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Research Article

Comparative study of drug release behaviour of Diltiazem Hydrochloride using Guar gum and HPMC as a polymer

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Abstract

The present study aimed to formulate and evaluate of Diltiazem Hydrochloride using guar gum and hydroxypropyl methylcellulose (HPMC) as release-retarding polymers for controlled drug delivery. The pellets were prepared by a layering technique, where guar gum was applied onto drug-loaded pellets using a suitable binder, followed by coating with HPMC in selected formulations. Preformulation studies, including drug–excipient compatibility using FTIR spectroscopy, confirmed the absence of any significant interaction, indicating the stability of the drug within the formulation. Dissolution studies were carried out using USP Type II apparatus in phosphate buffer (pH 7.2) for a period of 8 hours. The results demonstrated that drug release was significantly influenced by the type and concentration of polymer used. Formulations containing guar gum exhibited relatively faster drug release due to rapid swelling and erosion, whereas HPMC-coated pellets showed a more controlled and sustained release profile owing to the formation of a strong gel barrier. Increasing polymer concentration multiparticulate pellets in both cases resulted in a decrease in drug release rate. Among all formulations, the 1:1 drug-to-polymer ratio exhibited a uniform and desirable release pattern. Comparative evaluation indicated that HPMC was more effective than guar gum in sustaining drug release. Overall, the study concludes that multiparticulate systems using appropriate polymer combinations can successfully modulate drug release and improve therapeutic efficacy.

Keywords: multiparticulate pellets, Diltiazem Hydrochloride, HPMC, Guargum, dissolution.

1. INTRODUCTION

Multiparticulate dosage forms (MPDFs) are advanced oral systems that improve drug delivery compared to single-unit forms. Tablets, widely used in pharmaceuticals, are increasingly preferred for incorporating pellets due to better cost-effectiveness and patient compliance. These tablets contain spherical pellets produced by pelletization, offering uniform drug distribution, enhanced absorption, reduced gastrointestinal irritation, and controlled release. Upon ingestion, they disintegrate rapidly, releasing coated pellets that maintain consistent release behavior. Multiparticulate tablets provide stable, predictable drug release with reduced dose dumping and variability in gastric transit[1-2].

Diltiazem Hydrochloride is a benzothiazepine calcium channel blocker used for hypertension, angina, and arrhythmias. It inhibits calcium influx into cardiac and vascular smooth muscle, causing vasodilation and reduced cardiac workload . The drug undergoes extensive first-pass metabolism and has a short half-life, making sustained-release formulations necessary for maintaining therapeutic levels[3-4]. Multiparticulate tablets are advantageous for Diltiazem as they provide controlled release, reduce plasma level fluctuations and dose dumping, improve bioavailability, and enhance patient compliance[5-6].

2. MATERIALS AND METHODS

Diltiazem Hydrochloride drug was procured from Varav Biogenesis Ltd.polyvinylpyrrolidone in isopropyl alcohol,Guar Gum, HPMC,isopropyl alcohol,methylene chloride, dibutyl phthalate, micro-crystalline cellulose (MCC), lactose, hydroxypropyl methylcellulose (HPMC), ethyl cellulose (EC), polyvinylpyrrolidone (PVP), and other excipients were used. All materials were of pharmaceutical grade.

Preparation of diltiazem hydrochloride pellets

Preformualtion studies

Preformulation studies were conducted to evaluate the physicochemical properties of Diltiazem Hydrochloride for multiparticulate tablet formulation like, organoleptic properties, HPLC analysis, melting point, drug excipient compatibility studies. The powder was also evaluated for

different parameters like, flow properties, including angle of repose, bulk density, Carr's index, and Hausner ratio etc[7-8].

Preparation of Pellets of Diltiazem Hydrochloride

Following steps ware used for the preparation of diltiazem HCl pellets

Drug Layering onto Non-pareil Seeds

Non-pareil seeds (300 g), composed of starch, were rotated in a coating pan at 20–22 rpm. Drug layering was performed using Diltiazem Hydrochloride by initially wetting the seeds with a 5% polyvinylpyrrolidone (PVP) binder solution in isopropyl alcohol, followed by gradual addition of drug powder. The process of alternate wetting and powder layering (~10 g per addition) was continued until the total drug load (750 g) was achieved. Such powder layering involves successive deposition of drug onto inert cores using a binding liquid to form uniform pellets[9]. The drug-loaded pellets were dried at 40°C for 24 hours to remove residual solvent and then sieved through a 20-mesh sieve to obtain uniform-sized pellets. Proper control of process parameters such as pan speed and binder concentration is essential to ensure uniform coating and pellet quality[10].

Formulation for Preparation of Pellets of Diltiazem Hydrochloride

- Non-pariel seeds (30–40#): 300 g
- Diltiazem Hydrochloride (200#): 750 g
- Binder solution: 5% polyvinylpyrrolidone in isopropyl alcohol

Layering of Pellets of Diltiazem Hydrochloride with Guar Gum

Diltiazem Hydrochloride-loaded pellets (100 g) were coated in a pan at 20–22 rpm. The pellets were wetted with a 5% polyvinylpyrrolidone (PVP) solution in isopropyl alcohol, followed by gradual dusting of guar gum (~5 g per addition) to achieve uniform coating. The alternate process of wetting and powder layering was continued until the desired amount of guar gum was applied. This method was used to prepare pellets with different drug-to-guar gum ratios. Such powder layering techniques are widely used to achieve uniform coating and controlled drug release in multiparticulate systems[11-12].

Table 1: Different ratios of Diltiazem Hydrochloride to guar gum

Ingredients	Ratio of drug: gum		
	1:0.5	1:1	1:1.5
Diltiazem Pellets (20-30 #)	100 g	100 g	100 g
Guargum	50 g	100 g	150 g

Procedure of HPMC Coating on Diltiazem Hydrochloride pellets

i. Preparation of HPMC Coating Solution

A weighed quantity of Hydroxypropyl Methylcellulose (HPMC) (2 g) was taken and dissolved in isopropyl alcohol (33 ml) under continuous stirring to obtain a clear solution. To this, methylene chloride (66 ml) was added gradually with constant mixing. Subsequently, dibutyl phthalate (0.2 g) was incorporated as a plasticizer to improve film flexibility and coating integrity. The solution was stirred until a homogeneous coating solution was obtained[13].

Formula for HPMC Coating Solution

- HPMC – 2%
- Isopropyl alcohol – 33%
- Methylene chloride – 66%
- Dibutyl phthalate – 0.2%

ii. HPMC Coating of Diltiazem Hydrochloride Pellets

The prepared coating solution was sprayed onto the previously prepared Diltiazem Hydrochloride pellets using a spray gun in a coating pan. For each batch, approximately 100 ml of coating solution was used to ensure uniform coating[14].

Dissolution studies

Dissolution studies of guar gum–layered and HPMC Diltiazem Hydrochloride pellets were performed using the USP Type II (paddle) apparatus. Accurately weighed pellets equivalent to the required drug dose were placed in 900 mL of 0.05 M phosphate buffer (pH 7.2) maintained at 37 ± 0.5 °C. The paddle rotation speed was set at 50 rpm[15]. At predetermined time intervals (every 1 hour up to 8 hours), 5 mL samples were withdrawn and replaced with an equal volume of fresh dissolution medium to maintain sink conditions. The collected samples were filtered and analyzed. Drug release was quantified using HPLC equipped with a UV detector. The analysis was carried out at a wavelength of 237 nm using a mobile phase consisting of acetonitrile and water (35:65 v/v). The flow rate was maintained as per standard method conditions, with a run time of 10 minutes and an injection volume of 20 µL[16].

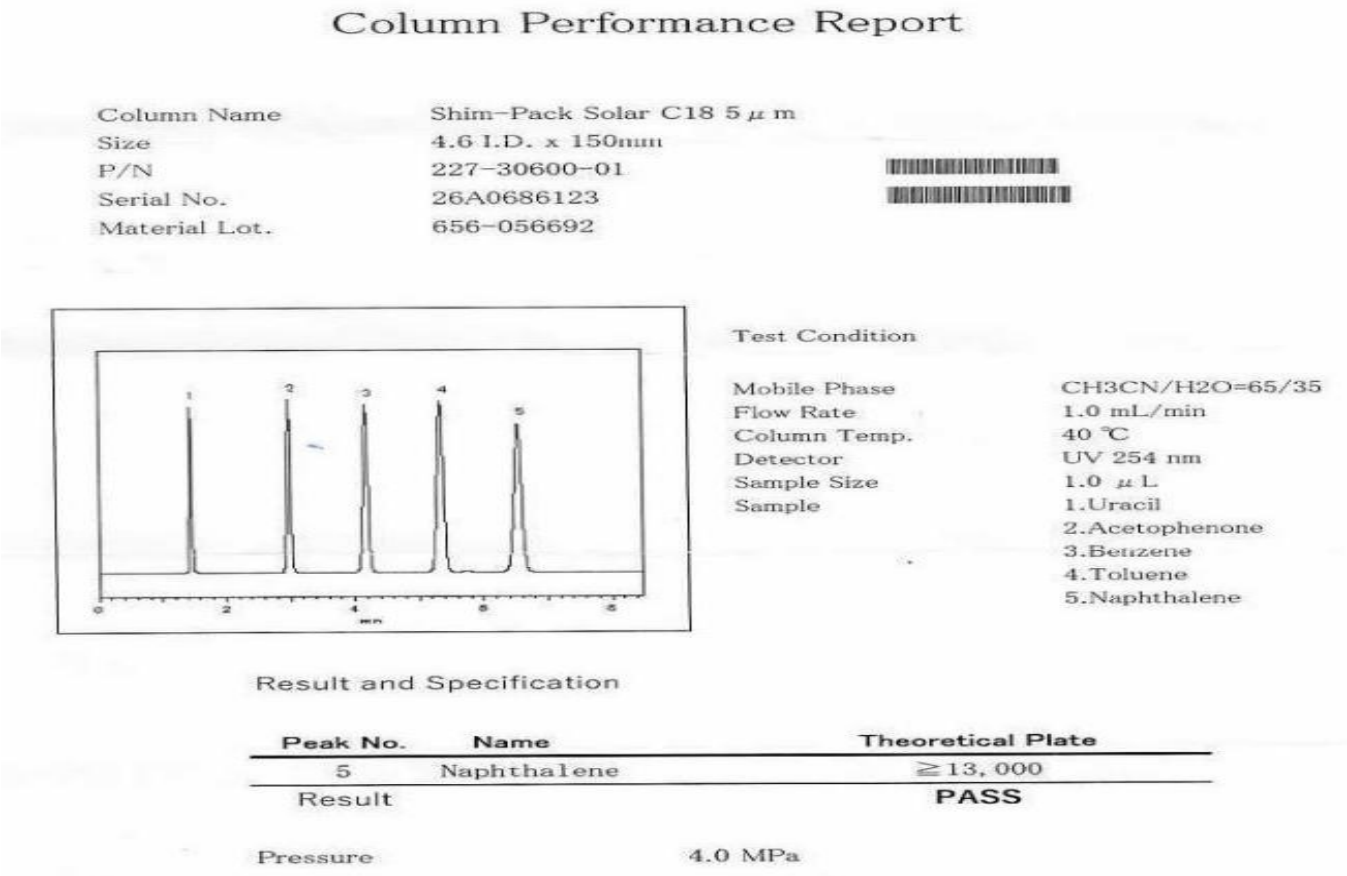
A standard solution was prepared by dissolving 5 mg of Diltiazem working standard in 10 mL water, followed by further dilution (1 mL to 100 mL) with the mobile phase. The percentage drug release at each time point was calculated using the calibration curve derived from the standard solution[17].

3. RESULT AND DISCUSSION

The drug was observed as a white, odorless crystalline powder. It exhibited good solubility in water and methanol, indicating hydrophilic nature . The melting point (210–214°C) confirmed drug purity. HPLC analysis showed as shown in **Figure 1** the purity off drug and FTIR

characteristic peaks corresponding to functional groups, confirming identity and compatibility off drug as shown in **Figure 2**. Drug–excipient compatibility studies using FTIR revealed no significant interactions with excipients such as guar gum, PVP, and MCC as shown in **Figure 3** .

Flow properties, including angle of repose, bulk density, Carr's index, and Hausner ratio, indicated acceptable flow behavior suitable for pelletization. Particle size analysis ensured uniformity for effective layering, while low moisture content (LOD) supported drug stability (3). These findings confirmed the suitability of Diltiazem Hydrochloride for the development of stable and controlled-release multiparticulate tablets.



Column Performance Report

Column Name	Shim-Pack Solar C18 5 μ m
Size	4.6 I.D. x 150mm
P/N	227-30600-01
Serial No.	26A0686123
Material Lot.	656-056692

Test Condition

Mobile Phase	CH3CN/H2O=65/35
Flow Rate	1.0 mL/min
Column Temp.	40 ℃
Detector	UV 254 nm
Sample Size	1.0 μ L
Sample	1.Uracil
	2.Acetophenone
	3.Benzene
	4.Toluene
	5.Naphthalene

Result and Specification

Peak No.	Name	Theoretical Plate
5	Naphthalene	≧13, 000
Result		PASS

Pressure 4.0 MPa

Figure 1: Lambra Max of drug

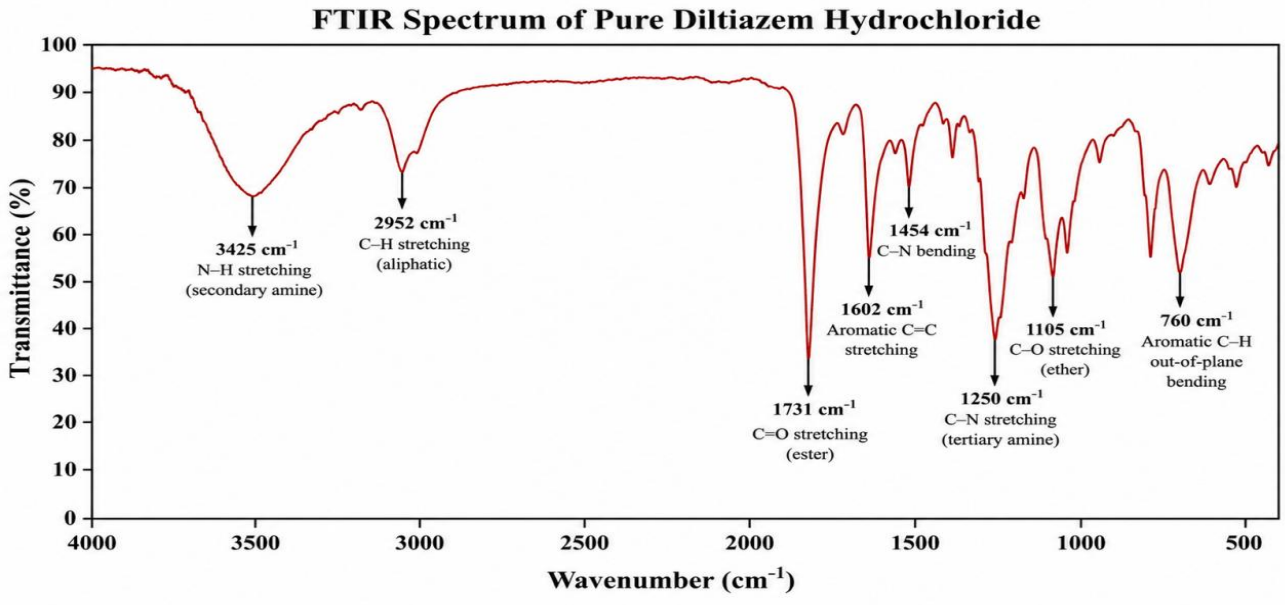


Figure 2: FTIR Spectra of drug Diltiazem Hydrochloride

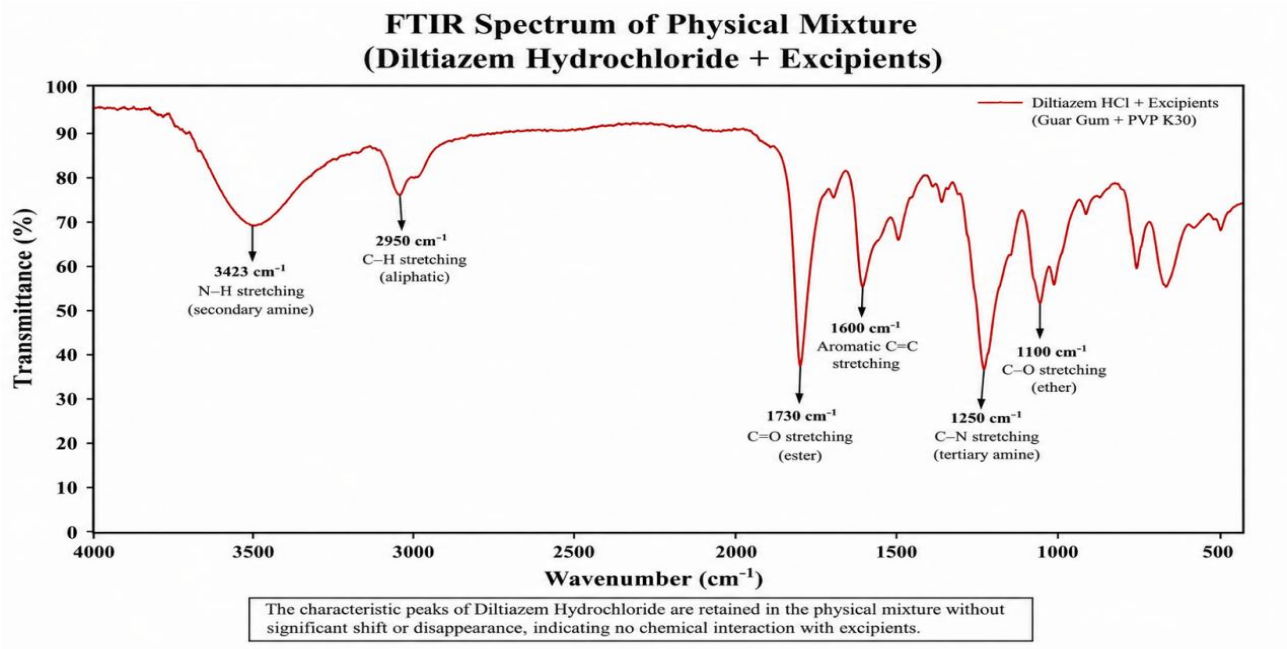


Figure 3: Drug and excipient compatibility studies.

The HPLC Peak clarity indicates the presence of drug Diltiazem Hydrochloride. The interaction between Diltiazem Hydrochloride and selected excipients (e.g., guar gum, PVP) was investigated using FTIR spectroscopy (4000–400 cm^{-1}). The pure drug exhibited characteristic peaks at ~3425 cm^{-1} (N–H), 2950 cm^{-1} (C–H), 1730 cm^{-1} (C=O), and 1600 cm^{-1} (aromatic C=C). In the drug–excipient mixtures, these peaks were carefully compared and noted that no chemical interaction was observed.

3.1. *In -Vitro* Dissolution Studies Of Pellets of Diltiazem

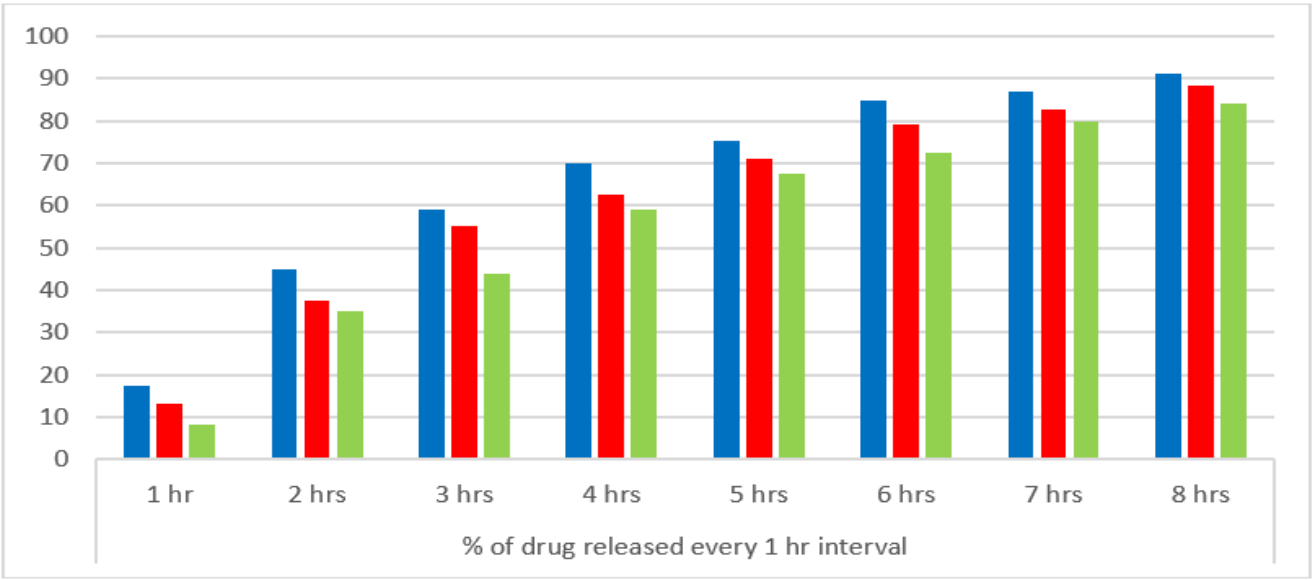
3.1.1. A. Dissolution studies of Gum layered pellets of Diltiazem.

The dissolution studies were carried out for the pellets of Diltiazem prepared by varying the guargum concentration. The release profile obtained are tabulated in table 2 and graphically represented in Figure 4 .

Table 2: Release of Diltiazem from guargum layered pellets

Ratio of Drug: Guargum	% of drug released every 1 hr interval							
	1 hr	2 hrs	3 hrs	4 hrs	5 hrs	6 hrs	7 hrs	8 hrs
1: 0.5	17.2	44.9	59.2	70.1	75.3	84.8	87.1	91.2
1: 1	13.2	37.5	55.2	62.7	71.1	79.3	82.6	88.4
1: 1.5	8.3	35.1	43.9	59.2	67.5	72.4	80.0	84.2

It has been observed from the figure 4 that the ratio of drug: gum - 1:1 showed uniform release profile.



Drug: Guargum, 1: 0.5 = Blue bar, 1: 1 = Red bar, 1: 1.5 = Green bar

Figure 4. Graphical representation of release of Diltiazem from guargum layered pellets

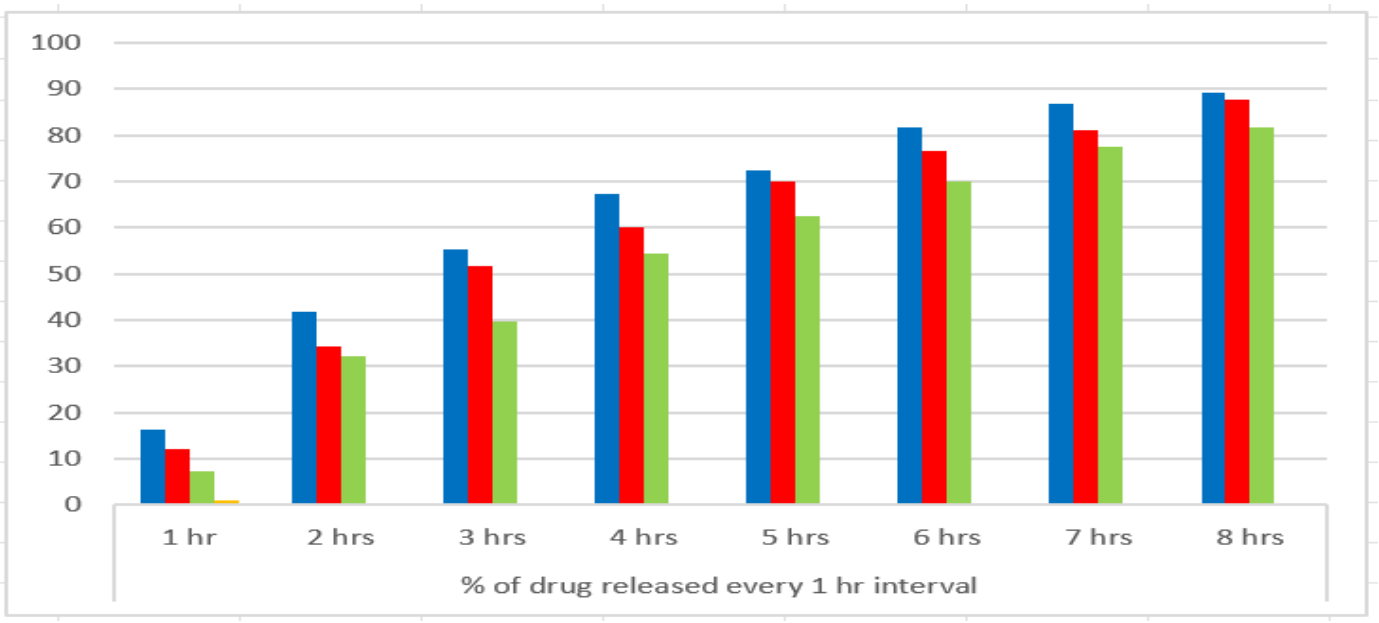
3.1.2. Dissolution studies of

HPMC coated pellets of Diltiazem

The dissolution studies were carried out for HPMC coated pellets of Diltiazem. The release profile is shown in Table 3 and graphically represented in Figure 5.

Table 3: Release profile of Diltiazem from HPMC coated pellets

Ratio of Drug: HPMC	% of drug released every 1 hr interval							
	1 hr	2 hrs	3 hrs	4 hrs	5 hrs	6 hrs	7 hrs	8 hrs
1: 0.5	16.4	41.8	55.4	67.3	72.5	81.6	86.7	89.2
1: 1	12.0	34.3	51.7	60.0	69.9	76.6	81.2	87.6
1: 1.5	7.2	32.1	39.6	54.3	62.4	69.9	77.5	81.7



Drug: HPMC, 1: 0.5 = Blue bar**,** 1: 1 = Red bar**,** 1: 1.5 = Green bar

Figure 5. Graphical representation of Release of Diltiazem from HPMC coated pellets

The comparative dissolution study of Diltiazem Hydrochloride pellets formulated with guar gum and HPMC clearly demonstrates that both polymers exhibit concentration-dependent control over drug release, though their release-retarding abilities differ. Guar gum formulations consistently showed a slightly higher percentage of drug release at all time intervals compared to HPMC, indicating a relatively faster release profile. This behavior can be attributed to the natural origin of guar gum, which hydrates and swells rapidly but forms a less dense gel barrier, allowing quicker diffusion of the drug.

In contrast, HPMC-coated pellets exhibited a comparatively slower and more controlled release pattern. The semi-synthetic nature of HPMC enables the formation of a stronger and more viscous gel layer upon hydration, which acts as an effective diffusion barrier. As a result, drug release from HPMC formulations is more sustained, particularly at higher polymer ratios. The difference becomes more evident at later time intervals, where HPMC formulations retain better control over drug release than guar gum.

At lower polymer concentrations (1:0.5), both polymers show relatively faster release due to insufficient matrix formation; however, guar gum still releases the drug more rapidly than HPMC. At the intermediate ratio (1:1), both polymers demonstrate a uniform and controlled release profile, though HPMC maintains slightly better regulation. At higher polymer concentration (1:1.5), the release rate decreases further for both systems, with HPMC showing superior retardation due to its stronger gel-forming capacity.

4. CONCLUSION

The study focused on the impact of release of Diltiazem Hydrochloride using polymers like, guar gum and

HPMC as release-retarding polymers. Preformulation and compatibility (FTIR) studies confirmed the stability of the drug with selected excipients. Dissolution studies demonstrated that drug release is dependent on polymer type and concentration, with increasing polymer content leading to slower release. Both polymers effectively controlled drug release; however, HPMC provided better sustained release due to its stronger gel-forming ability. The 1:1 drug-to-polymer ratio showed the most uniform release profile, making it optimal for controlled-release formulations.

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Conflict of Interest: The authors declare that there is no conflict of interest related to this study. No financial, personal, or professional affiliations have influenced the design, execution, or reporting of the research work.

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