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Original Article

Dual-Release Gastroretentive System of Tizanidine Hydrochloride: Formulation and Evaluation of Floating Bilayer Tablets

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ABSTRACT

Background: To formulate and assess floating bilayer tablets of Tizanidine Hydrochloride (TZN) intended to extend gastric retention and for sustained release of the drug. **Materials and Methods:** Six bilayered floating tablets(F7-F12) were prepared using one of the best immediate release formulations out of the six immediate release formulations (F1-F6) prepared and the other is sustained release layer. The Immediate-Release (IR) layer contained super-disintegrants Lycoat and Ludiflash, while the Sustained-Release (SR) layer included Sodium Alginate and Carbopol 934P. Formulation additives comprised Magnesium stearate, Sodium bicarbonate, Citric acid, Talc, PVP K30, Microcrystalline Cellulose (MCC), Lactose, and Isopropyl alcohol. The compressed bilayered tablets were evaluated for post compression parameters like drug release studies, lag time, floating time etc. **Results and Discussion:** Formulations F3 (IR) and F12 (SR) were identified as optimal. The F12 tablets exhibited excellent buoyancy, with a lag time of 123 sec and remained floating beyond 12 hr; they delivered approximately 99.12% of the drug over this period. The release of drug from the SR layer was zero-order kinetics and Super Case II transport, reflecting a stable, controlled release pattern. FTIR spectra showed no interactions between TZN and formulation components. **Conclusion:** The developed tizanidine hydrochloride floating bilayer tablets especially F12 successfully combined prolonged gastric residence with sustained drug release, highlighting a promising gastro-retentive delivery system to improve TZN's therapeutic efficiency and bioavailability.

Keywords: Tizanidine hydrochloride, Ludiflash, Carbopol 934P, FTIR, Bilayered Tablets.

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INTRODUCTION

Despite the emergence of new routes of delivery of drugs, oral drug delivery remains the most preferred, being most convenient, with the highest patient compliance and a range of formulations available for various drug types (Rathod *et al.*, 2016). Tizanidine hydrochloride, a centrally acting α_2-adrenergic agonist, is commonly prescribed as a muscle relaxant. However, its clinical efficacy is limited by a short elimination half-life of approximately 2.5 hr and a relatively low oral bioavailability ranging from 34% to 40%. This necessitates frequent dosing typically 2-4 mg three times daily to maintain therapeutic plasma concentrations. To address these pharmacokinetic challenges and enhance patient compliance, developing floating bilayer tablets capable of sustained drug release is a promising strategy. Such formulations can prolong gastric residence time, reduce dosing frequency, and improve overall bioavailability (Arora *et al.*, 2005).

Altered density drug delivery systems are designed to prolong the residence time of the drug in the stomach by virtue of buoyant properties (Singh *et al.*, 2000). This is advantageous for drugs such as Tizanidine, which is absorbed both from the stomach and the upper gastrointestinal tract. By prolonging the GRT, the release of Tizanidine can be regulated, resulting in enhanced bioavailability and extended therapeutic action (Deshpande *et al.*, 1997). Bilayer tablet formulations are composed of two layers, one for immediate release and the other for controlled release, providing both quick onset and prolonged drug release. The floating bilayer tablet can be designed to accomplish dual functions: immediate release of Tizanidine

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to give quick relief, and a floating layer to keep it in the stomach for sustain release (Pravin *et al*., 2008).

Wet granulation is widely employed in the manufacture of floating bilayer tablets due to its ability to ensure uniform mixing of components and produce tablets with excellent mechanical strength. This method involves using a liquid binder commonly isopropyl alcohol to agglomerate powders, significantly enhancing the blend's flow characteristics and compressibility (Kumar *et al*., 2011). *In vitro* evaluation of the tablets encompassed key performance metrics such as buoyancy characteristics, drug release profiles, and formulation stability. These assessments ensure that the dosage form aligns with targeted therapeutic standards, ultimately supporting improved patient adherence and clinical efficacy.

MATERIALS AND METHODS

Materials

Tizanidine HCl were used as active ingredient and obtained as a gift sample from Vani Pharma Labs Ltd., Hyderabad. Lyocoat, Ludiflash, Carbopol 934p was purchased from Narmada Chemicals., Hyderabad. Sodium alginate was purchased from BMR Chemicals., Hyderabad. Mcc, Poly vinyal pyrrolidone was purchased from SD Fine Chemicals., Hyderabad. And all other chemicals/Solvents used were of AR grade.

Analytical Methods

UV Spectroscopy

A 10 mg sample of Tizanidine hydrochloride was weighed accurately and dissolved in 10 mL of 0.1 N HCl to prepare a 1000 µg/mL stock solution. From this, 1 mL was diluted to 10 mL with the same buffer to yield a 100 µg/mL solution, and a further 1 mL was diluted similarly to obtain a 10 µg/mL solution. The resulting solution was scanned across the 200–400 nm wavelength range using UV–visible spectroscopy to determine its absorbance profile (Mehta *et al*., 2011).

Calibration curve of Tizanidine hydrochloride

A precise 10 mg quantity of Tizanidine hydrochloride was dissolved in 10 mL of 0.1 N HCl to create a stock solution with a concentration of 1000 µg/mL. An aliquot of this stock was further diluted to 10 mL with the same buffer to yield a 100 µg/mL working standard. Serial dilutions were then performed using the 0.1 N HCl buffer to prepare calibration standards ranging from 2 to 10 µg/mL. Absorbance measurements were recorded at 320 nm using a UV-visible spectrophotometer, with the pH 1.2 acid buffer serving as the blank reference. A calibration curve was generated to correlate absorbance and concentration (Mohideen *et al*., 2011).

FT-IR Studies

To assess the interaction between Tizanidine hydrochloride and excipients, FTIR spectroscopy was conducted using the Potassium Bromide (KBr) pellet technique. The drug and excipient powders were thoroughly mixed, dried, and then compressed into pellets under vacuum pressure. Spectra from these pellets were acquired and overlaid with reference spectra. The characteristic absorption peaks (minimum transmission points) of the sample matched in both position and relative intensity to those from the pure drug standard, indicating no significant interactions occurred (Suryawanshi *et al*., 2015).

Preparation of Floating Bilayer Tablets

The bilayer floating tablets of Tizanidine hydrochloride were formulated using a wet granulation method, as detailed in Tables 1 and 2. The tablets consist of two distinct layers: an Immediate-Release (IR) layer and a Sustained-Release (SR) layer. All excipients were sifted through a 20-mesh sieve and blended in a mortar. Granules were prepared by incorporating isopropyl alcohol solution and subsequently dried at 60°C for 30 min using a tray dryer. After drying, the granules were passed through a 30-mesh sieve to ensure uniformity. Some granules were lubricated with magnesium stearate and talc. For the IR layer, Ludiflash and Lycoat were utilized as superdisintegrants at concentrations of 2, 4, and 6 mg to formulate the granules formula is given in Table 1. These granules were compressed using a 10-station B tooling compression machine to optimize the bilayer tablets. For the SR layer, the same procedure was followed using sodium alginate, Carbopol 934P, and sodium bicarbonate as given in Table 1. The IR and SR layers were then compressed together to form the final bilayer tablet (Pallavi *et al*., 2022).

Evaluation of Tablets

Pre-compression Parameters

Angle of Repose: It is determined by fixed funnel method and is calculated by using the equation:

$\tan ø = h/r$

Where, h and r are the height and radius of the powder cone.

Bulk Density & Tapped Density

It is calculated using the equation given below:

BD= Weight of powder blend / Untapped Volume of the packing

TD=Weight of the powder blend / Tapped Volume of the packing (Gibson, 2001).

Compressibility Index

It is used to assess the flow properties of powders. The formula for Carr's Index is as below:

Carr's Index (%) = (Tapped Density-Bulk Density) x 100 / TD

Hausner's Ratio

The hausner's ratio is a value that is correlated with the flowability of a granular material or powder material (Fell, 1996).

Post-compression Parameters

Thickness: Vernier caliper is used to determine the tablet thickness. Five tablets were used, and the average values were calculated (Lachman *et al.*, 1976).

Hardness Test: It is used to determine the ability of the tablet to withstand mechanical shocks while handling. 3 tablets were picked randomly picked; the hardness was determined by Monsanto Hardness tester it is expressed in kg/cm^2.

Friability Test: This is determined by the help of Roche Friabilator, and is calculated by using the following formula:

%F = 100 (1-W0/W)

% Friability of tablets less than 1% are considered acceptable (Pawar HA *et al.*, 2013).

Average Weight: It is an official test given in pharmacopoeia. An average weight of 20 tablets was taken from the prepared batch and is divided by 20.

Uniformity of Contents: 30 tablets were selected randomly. 10 of them assayed individually using UV analytical method (Kulkarni *et al.*, 2009).

In vitro Buoyancy Studies

The *in vitro* buoyancy of the tablets was assessed using the floating lag time method. Each tablet was kept in a beaker containing100 mL 0.1 N HCl buffer. The time required for the tablet to arise to the surface was recorded as the Floating Lag Time (FLT) or Buoyancy Lag Time (BLT). The time period the tablet remains floating on the surface is noted as the Total Floating Time (TFT) (Tiwari, 2016).

In vitro Dissolution Studies

Dissolution for Immediate release tablets of Tizanidine hydrochloride

The release profile of Tizanidine hydrochloride from immediate-release tablets was evaluated using a USP Type II (paddle) dissolution apparatus. The tablets were immersed in 900 mL of 0.1 N HCl buffer maintained at 37.5 ± 0.5°C and stirred at 75 rpm. At time intervals of 5, 10, 15, 20, 30, 40, 50, and 60 min, a 5 mL sample was withdrawn and immediately replaced with fresh medium. Each sample was filtered and analyzed for drug content at 320 nm using a single-beam UV-visible spectrophotometer

In vitro drug release studies of bilayer tablets

In vitro release testing of the bi-layer tablets was performed in USP Type II (paddle) dissolution apparatus. The dosage forms were immersed in 900 mL of 0.1 N HCl (pH 1.2) maintained at 37 ± 0.5°C, with paddle rotation sustained for up to 12 hr. At predetermined intervals, aliquots were taken out, filtered, and analyzed for drug concentration using a single-beam UV–visible spectrophotometer (Preethi *et al.*, 2014).

Release kinetic studies

The kinetic release study of Tizanidine Hydrochloride floating bilayer tablets was conducted using dissolution profile:

Zero order Qt = Q0 + K0t

Table 1: Formulation of Immediate release layer F1-F6 & SR bilayer F7-F12 tablets of Tizanidine hydrochloride.

Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
Tizanidine hydrochloride	02	02	02	02	02	02	04	04	04	04	04	04
Ludiflash	02	04	06	-	-	-	-	-	-	-	-	-
Lycoat	--	--	--	02	04	06	-	-	-	-	-	-
Lactose	44	42	40	44	42	40	-	-	-	-	-	-
Immediate release	-	-	-	-	-	-	50	50	50	50	50	50
Sodium alginate	-	-	-	-	-	-	05	10	15	-	-	-
Carbopol 934P	-	-	-	-	-	-	-	-	-	05	10	15
Sodium bicarbonate	-	-	-	-	-	-	15	15	15	15	15	15
Citric acid	-	-	-	-	-	-	03	03	03	03	03	03
PVP K30	-	-	-	-	-	-	10	10	10	10	10	10
MCC	-	-	-	-	-	-	61	56	51	61	56	51
Magnesium stearate	01	01	01	01	01	01	01	01	01	01	01	01
Talc	01	01	01	01	01	01	01	01	01	01	01	01
Isopropyl alcohol	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S	Q.S
Total	50	50	50	50	50	50	150	150	150	150	150	150

First order Log C= Log Co-kt/2.303

Higuchi model Q = KH - t1/2

Korsemeyer peppas model Mt / M∞ = Ktn

Where Qt is the amount of drug dissolved at time t, Q0 is the initial amount of drug, K is the first order release constant, KH is the Higuchi constant, K is the korsemeyer peppas model release constant and n is the diffusional release exponent indicative of the operating release mechanism. The correlation coefficient R2 value was used as an indicator of best fitting for each of the models considered (Sudhakar *et al.*, 2013).

RESULTS

Floating bilayer tablets of Tizanidine HCl were formulated and evaluated. In the present study 12 batches with variable concentration of polymers were prepared and evaluated for physicochemical parameters, *in vitro* release study, in vitro buoyancy studies and kinetics studies.

Pre-formulation studies

FT-IR Studies

In the present study from FT-IR data The IR spectra revealed that there is no interaction between the drug and the excipients.

Physical characteristics of powder blend

The physical characteristics of powder blend of immediate release (F1-F6) & SR (F7-F12) was found to be within the limits showing good flow character given in Table 2.

Post compression parameters

The post compression parameter like hardness, friability and % drug content for all the of immediate release formulations

Table 2: Physical characteristics of powder blend of immediate release (F1-F6) & SR (F7-F12) formulations.

Code	Angle of Repose	Bulk Density (g/mL)	Tapped Density (g/mL)	Carr's Index. (%)	Hausner's ratio
F1	27.12±1.74	0.217±0.005	0.304±0.002	14.19±1.24	1.17±0.03
F2	28.56±1.18	0.236±0.003	0.327±0.006	12.43±1.25	1.14±0.02
F3	29.36±1.75	0.251±0.004	0.342±0.005	11.34±1.42	1.12±0.01
F4	28.25±1.46	0.211±0.007	0.309±0.008	16.26±1.19	1.18±0.03
F5	27.13±1.26	0.229±0.005	0.313±0.005	14.37±1.26	1.16±0.02
F6	28.54±1.85	0.246±0.006	0.335±0.007	13.51±1.26	1.14±0.01
F7	29.16±1.24	0.317±0.005	0.403±0.002	17.4±1.18	1.17±0.03
F8	27.7±1.36	0.325±0.003	0.415±0.005	15.52±1.36	1.14±0.02
F9	26.1±1.42	0.359±0.004	0.435±0.003	13.46±1.25	1.13±0.01
F10	28.20±1.36	0.327±0.007	0.413±0.004	16.54±1.19	1.15±0.02
F11	27.45±1.16	0.338±0.006	0.425±0.001	14.37±1.26	1.13±0.01
F12	25.20±1.98	0.36±0.008	0.446±0.005	12.49±1.18	1.11±0.02

Table 3: Post compression parameter of immediate release (F1-F6) & SR (F7-F12) formulations.

Formulation	Mean Hardness Kg/cm²	Average weight (mg)	Friability % w/w	Mean drug content %	Swelling index (%)	Floating Lag Time (sec)	Floating Time (hr)
F1	4.5±0.2	51.17±1.37	0.75±0.03	94.15±1.16	-	-	-
F2	4.9±0.1	48.21±1.46	0.51±0.02	97.05±1.45	-	-	-
F3	5.2±0.2	50.28±1.43	0.43±0.07	99.16±1.28	-	-	-
F4	4.4±0.3	52.39±1.16	0.79±0.02	93.28±1.46	-	-	-
F5	4.8±0.2	51.42±1.28	0.65±0.05	95.05±1.34	-	-	-
F6	5.0±0.1	49.1±1.24	0.59±0.03	98.23±1.15	-	-	-
F7	148.43±1.24	6.6±0.3	0.57±0.07	95.42±1.34	142.68±1.42	152	>10
F8	151.24±1.29	6.8±0.1	0.66±0.06	96.24±1.16	175.14±1.74	148	>11
F9	149.45±1.14	7.4±0.1	0.52±0.07	98.23±1.18	181.37±1.75	137	>11
F10	151.34±1.12	6.8±0.2	0.73±0.03	96.34±1.42	150.37±1.06	140	>10
F11	149.28±1.85	7.5±0.1	0.52±0.05	98.26±1.42	159.45±1.19	136	>11
F12	150.26±1.26	7.9±0.2	0.45±0.09	99.16±1.20	172.84±1.86	123	>12

(F1-F6) and for all the of sustained release formulations (F7- F12) was found to be within the limits. given in Table 3. The % Swelling index was found to be between 142.68±1.42% - 181.37±1.75% as given in Table 3. The *in vitro* buoyancy studies showed that the Floating lag time of the all the bilayer sustained release formulations (F7-F12) is between 123 sec – 152 sec and the total floating time was shown to be >11 hr as given in Table 3.

In vitro buoyancy studies

The above studies in Table 8 show that the Floating lag time of the all the formulations (F7-F12) is between 123 sec – 152 sec and the total floating time was shown to be >11 hr.

IN VITRO DISSOLUTION STUDIES

From the *in vitro* drug release profile of all the immediate release formulations (F1-F6), the formulation F3 which containing maximum concentration of Ludiflash shows maximum drug release at the end of 30 min i.e., 99.19±1.43% as shown in Figure 1.

From the *in vitro* drug release profile of all the sustained release formulations (F7-F12), the formulation F12 containing maximum concentration of Carbopol 934P shows maximum drug release i.e.., 9.12±1.09% at the end of 12th hr as shown in Figure 2.

Release kinetic studies

The *in vitro* drug release data for best formulation F12 were fitted into kinetic models i.e., zero order, first order, Higuchi and korsemeyer-peppas equation. Optimized formulation shows R^2

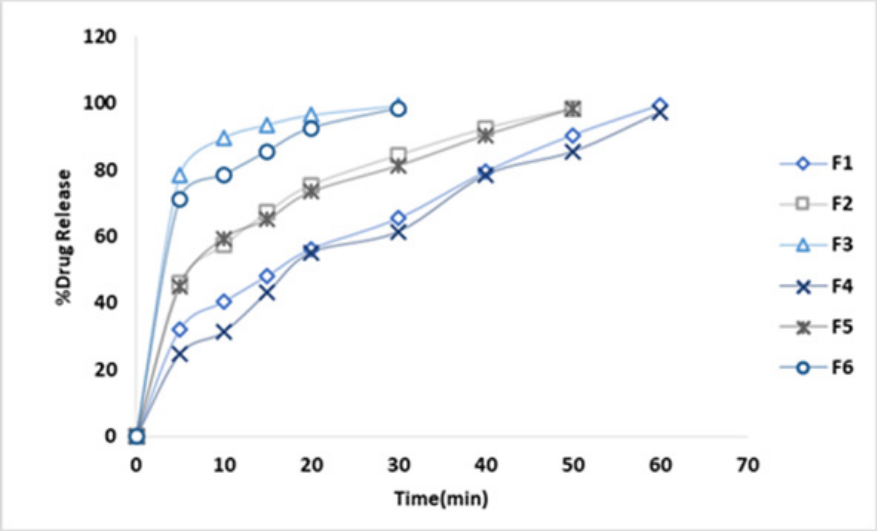

Figure 1: Percent Drug Release versus Time Plots of Tizanidine hydrochloride Tablets F1-F6.

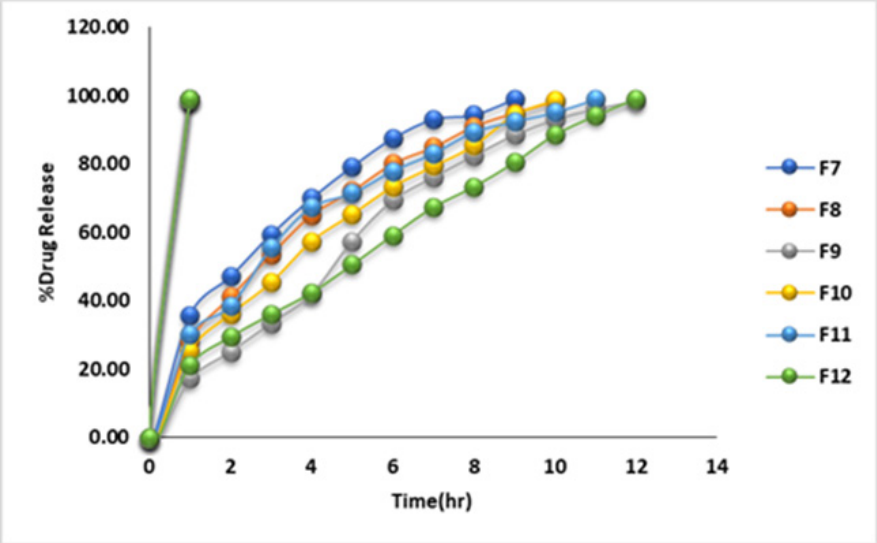

Figure 2: *In vitro* drug release profile of Bilayer tablets of Formulation F7-F12.

Table 4: Regression coefficients fit to different drug release kinetics models for best formulation F12.

Best Formulation code	Zero order	First order	Higuchi	Peppas	
	r2	r2	r2	r2	n value
F12	0.984	0.784	0.970	0.675	1.160

value of 0.984 as given in Table 4. This shows it follows zero order release with Super case II transport Mechanism.

DISCUSSION

The physical characteristics of powder blend of immediate release formulation (F1-F6) was found to be within the limits. The post compression parameter like hardness, friability and % drug content for all the of immediate release formulations and bilayer sustained release formulations (F7- F12) were found to be within the limits. The % Swelling index was found to be between 142.68±1.42% - 181.37±1.75%. The Floating lag time and the total floating time of the all the formulations (F7-F12) is found to be good. The *in vitro* drug release profile of all the immediate release formulations reveal that F3 formulation released maximum drug at the end of 30 min. The drug release profile of sustained release formulations (F7-F12), reveal that the formulation F12 had maximum drug release at the end of 12th hr. The *in vitro* drug release data for best formulation F12 were fitted into kinetic models i.e., zero order, first order, Higuchi and korsemeyer-peppas equation. Optimized formulation shows R^2 value of 0.984. This shows it follows zero order release with Super case II transport Mechanism.

CONCLUSION

Tizanidine hydrochloride (Zanaflex) is an $\alpha_2$adrenergic agonist commonly used for the short-term management of muscle spasticity. The goal of this work was to improve its bioavailability by increasing gastric retention through the development of a floating, bi-layer tablet combining both immediate- and extended-release mechanisms. Maintaining steady plasma concentrations is expected to boost the drug's therapeutic performance.

The formulation process involved using Lycoat and Ludiflash as super-disintegrants for the rapid-release layer, while sodium alginate and Carbopol 934P served to control release in the sustained-release layer. Additional excipients included magnesium stearate, sodium bicarbonate, citric acid, talc, PVP K30, microcrystalline cellulose, and lactose. FTIR analysis confirmed compatibility, showing no significant interactions between the drug, polymers, or excipients.

Immediate release tablets of tizanidine hydrochloride were prepared and evaluated for physical and pharmaceutical attributes hardness, weight variation, thickness, friability, content uniformity, and *in vitro* dissolution. Among various IR formulations tested, F3 (immediate release) was used to prepare the immediate release layer if the bilayer sustained release formulations (F7-F12) and F12 (sustained release) was found to be optimal. Notably, F12 demonstrated superior total floating duration, indicating enhanced gastric retention.

Drug release studies showed that both layers achieved high drug release, and kinetic analysis of F12 fitted a zero-order model with a Super Case II transport mechanism. In conclusion, this bi-layer tablet design successfully produced a stable formulation delivering Tizanidine hydrochloride with an immediate-release layer for fast onset and an extended-release layer for prolonged therapeutic effect.

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ABBREVIATIONS

TZN: Tizanidine Hydrochloride; **SR:** Sustained Release; **IR:** Immediate-Release; **PVP:** Polyvinylpyrrolidone; **BD:** Bulk Density; **Td:** Tapped Density; **FDDS:** Floating Drug Delivery Systems; **GRT:** Gastric Residence Time; **FTIR:** Fourier Transform Infrared Spectroscopy; **MCC:** Microcrystalline Cellulose; **FLT:** Floating Lag Time; **BLT:** Buoyancy Lag Time; **TFT:** Total Floating Time.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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