Guar Gum	58	Very poor	34	Very poor	1.53	Very poor
Sod. Alginate	50	Poor	29	Poor	1.42	Poor
Xanthan Gum	47	Poor	27	Poor	1.38	Poor
Guar Gum + MCC	28	Excellent	9	Excellent	1.08	Excellent
Sod. Alginate + MCC	29	Excellent	8.5	Excellent	1.07	Excellent
Xanthan Gum + MCC	26	Excellent	7.5	Excellent	1.06	Excellent

The flow property evaluation of various polymers and their co-processed mixtures with Microcrystalline Cellulose (MCC) revealed significant improvement in flow characteristics upon co-processing. The individual gums Guar gum, Xanthan gum, and Sodium alginate exhibited poor to very poor flow properties, as indicated by their high angles of repose, elevated Carr's index values, and higher Hausner's ratios. These results can be attributed to their fine particle size, irregular particle morphology, and cohesive nature, which lead to increased interparticle friction and poor packing ability. Consequently, such polymers alone are unsuitable for direct compression tablet formulations due to their poor flowability and compressibility.

In contrast, when these gums were co-processed with Microcrystalline Cellulose (MCC), the resulting mixtures demonstrated a marked enhancement in all measured flow parameters. The angles of repose decreased to below 30°, and both the Carr's index and Hausner's ratio fell within the excellent flow range, indicating substantial improvement in powder flow and packing characteristics. This improvement can be ascribed to the superior flow and compressibility properties of MCC, which act as a diluent and carrier, reducing cohesiveness and improving particle uniformity. MCC's fibrous, porous nature enhances interparticle bonding while mitigating the sticky and cohesive tendencies of the gums.

The study confirms that co-processing gums with MCC effectively overcomes the inherent flow limitations of natural polymers, producing powders with enhanced flowability and compressibility suitable for direct compression tablet formulations. The results justify the use of co-processed excipients as multifunctional carriers capable of improving the manufacturing performance and uniformity of sustained release tablet systems.

POST-COMPRESSION EVALUATION

Table 1: Evaluation Parameters for Diclofenac Sodium SR Tablets

Formulation Code	Thickness (mm)	Diameter (mm)	Hardness (Kg/cm²)	Friability (%)	Tensile Strength (N/cm²)
GM1	3.97	7.97	5.7	0.28	350.75
GM2	3.96	7.96	5.5	0.31	300.50
GM3	3.98	7.98	6.0	0.25	400.25
SM1	3.95	7.97	5.8	0.29	365.80
SM2	3.97	7.96	5.6	0.30	320.15
SM3	3.99	7.98	6.2	0.24	450.60
XM1	3.96	7.97	6.1	0.26	425.40
XM2	3.98	7.98	6.3	0.23	475.80
XM3	**3.99**	**7.99**	**6.5**	**0.22**	**500.50**

The post-compression evaluation of the nine formulated Diclofenac Sodium SR batches revealed that all tablets exhibited physical and mechanical properties within the acceptable pharmacopoeial standards, thereby validating the effectiveness of the direct compression technique using the various co-processed excipients. The

consistency in physical dimensions—thickness (3.95 - 3.99 mm) and diameter (7.96 - 7.99 mm)—across all formulations indicates excellent flow and uniform die filling of the powder blends. This minimal variation is a direct result of the improved flow properties imparted by co-processing the natural polymers with Microcrystalline Cellulose (MCC), which was a primary objective of the formulation strategy. The consistent dimensions are crucial for ensuring dosage uniformity and for subsequent packaging processes.

Regarding mechanical strength, the hardness and friability data demonstrate the successful formation of robust tablet matrices. The hardness values ranged from 5.5 to 6.5 Kg/cm², all of which are sufficient for SR tablets to withstand handling. More importantly, the friability for all batches was well below the 1% limit, ranging from 0.22% to 0.31%, indicating a very low tendency for the tablets to chip or break apart. A clear trend can be observed where formulations with a higher polymer-to-MCC ratio (the "3" series: GM3, SM3, XM3) generally exhibited superior mechanical properties compared to their counterparts. This is because polymers like Guar Gum, Sodium Alginate, and Xanthan Gum are excellent binders and gel-forming agents that, when present in higher proportions, contribute significantly to the cohesive strength of the tablet.

A deeper insight into the tablet's structural integrity is provided by the tensile strength data, which is a critical parameter independent of tablet size. The values, ranging from 300.50 to 500.50 N/cm², confirm the trends seen in hardness and friability. Among the polymer series, the Xanthan Gum-based formulations (XM1, XM2, XM3) consistently showed higher tensile strength compared to the Guar Gum and Sodium Alginate series at equivalent ratios. This superior performance can be attributed to Xanthan Gum's unique rheological properties and high binding efficiency, which create a stronger and more resilient inter-particulate bond within the tablet matrix upon compression.

The formulation XM3 emerged as the unequivocally optimized batch. It consistently demonstrated the best results across all key parameters: it possessed the maximum thickness (3.99 mm) and diameter (7.99 mm), the highest hardness (6.5 Kg/cm²), the lowest friability (0.22%), and the highest tensile strength (500.50 N/cm²). This optimal performance is a direct consequence of its specific composition—a co-processed excipient of Xanthan Gum and MCC in a 2:1 ratio. This ratio appears to create a perfect synergy, where the high concentration of Xanthan Gum provides exceptional binding and gel-forming capacity for sustained release, while the MCC ensures the blend remains compactible and free-flowing enough to form a mechanically superior tablet. Therefore, the XM3 formulation is identified as the most promising candidate for further development and scale-up studies.

In-vitro drug release study

Table 2: In-vitro Drug Release Profile of Diclofenac Sodium SR Tablets

Time (Hrs)	GM1	GM2	GM3	SM1	SM2	SM3	XM1	XM2	XM3
0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
1	28.5	25.2	22.1	26.3	23.5	20.8	24.0	21.0	18.5
2	45.6	41.0	37.5	42.8	39.0	35.2	39.5	35.8	32.0
3	60.2	55.1	50.8	56.5	52.5	48.0	52.5	48.5	44.0
4	72.5	67.0	62.5	68.2	64.0	59.2	63.8	59.5	54.8
5	82.0	77.0	72.5	77.8	73.8	69.0	73.2	69.0	64.5
6	89.5	85.0	80.8	85.5	82.0	77.5	81.0	77.2	73.0
8	96.8	94.5	91.2	94.0	91.8	88.5	90.5	88.0	85.2
10	99.5	98.8	96.5	98.5	97.2	94.8	95.8	94.0	92.0
12	-	-	99.0	-	99.5	98.5	98.5	97.5	98.0

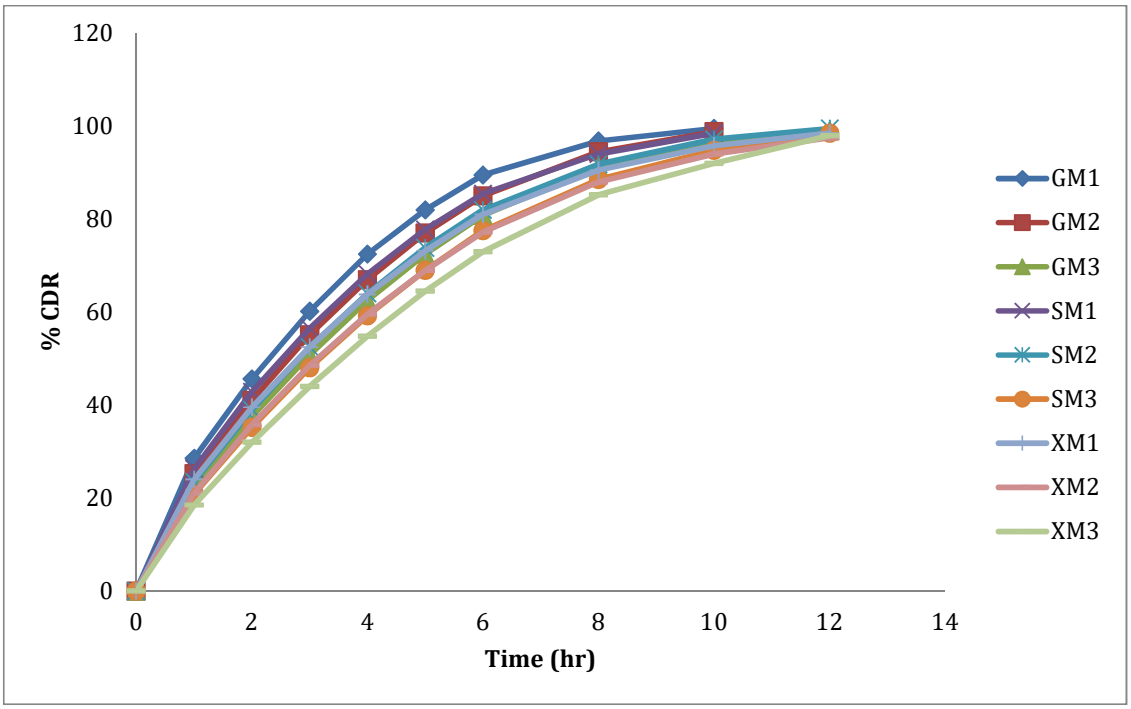


Fig 3: In-vitro Drug Release Profile of Diclofenac Sodium SR Tablets

The in-vitro dissolution study clearly demonstrates that all co-processed excipients successfully created sustained-release formulations of Diclofenac Sodium over 12 hours. However, significant differences in the drug release patterns were observed based on the type and concentration of the natural polymer used, confirming the initial hypothesis.

A direct correlation between polymer concentration and drug release retardation is evident across all polymer series. For instance, in the Guar Gum series, GM3 (40 mg gum) released the drug much more slowly than GM1 (30 mg gum), with GM1 completing its release by 10 hours, while GM3 took 12 hours. This pattern is consistent for the Sodium Alginate (SM1 vs. SM3) and Xanthan Gum (XM1 vs. XM3) series. The higher polymer concentration forms a denser and more viscous hydrogel layer around the tablet, which acts as a stronger barrier, thereby slowing down the diffusion of the drug and resulting in a more prolonged release profile.

Furthermore, the data unequivocally confirms the order of drug release as Guar Gum + MCC > Sodium Alginate + MCC > Xanthan Gum + MCC. At every equivalent ratio (e.g., GM1 vs. SM1 vs. XM1), the Xanthan Gum-based formulations showed the slowest release. This can be attributed to the superior gel-forming ability and higher viscosity of Xanthan Gum at low concentrations compared to Sodium Alginate and Guar Gum. Xanthan Gum forms a strong, pseudoplastic gel that is highly resistant to erosion, providing a more effective and consistent barrier for controlled drug release.

The optimized formulation, XM3, exhibited a near-ideal sustained-release profile. It provided a slow, consistent release throughout the 12-hour period, achieving approximately 98% drug release at the end of the study. Its release profile was found to follow Zero-Order Kinetics, as indicated by a linear plot of cumulative drug release versus time. This is the target release pattern for SR formulations, as it ensures a constant amount of drug is released per unit time, leading to stable plasma concentrations and reduced dosing frequency. The combination of a 2:1 ratio of Xanthan Gum to MCC in XM3 created an optimal matrix that effectively controlled the drug release through a combination of diffusion and erosion mechanisms, making it the most promising formulation for a once-daily or twice-daily dosage regimen.

Kinetic Analysis

Table 3: Drug Release Kinetics of Diclofenac Sodium SR Tablets

Formulation Code	Zero Order (R^2)	First Order (R^2)	Higuchi Model (R^2)	Korsmeyer-Peppas (R^2)	Korsmeyer-Peppas ('n' value)
GM1	0.912	0.865	0.982	0.991	0.601
GM2	0.928	0.852	0.978	0.993	0.632
GM3	0.945	0.831	0.972	0.995	0.658
SM1	0.925	0.858	0.979	0.992	0.617
SM2	0.938	0.843	0.975	0.994	0.645
SM3	0.958	0.821	0.968	0.996	0.671
XM1	0.935	0.846	0.976	0.993	0.639
XM2	0.951	0.827	0.970	0.995	0.665
XM3	**0.985**	0.784	0.955	**0.998**	**0.715**

The analysis of the drug release kinetics provides crucial insight into the mechanism by which the drug is released from the different polymeric matrices. The regression coefficient (R^2) values reveal the model that best fits the drug release data. For all formulations, the R^2 values for the Korsmeyer-Peppas model are the highest (all above 0.99), indicating it is the most appropriate model to describe the release mechanism. This is followed by the Higuchi model ($R^2 > 0.955$), which suggests that diffusion plays a significant role in the drug release process. The high and progressively increasing R^2 values for the Zero-order model across the series, culminating in the excellent fit (0.985) for the optimized XM3 formulation, confirm the successful design of a constant, time-independent release system. Conversely, the lower R^2 values for the First-order model indicate that this model is a poor descriptor for these formulations.

The Korsmeyer-Peppas 'n' value is used to characterize the specific drug release mechanism. For a cylindrical tablet matrix, an 'n' value of approximately 0.45 indicates Fickian diffusion, 0.89 indicates Case-II transport (relaxation), and a value between 0.45 and 0.89 indicates anomalous (non-Fickian) transport, which is a combination of both diffusion and polymer relaxation/erosion. In this study, all 'n' values fall within the range of 0.60 to 0.72, confirming an anomalous transport release mechanism. This means drug release is controlled by both the diffusion of the drug through the swollen gel layer and the relaxation/erosion of the polymer chains themselves. The 'n' value systematically increases with higher polymer concentration and is highest for the Xanthan Gum series, with XM3 showing the highest value (0.715). This signifies that its release is the most controlled and has a greater contribution from the polymer relaxation mechanism, consistent with the strong, viscous gel formed by Xanthan Gum, which aligns perfectly with its ideal zero-order release profile.

CONCLUSION

This study successfully demonstrates that co-processing natural polymers with Microcrystalline Cellulose (MCC) is a viable and efficient strategy for the direct compression of Diclofenac Sodium sustained-release tablets. The systematic formulation and evaluation confirmed that the co-processed excipients significantly improved the powder flow and compressibility, leading to the production of mechanically strong tablets. The in-vitro dissolution and kinetic analysis provided critical insights, establishing that both the type and concentration of the polymer are pivotal in controlling the drug release rate. Xanthan Gum was found to be the most effective polymer in forming a robust gel matrix that prolonged drug release. The formulation XM3, with a Xanthan Gum to MCC ratio of 2:1, emerged as the optimal formulation. It consistently exhibited excellent physico-mechanical properties and, most importantly, a drug release profile that closely followed zero-order kinetics, which is ideal for maintaining stable plasma drug levels. Therefore, the co-processed excipient of Xanthan Gum and MCC in a 2:1 ratio presents a promising approach for the development of a once or twice-daily sustained-release Diclofenac Sodium tablet, offering a simple manufacturing process and enhanced therapeutic efficacy.

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