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Original Research Article

Design and Evaluation of Once-Daily Sustained-Release Diclofenac Sodium Matrix Tablets Using Xanthan Gum

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Abstract: The present study describes the formulation and evaluation of sustained-release matrix tablets of diclofenac sodium using xanthan gum as a natural release-retarding polymer. Diclofenac sodium is a non-steroidal anti-inflammatory drug with a relatively short plasma elimination half-life, making controlled drug release a useful formulation objective. Nine matrix formulations (F1–F9) were developed with a fixed dose of diclofenac sodium and progressively varied xanthan gum concentrations, together with HPMC and other formulation excipients. Preformulation characterization included physicochemical assessment, UV spectrophotometric analysis, FTIR compatibility testing and differential scanning calorimetry. The analytical method showed a λmax of 276 nm in phosphate buffer pH 6.8 and a calibration relationship of Y = 0.0303x with R^2 = 0.9983. Granule flow and tablet properties were evaluated by standard parameters including angle of repose, bulk/tapped density, compressibility, hardness, friability and drug content. Swelling increased with time and polymer level, supporting the role of hydrated polymer matrices in controlling drug diffusion. In-vitro dissolution was performed in phosphate buffer and the release profiles were fitted to zero-order, first-order, Higuchi and Korsmeyer–Peppas models. The thesis identified F3 as the selected formulation and reported satisfactory physical quality, drug content and sustained release behaviour. Stability evaluation of F3 for three months at 37 ± 2°C/72 ± 5% RH showed no major visual change, while hardness, drug content and 10-h drug release remained within the reported ranges. The findings support xanthan gum as a useful natural polymer for development of sustained-release diclofenac sodium matrix tablets.

Keywords: Diclofenac Sodium, Xanthan Gum, Matrix Tablet, Sustained Release, Hydrophilic Polymer, Dissolution Kinetics, Korsmeyer–Peppas.

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1. INTRODUCTION

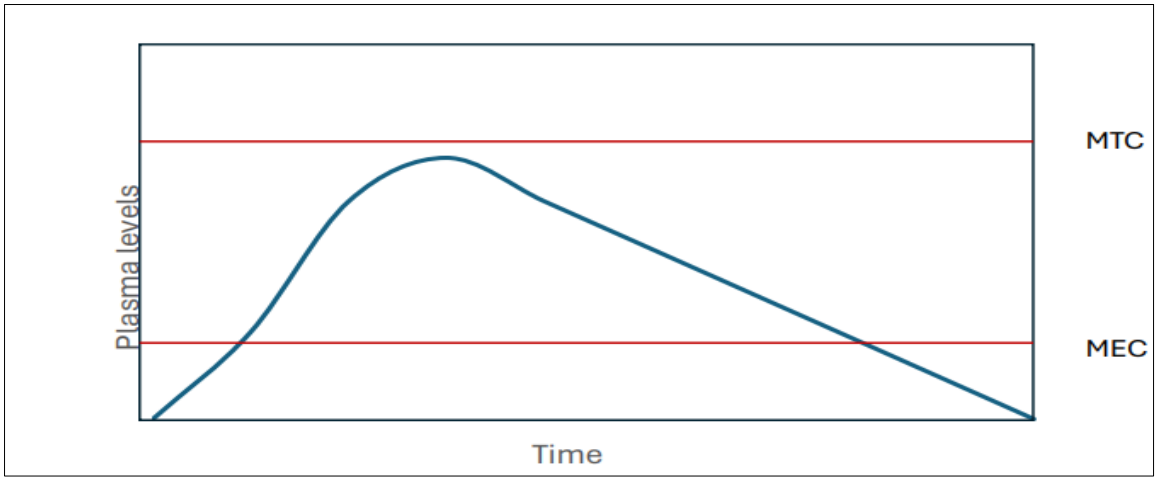
Oral sustained-release drug delivery systems are designed to modify the rate at which an active pharmaceutical ingredient becomes available after administration. Conventional immediate-release dosage forms can produce relatively rapid changes in drug concentration and may require repeated administration, particularly when the drug has a short biological half-life. Matrix systems provide a comparatively simple approach for controlling release because the drug is dispersed within a polymeric structure and is liberated through processes such as hydration, diffusion and matrix erosion [1, 2].

Diclofenac sodium is an NSAID used for analgesic and anti-inflammatory therapy. The thesis describes its plasma elimination half-life as approximately 1–2 h and notes that therapeutic effects may persist longer than the circulating drug concentration. Such pharmacokinetic characteristics provide a formulation rationale for exploring sustained-release delivery [3, 4].

Hydrophilic polymers are widely used as matrix-forming agents. When exposed to aqueous medium, they hydrate and may form a viscous gel barrier around the dosage form. Drug molecules then move through this hydrated barrier by diffusion, while polymer relaxation and erosion can also contribute to release. The extent and rate of hydration depend on polymer concentration, polymer properties, drug–polymer ratio and formulation processing variables [5-8].

Xanthan gum is a microbial polysaccharide produced commercially by fermentation involving Xanthomonas species. Its hydrophilic nature, viscosity-building ability and swelling behaviour make it relevant to oral controlled-release formulations. The thesis literature review describes xanthan gum as a natural, biocompatible polymer capable of forming a hydrated matrix that can retard drug release [9-12].

Previous work cited in the thesis has investigated xanthan gum alone or in combination with other polymers for sustained-release formulations. Studies involving diclofenac sodium have reported that polymer concentration, matrix structure and hydration influence the release profile. These observations provided the basis for evaluating a systematic series of xanthan gum-containing diclofenac sodium matrix tablets in the present work [13-16].



Graph 1: Conceptual representation of the rationale for sustained drug release. Insert the corresponding original thesis figure at this location

2. Formulation Rationale

Matrix technology is one of the established approaches for sustained drug delivery because it can be manufactured using conventional pharmaceutical processing equipment and can accommodate hydrophilic, hydrophobic or combined polymer systems. In hydrophilic matrices, contact with dissolution medium produces polymer hydration and gel formation, creating a diffusional barrier. The release profile can therefore be altered by changing polymer concentration and the relative contribution of diffusion and erosion [5, 6].

Xanthan gum has attracted interest as a natural matrix former. The thesis review cites work showing that xanthan gum exhibits swelling, viscosity and pseudoplastic characteristics and can be incorporated into oral matrix systems. The hydration of xanthan gum may increase the diffusional path length and thereby reduce the rate at which a soluble drug escapes from the matrix [9-12].

For diclofenac sodium, sustained release may be useful because repeated administration can be associated with fluctuating drug concentrations. Literature summarized in the thesis includes studies in which xanthan gum-based matrices were used to modulate diclofenac sodium release. Yeole *et al*., reported the design and evaluation of xanthan gum-based sustained-release matrix tablets of diclofenac sodium, while Billa *et al*., investigated xanthan gum matrices using gastrointestinal transit and dissolution approaches [13, 14].

Other cited studies have examined the effect of polymer blends, drug-to-polymer ratio and compression variables on diclofenac release. These studies collectively indicate that formulation composition is an important determinant of

hydration, matrix integrity and drug liberation. The present thesis therefore investigated nine formulations with progressively different xanthan gum levels while retaining diclofenac sodium at 50 mg per tablet [15-18].

2.1 Formulation Strategy

The formulation series was designed to compare the influence of xanthan gum concentration on matrix performance. HPMC, ethyl cellulose, PVP, talc and magnesium stearate were also included in different proportions. According to the thesis formulation table, F1–F9 contained 50 mg diclofenac sodium per tablet, while xanthan gum increased from 15 mg in F1 to 90 mg in F9. The formulation designated F3 contained 35 mg xanthan gum together with 18 mg HPMC and the other excipients specified in the thesis [19].

Table 1: Original thesis formulation composition should be inserted here without changing the reported quantities

Ingredients	Formulation(mg/tablet)								
	F1 D:X(1:0.25)	F2 D:X(1:0.5)	F3 D:X(1:0.75)	F4 D:X(1:1)	F5 D:X(1:1.25)	F6 D:X(1:1.50)	F7 D:X(1:1.75)	F8 D:X(1:2)	F9 D:X(1:2.25)
Diclofenac sodium	50	50	50	50	50	50	50	50	50
HPMC	20	20	18	18	15	15	12	12	12
Xanthan gum(mg)	15	30	35	45	50	55	60	75	90
Ethyl cellulose	207	167	117	17	07	207	167	117	17
Polyvinyl pyrrolidine	75	75	80	85	85	100	120	120	130
Isopropyl Alcohol	Q.s.	Q.s.	Q.s.	Q.s.	Q.s.	Q.s.	Q.s.	Q.s.	Q.s.
Magnesium sterate	5	5	4	4	3	3	3	2	2
Talc	2	2	2	3	3	3	3	4	5

2.2 Working Hypothesis

Increasing the concentration of xanthan gum was expected to increase hydration and matrix resistance and thereby modify the rate of diclofenac sodium release. At an appropriate polymer level, the matrix should provide prolonged release without compromising tablet integrity or drug content uniformity [6-16].

3. MATERIALS AND METHODS

3.1 Materials

Diclofenac sodium was used as the model drug. Xanthan gum was employed as the principal natural release-retarding polymer. HPMC, ethyl cellulose, polyvinylpyrrolidone, talc, magnesium stearate and isopropyl alcohol were used as formulation excipients/process materials as described in the thesis. The complete source-wise material list was provided in the thesis and should be retained in the final manuscript according to the actual laboratory records [19].

3.2 Preparation of Matrix Tablets

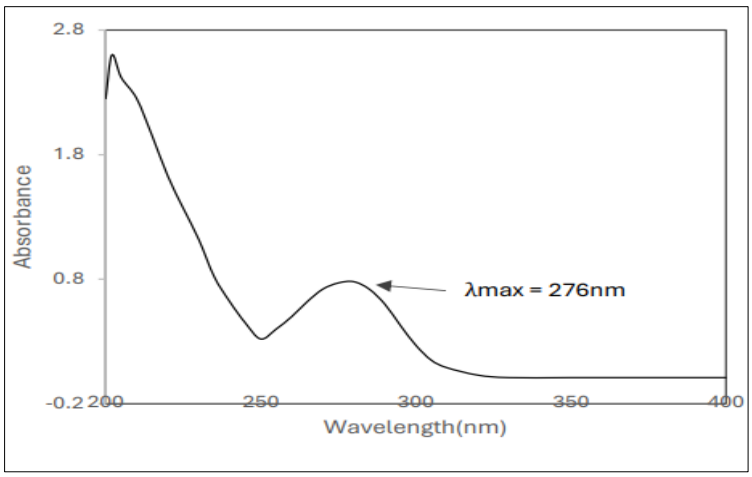
The thesis describes preparation of diclofenac sodium matrix tablets using a formulation-dependent processing approach. Required ingredients were weighed and passed through suitable sieves, blended to achieve uniformity and processed for tablet manufacture. Magnesium stearate was incorporated as lubricant. The prepared material was compressed into matrix tablets. The thesis also describes wet granulation as a process option, including preparation of a PVP-containing binder solution in isopropyl alcohol, wet massing, drying and screening before lubrication and compression [19].

The tablet preparation described in the thesis used a target tablet weight around 350 mg and compression with a rotary tablet machine. Because the source thesis contains some internally inconsistent statements concerning direct compression, wet granulation, punch size and tablet weight, the manuscript should be finalized against the laboratory batch record before journal

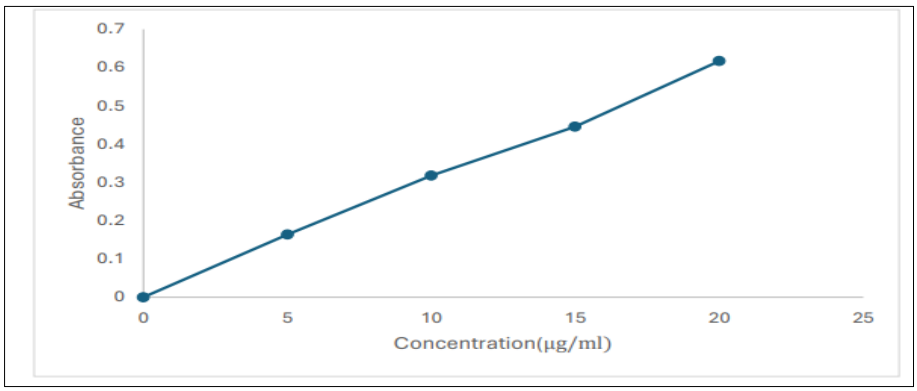
submission. No unreported processing condition has been added here.

3.3 UV Spectrophotometric Method

Diclofenac sodium was scanned in the UV region using phosphate buffer pH 6.8. The thesis reports a maximum absorption wavelength of 276 nm. Standard solutions were prepared over the reported concentration range and absorbance was measured to construct the calibration curve. The calibration relationship reported in the results section was Y = 0.0303x with R^2 = 0.9983 [19].



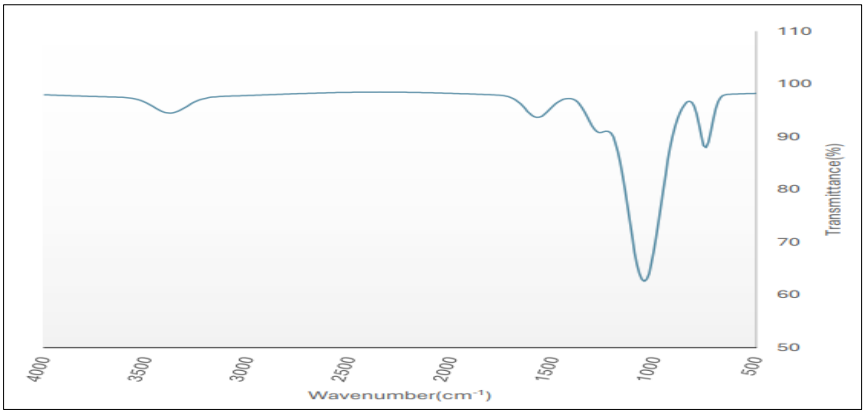
Graph 2: UV absorption spectrum of diclofenac sodium



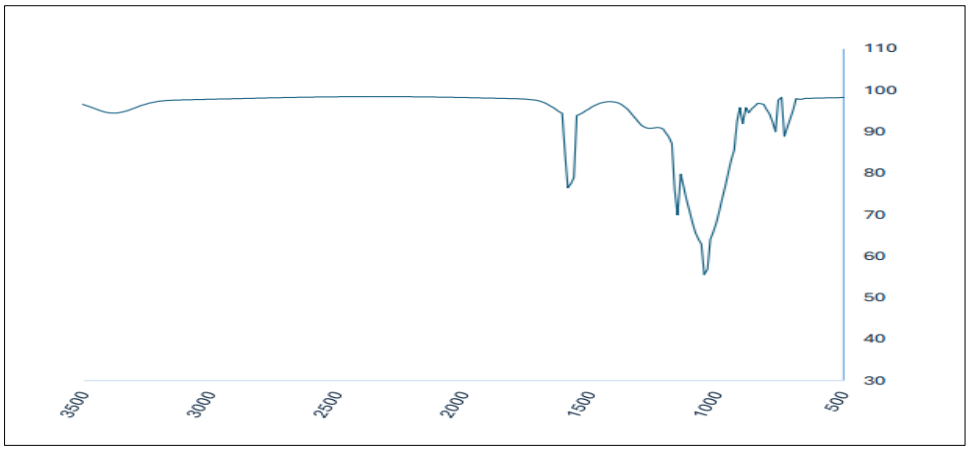
Graph 3: Calibration curve

3.4 Drug–Excipient Compatibility

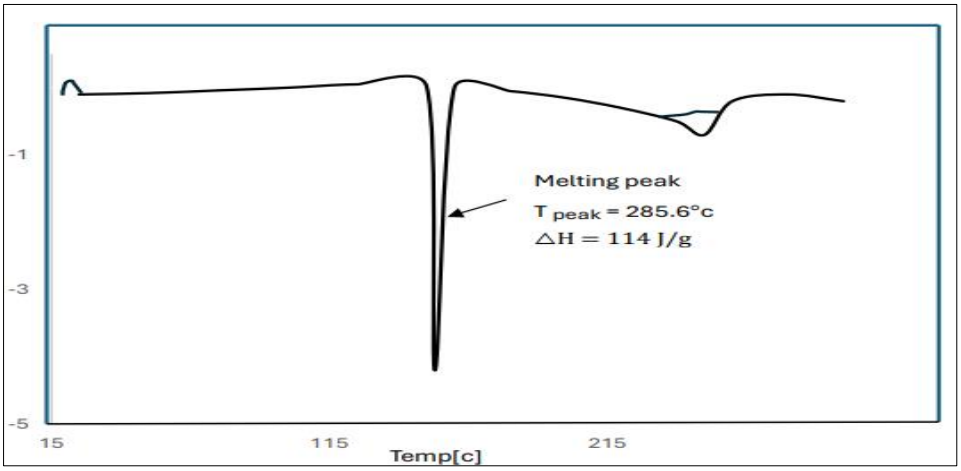
Compatibility between diclofenac sodium and the selected polymer system was evaluated using FTIR spectroscopy. The thesis reports that characteristic peaks remained present in the formulation spectrum without appearance/disappearance of peaks suggestive of a major chemical interaction. DSC was also used to compare the thermal behaviour of diclofenac sodium with the drug–polymer combination [19].



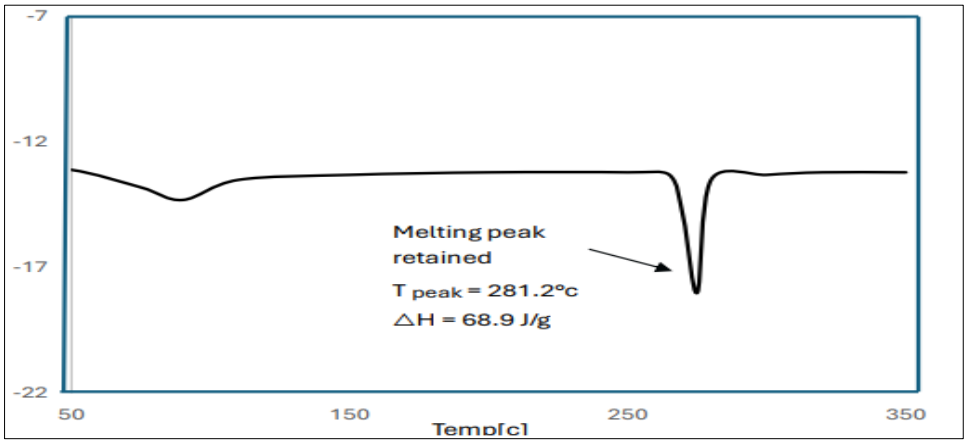
Graph 4: FTIR of diclofenac sodium



Graph 5: FTIR of optimized formulation



Graph 6: DSC thermograms]

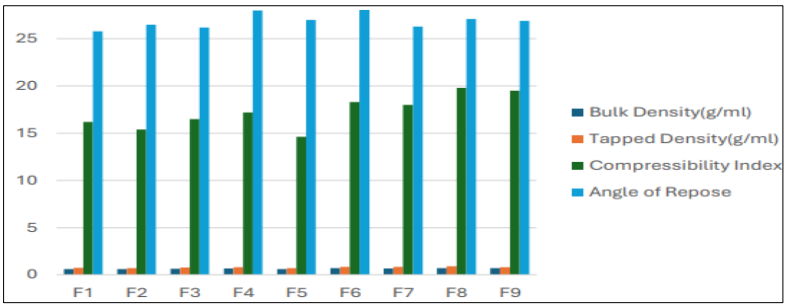


Graph 7: DSC thermograms]

4. Evaluation Methods

4.1 Pre-Compression Evaluation

The thesis evaluated granules using angle of repose, bulk density, tapped density and compressibility index. These parameters were used to characterize flow and packing behaviour before compression. For F1–F9, the reported angle of repose ranged from 23.69° to 30.23°, while compressibility values ranged from 12.17% to 20.50%. F3 showed an angle of repose of 27.10°, bulk density of 0.519 g/mL, tapped density of 0.599 g/mL and compressibility of 13.51% [19].



Graph 8: Pre-compression parameters of F1–F9

4.2 Tablet Evaluation

The prepared tablets were evaluated for weight variation, hardness, friability and drug content. The thesis reports average tablet weights close to the target, friability values below 1% for all listed batches, hardness values varying among formulations and drug content values between approximately 96 and 100%. F3 showed a reported weight of 0.352 ± 0.005 g, friability of 0.81%, hardness of 13 kg/cm^2 and drug content of 98.28% [19].

Table 2: Evaluation data for physical parameters of matrix tablets

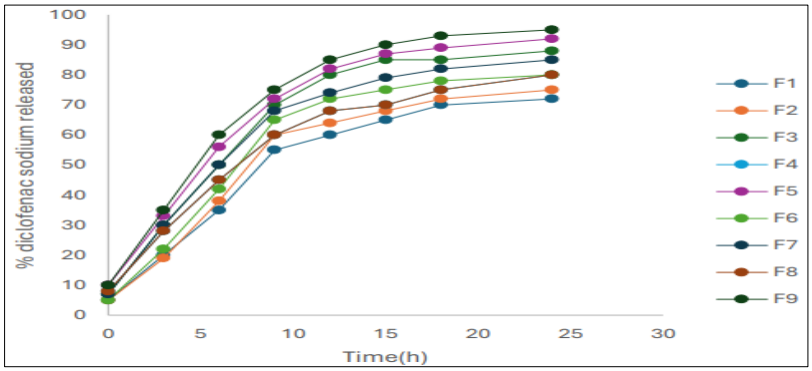
S.No	Formulation Batch	Weight Variation test(mg)	Friability (%)	Hardness (Kg/cm^2)	Drug Content(%)
1	F1	0.351 ± 0.005	0.83	7.9	96.42
2	F2	0.345 ± 0.004	0.76	12.2	98.86
3	F3	0.352 ± 0.005	0.81	13	98.28
4	F4	0.350 ± 0.006	0.65	10.5	99.70
5	F5	0.339 ± 0.005	0.72	8.1	96.92
6	F6	0.355 ± 0.004	0. 82	8.9	97.97
7	F7	0.347 ± 0.005	0.69	12.5	99.21
8	F8	0.354 ± 0.004	0.77	12.1	98.80
9	F9	0.352 ± 0.005	0.74	12.2	97.82

4.3 Swelling Study

Swelling was assessed by determining the increase in tablet weight after hydration. The thesis used the expression: swelling index (%) = [(Mt − M0)/M0] × 100, where Mt is tablet weight at time t and M0 is the initial tablet weight. F3 showed swelling values of 45%, 82%, 118%, 156%, 192%, 228%, 251%, 268%, 279% and 285% at 1, 2, 3, 4, 5, 6, 7, 8, 10 and 12 h, respectively [19].

4.4 *In-Vitro* Dissolution

The thesis reports dissolution testing using phosphate buffer, controlled temperature and rotational speed, with periodic sampling and replacement of medium. Samples were analyzed spectrophotometrically at 276 nm and cumulative percentage drug release was calculated. The dissolution dataset in the thesis is reported for F1–F9 at 0, 3, 6, 9, 12, 15, 18 and 24 h in pH 6.8 phosphate buffer [19].



Graph 9: *In-vitro* drug release profiles of F1–F9

5. RESULTS

5.1 Preformulation and Analytical Characterization

The thesis describes xanthan gum as an off-white to light-coloured, faintly odorous material with measurable moisture and ash content. The reported loss on drying was 7.6%, total ash was 2.95%, pH was 6.5, angle of repose was 28.90°, bulk density was 0.58 g/cc, tapped density was 0.67 g/cc, Hausner's ratio was 1.28 and Carr's index was 21.74%. These observations established the basic physical characteristics of the polymer used in the matrix system.

Diclofenac sodium showed a reported aqueous solubility of 20.6 mg/mL in the thesis. UV analysis gave a λmax of 276 nm in phosphate buffer pH 6.8. The calibration curve demonstrated a high linearity with R^2 = 0.9983, supporting the use of the UV method for the dissolution analysis performed in the study.

The DSC thermogram of diclofenac sodium showed a melting peak at 285.6°C with ΔH of 114 J/g. In the drug–xanthan gum combination, the thesis reports retention of the melting peak at approximately 281.2°C with ΔH of 68.9 J/g. FTIR comparison likewise did not indicate a major incompatibility between drug and polymer.

5.2 Granule and Tablet Properties

All nine formulations demonstrated measurable flow and packing characteristics suitable for processing. F3 had a comparatively low reported compressibility value of 13.51%. The post-compression results showed that F3 had 0.81% friability and 98.28% drug content. Across F1–F9, the reported drug content values were 96.42–99.70%, while friability ranged from 0.65 to 0.83%.

Table 3: Granules Characteristics

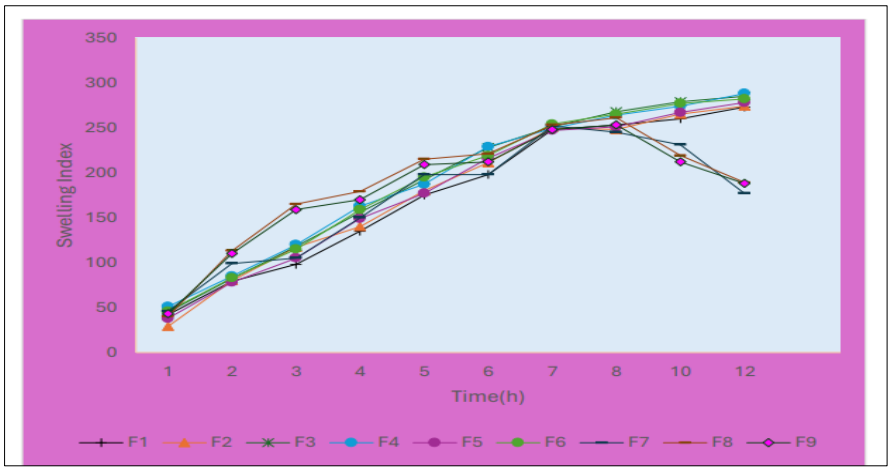
S.No.	Granule batch	Angle of Repose(*θ*)	Bulk density gm/ml	Tapped Density gm/ml	Compressibility (%)
1	F1	26.23	0.492	0.620	20.50
2	F2	26.69	0.471	0.581	19.52
3	F3	27.10	0.519	0.599	13.51
4	F4	28.45	0.532	0.611	12.75
5	F5	30.23	0.572	0.657	12.17
6	F6	23.69	0.669	0.778	18.0
7	F7	27.10	0.424	0. 535	19.08
8	F8	27.55	0.506	0.664	16.1
9	F9	27.69	0.509	0.670	17.5

Table 4: Evaluation data for physical parameters of matrix tablets

S.No	Formulation Batch	Weight Variation test(mg)	Friability (%)	Hardness (Kg/cm^2)	Drug Content(%)
1	F1	0.351 ± 0.005	0.83	7.9	96.42
2	F2	0.345 ± 0.004	0.76	12.2	98.86
3	F3	0.352 ± 0.005	0.81	13	98.28
4	F4	0.350 ± 0.006	0.65	10.5	99.70
5	F5	0.339 ± 0.005	0.72	8.1	96.92
6	F6	0.355 ± 0.004	0. 82	8.9	97.97
7	F7	0.347 ± 0.005	0.69	12.5	99.21
8	F8	0.354 ± 0.004	0.77	12.1	98.80
9	F9	0.352 ± 0.005	0.74	12.2	97.82

5.3 Swelling Behaviour

Swelling increased progressively during the initial hydration period in all formulations, although the magnitude differed with polymer concentration. F3 reached 285% swelling at 12 h. The increase in swelling provides a mechanistic explanation for the sustained release behaviour because hydration can increase gel-layer thickness and lengthen the diffusional pathway for drug molecules.



Graph 10: Swelling index profile

6. *In-vitro* Drug Release and Kinetic Analysis

6.1 Dissolution Profiles

The thesis dissolution data demonstrate formulation-dependent release. At 24 h, the reported cumulative release values were 42% for F1, 50% for F2, 50% for F3, 46% for F4, 52% for F5, 80% for F6, 88% for F7, 80% for F8 and 84% for F9. The dataset shows that the release profile was strongly affected by formulation composition and polymer level [19].

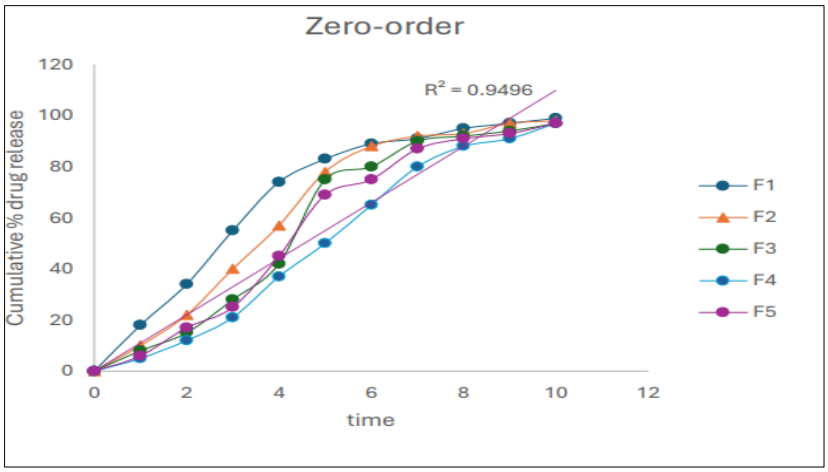
Table 5: Cumulative drug release at 24 h as reported in the thesis.

Batch	F1	F2	F3	F4	F5	F6	F7	F8	F9
24-h release (%)	42	50	50	46	52	80	88	80	84

The thesis discussion states that increasing polymer level reduced the release rate and identifies a polymer level described as 40% as suitable for sustained-release matrix development. However, the exact percentage assignment should be checked against the original formulation sheet because the formulation table and narrative contain some inconsistencies in excipient quantities. The manuscript therefore retains the experimentally reported F1–F9 data without recalculating an unreported polymer percentage.

6.2 Release Kinetics

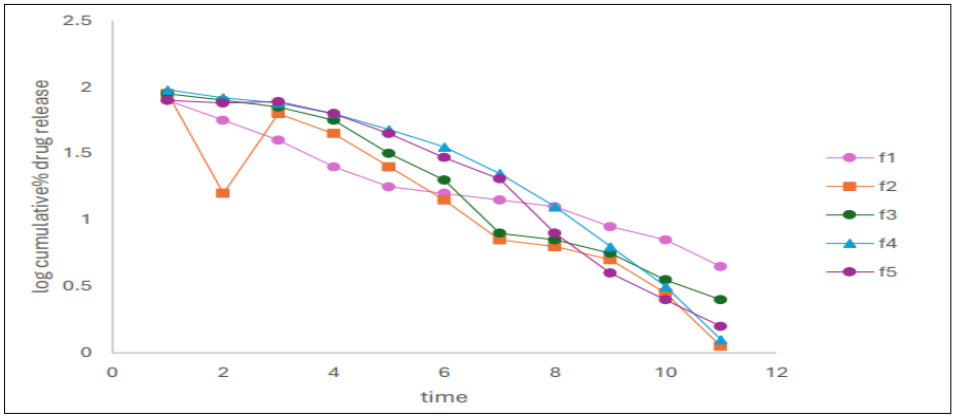
The dissolution data were fitted to zero-order, first-order, Higuchi and Korsmeyer–Peppas models. The thesis presents linear plots for each model and uses the coefficient of determination (R^2) to describe the fit. For the selected data sets, the thesis reports examples of high linearity, including a zero-order fit with $R^2 = 0.9923$ for one formulation, a first-order fit with $R^2 = 0.9718$ for one formulation, a Higuchi fit with $R^2 = 0.9344$ for one formulation and a Korsmeyer–Peppas fit with $R^2 = 0.982$ for one formulation. These values should be interpreted together with the individual formulation plots rather than as a single universal kinetic constant for all batches [19].



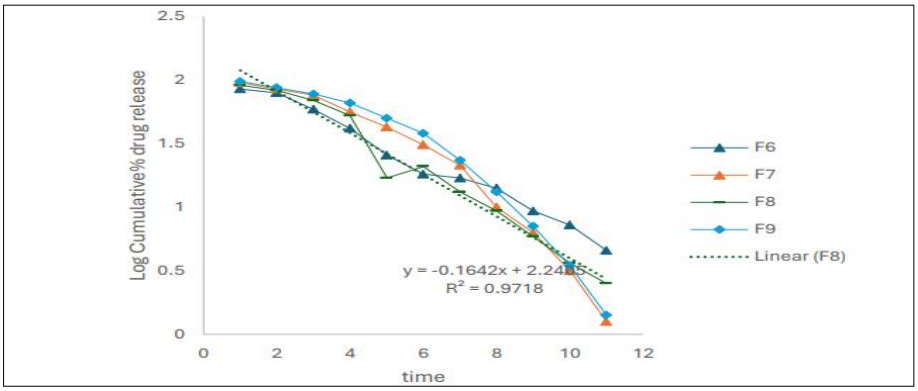
Graph 11: Zero-order model of Diclofenac Sodium from Formulation F1, F2, F3, F4, F5



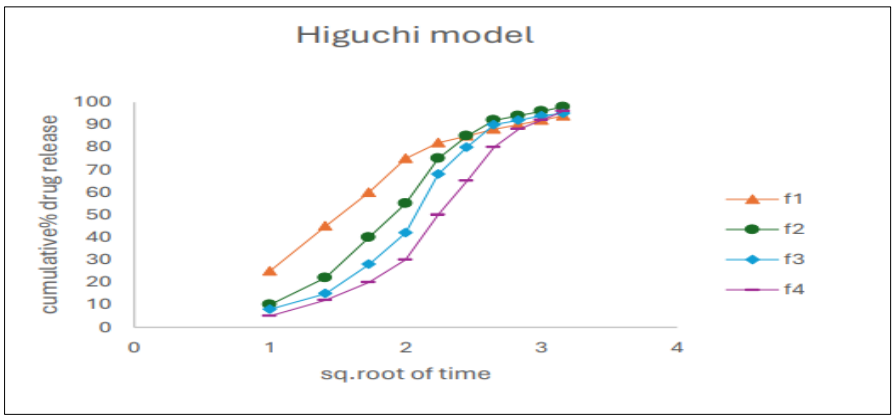
Graph 12: Zero-order model of Diclofenac Sodium from Formulation F6, F7, F8, F9



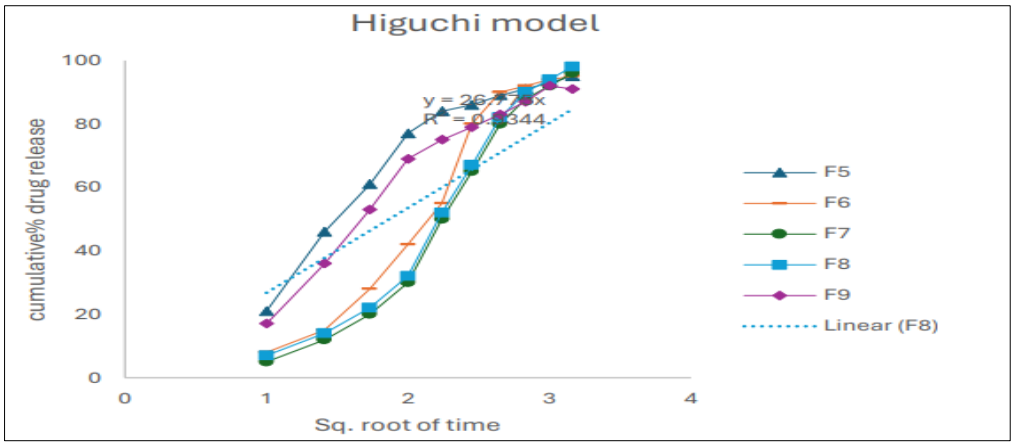
Graph 13: First-order Plots of Diclofenac Sodium from Formulation F1, F2, F3



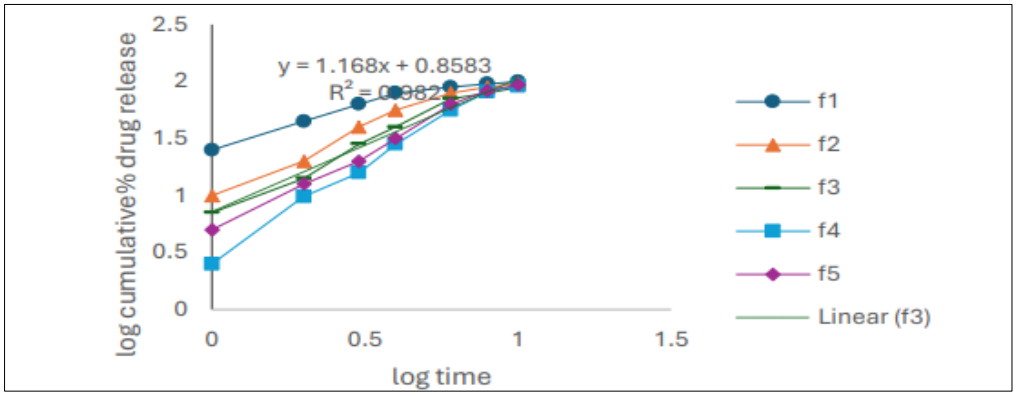
Graph 14: First-order plots of Diclofenac Sodium from Formulation F6, F7, F8, F9



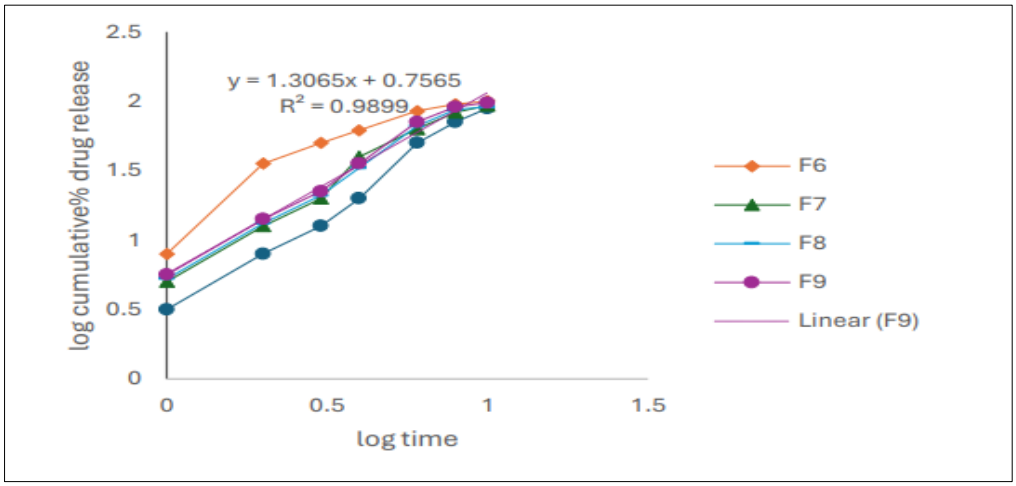
Graph 15: Higuchi order plots of Diclofenac Sodium from Formulation F1, F2, F3, F4



Graph 16: Higuchi order plots of Diclofenac Sodium from Formulation F5, F6, F7, F8, F9



Graph 17: Korsmeyer-peppas order plots of Diclofenac Sodium from Formulation F1, F2, F3, F4, F5



Graph No. 18: Korsmeyer-peppas order plots of Diclofenac Sodium from Formulation F6, F7, F8, F9

6.3 Release Mechanism

The Korsmeyer–Peppas model was applied to the initial portion of release data. The thesis describes the diffusional exponent n as an indicator of the release mechanism, with values around 0.5 associated with Fickian diffusion and higher values indicating increasing contributions from anomalous or case-II transport. The reported fitted equations should be presented batch-wise in the final journal version if the corresponding n values are required by the target journal.

The overall formulation findings indicate that xanthan gum can function as a matrix-forming polymer for diclofenac sodium sustained release. The most important formulation variable examined in the thesis was polymer level. As xanthan gum concentration increased, hydration and swelling generally increased, while drug liberation was modified. This relationship is consistent with the expected behaviour of hydrophilic matrices in which polymer hydration produces a barrier to drug diffusion.

The selected F3 formulation demonstrated acceptable physical quality in the reported study. Its friability was 0.81% and drug content was 98.28%, indicating adequate mechanical integrity and content uniformity within the thesis dataset. Its swelling increased continuously over the study period, reaching 285% at 12 h. This pronounced hydration is relevant to the formation of a hydrated matrix capable of sustaining drug release.

The release data should be considered alongside the formulation composition. F1–F5 displayed comparatively low 24-h release values (42–52%), whereas F6–F9 displayed higher cumulative release values (80–88%). Because the formulations also varied in HPMC, ethyl cellulose, PVP and lubricant levels, the observed differences cannot be attributed to xanthan gum alone without a controlled experimental design isolating each factor. This is an important consideration for a journal manuscript and prevents overinterpretation of the polymer effect.

The compatibility results provide supportive evidence for formulation development. FTIR spectra did not show major disappearance or appearance of characteristic peaks, and DSC retained the drug-related thermal event in the drug–polymer mixture. The thesis therefore interpreted the combination as compatible under the conditions tested. These findings support physical formulation compatibility but do not, by themselves, establish long-term chemical stability.

The dissolution kinetics further indicate that drug release involved matrix-controlled processes rather than simple immediate dissolution. The thesis used multiple mathematical models because no single model fully describes every stage of matrix release. Zero-order analysis describes release at a relatively constant rate, Higuchi analysis evaluates diffusion-controlled behaviour, and Korsmeyer–Peppas analysis provides an empirical description of the mechanism.

7. Stability Study and Conclusion

7.1 Stability of selected formulation F3

The selected F3 formulation was subjected to stability evaluation for three months at 37 ± 2°C and 72 ± 5% relative humidity. The thesis reports no substantial change in appearance and provides month-wise results for hardness, drug content and drug release at 10 h. Hardness increased from 12.59 kg/cm^2 initially to 13.08 kg/cm^2 at the third month. Drug content increased from 96.17% to 98.28%, while the reported 10-h in-vitro release increased from 94.3% to 96.2%. The tablets remained white throughout the reported stability period [19].

Table 6: Stability study of best formulation F3

Characteristic	Initial	1st month	2nd month	3rd month
Hardness(kg/cm)^2	12.59	12.88	12.81	13.08
Drug content (%)	96.17	96.9	97.8	98.28
In vitro drug release at 10th hours	94.3	95.4	95.9	96.2
Appearance	white	white	white	white

The stability results indicate that the selected formulation retained its measured physical appearance and the tested performance parameters over the three-month period under the reported conditions. Because the study duration was three months and the reported conditions were elevated relative to normal storage, the findings should be described as short-term/accelerated stability evidence rather than as proof of full shelf-life stability.

8. CONCLUSION

The thesis-based study demonstrates the feasibility of developing diclofenac sodium sustained-release matrix tablets using xanthan gum. Nine formulations were prepared and evaluated for pre-compression and post-compression characteristics, drug–excipient compatibility, swelling and dissolution. The analytical method showed a λmax of 276 nm and high linearity (R^2 = 0.9983). The formulations generally showed acceptable physical quality, with friability below 1% and drug content within the reported range.

F3 was identified in the thesis as the selected formulation. It exhibited 98.28% drug content, 0.81% friability and progressive swelling, while its dissolution behaviour was evaluated using standard kinetic models. Three-month stability testing showed no major change in appearance and maintained the reported hardness, drug content and release values.

Overall, the study provides a formulation-development basis for xanthan gum-containing diclofenac sodium matrix tablets.

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