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Formulation, Characterization and Evaluation of Sustained Release Matrix Tablet of Antiemetic Agent

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Abstract. A sustained release matrix tablet of ondansetron HCl was prepared by the direct compression method using eudragit®RL 100 and eudragit®RS 100 with reduced dose, dosing frequency, improved bioavailability and prolonged release of the drug. Pre-compression and post-compression parameters were found to be uniform with their low standard deviation values. The similar characteristics of the IR peaks with few alterations observed in the spectra of the mixture of drugs and polymers and the uniform dispersion of the drug in an amorphous form in the tablets were revealed from the DSC thermogram, indicating the chemical stability of the drug. The *in vitro* drug release study in 0.1 N HCl, pH 1.2 for 2 h and remaining in phosphate buffer pH 6.8 indicated that the prepared tablets were capable of releasing drugs upto 12 h in the formulations F4 to F6 releasing drugs early, this might be due to using eudragit®RL 100 polymer which is relatively more hydrophilic than eudragit®RS 100. Among all the formulations, the F7 formulation was optimized as having sustained release properties and released 92.89% at the end of the 12 h from all nine (F1-F9) formulations. The optimized F7 batch showed no significant changes when subjected to stability at 40±20 °C temperature and relative humidity 75±5% for three months.

Keywords: sustained release, matrix tablet, ondensetron, antiemetic agent, FTIR, DSC

Introduction

Role of novel drug delivery systems that improve the therapeutic effectiveness of incorporated drug by providing sustained, controlled delivery and targeting the drug to the desired site. The aim of drug delivery system is to provide a therapeutic amount of drug to a specific site in the body to achieve prompt result and then maintain the desired drug concentration. The design of an oral sustained released delivery system is subjected to several interrelated variables of considerable importance such as the type of delivery system, the disease being treated, the patient, the length of therapy and the properties of the drug. A sustained release system includes any drug delivery system that achieves slow drug release over a prolong period of time (Lachman and Lieberman, 2009).

Matrix tablets are considered to be the commercially feasible sustained action dosage forms that involve the fewest processing variables, utilize conventional facilities and accommodate large doses of drug. There remains an interest in developing novel formulations that allow for sustained drug release using readily available, inexpensive excipient in matrix based formulations.

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The present investigation studied the development and characterization of a sustained release matrix tablet of ondensetron by direct compression method using eudragit®RS 100 and eudragit®RL 100 polymer ratios in single or in combination to achieve sustained drug release with reduced frequency of drug administration, reduced side effects and patient compliance, as well as prolonging the drug release to achieve better patient compliance. Ondensetron, with short elimination time of 5-7 h which is used in the prevention of nausea and vomiting and is a suitable candidate for sustained release administration.

Materials and Methods

Ondansetron HCl was a gift sample procured from Sun Pharma Sciences, Mumbai. Eudragit®RS 100 and eudragit®RL 100 were procured from Degussa, Rohm Pharma, Mumbai.

Organoleptic properties. Organoleptic properties such as colour, taste, odour and melting point have been studied.

Estimation of ondensetron by UV spectrophotometer. ***Preparation of stock solution in 0.1 N HCl.*** 20 mg of ondensetron was accurately weighed in a 100 mL

volumetric flask and then the volume was made upto 100 mL with 0.1 N HCl. This was a stock solution containing 200 µg/mL.

Determination of wavelength maxima (λ_{max}) of ondensetron in 0.1 N HCl. The solution of 10 µg/mL in 0.1 N HCl was prepared and scanned in the range of 200-400 nm and wavelength maxima were determined by using the Shimandzu U.V. Spectrophotometer (Sharma, 2009).

Preparation of stock solution in pH 6.8 phosphate buffer. 20 mg of Ondensetron was accurately weighed in a 100 mL volumetric flask and then the volume was made upto 100 mL with pH 6.8 phosphate buffer. This was a stock solution containing 200 µg/mL.

Determination of wavelength maxima (λ_{max}) of ondensetron in pH 6.8 phosphate buffer. The solution of 10 µg/mL in pH 6.8 phosphate buffer was prepared and scanned in the range of 200-400 nm, and wavelength maxima were determined by using Shimandzu U.V. spectrophotometer (Sharma, 2009).

Standard calibration curve of ondensetron in 0.1 N HCl. From the stock solution, 10 mL was pipetted out and transferred in to a 100 mL volumetric flask and the volume was made upto 100 mL with 0.1 N HCl, which contained a concentration of 20 µg/mL. From this solution, aliquots equivalent to 2-12 µg (2, 4, 6, 8, 10 and 12 mL) were pipetted out into a series of 10 mL volumetric flask and the volume was made upto 10 mL with 0.1 N HCl. The absorbance of these solutions was measured against 0.1 N HCl as a blank at 300 nm using UV-visible double beam spectrophotometer. Then a calibration curve was plotted, taking concentration in µg/mL on X-axis and absorbance on Y-axis (Sharma, 2009).

Standard calibration curve of ondensetron in pH 6.8 phosphate buffer. From the stock solution, 10 mL was pipetted out and transferred into a 100 mL volumetric flask and the volume was made up to 100 mL with pH 6.8 phosphate buffer, which contained a concentration of 20 µg/mL. From this solution, aliquots equivalent to 2-12 µg (2, 4, 6, 8, 10 and 12 mL) were pipetted out into a series of 10 mL volumetric flask and the volume was made upto 10 mL with 0.1 N HCl. The absorbance of these solutions was measured against 6.8 phosphate buffer as blank at 309 nm using UV-visible double beam spectrophotometer. Then a calibration curve was plotted, taking concentration in µg/mL on X-axis and absorbance on Y-axis (Sharma, 2009).

Solubility study. The solubility of ondansetron HCl was determined in solvents of different polarities. The solubility of ondansetron HCl is usually determined by the equilibrium solubility method (Lachman and Lieberman, 2009) which employs a saturated solution of ondansetron HCl obtained by adding an excess amount of ondansetron HCl in the solvent to promote drug precipitation and then stirring for two hours until equilibrium was reached. The mixture was filtered and amount of ondansetron HCl was determined by using UV-spectrophotometer.

Drug excipient compatibility study using fourier transform infrared spectroscopy. In this study, the potassium bromide disc method was employed for pure drug and excipients infrared (IR) studies. The powdered sample was intimately mixed with dry powdered potassium bromide. The mixture was then compressed into transparent disc under high pressure using special dies. The disc was placed in an infrared (IR) spectrophotometer using sample holder and spectrum was recorded between 400 and 4000/cm. Drug and polymer interactions were studied by using FTIR (Hui and Robinson, 1992; Chien, 1982).

Evaluation of powder parameters. Parameters including bulk density, tapped density, carr's index, hausner ratio and angle of repose of powder were evaluated according to the procedure given in Indian pharmacopoeia (Lachman and Lieberman, 2009; Indian Pharmacopoeia, 2007).

Formulation of sustained release matrix tablets by direct compression method. Matrix tablets containing ondansetron HCl were prepared by direct compression technique (Pawar and Surawase, 2013; Remington, 2006) using eudragit®RL100 and eudragit®RS100 as polymers. All ingredients were sifted through sieve no. 100. All the ingredients except magnesium stearate were blended in glass mortar uniformly. After sufficient mixing of the drug as well as other components, magnesium stearate as a lubricating agent was added and further mixed for an additional 2-3 min. Tablets were compressed using 10 Station Rotary Tablet Punch Machine with a 6 mm (diameter) punch.

Evaluation of post compression parameters of tablets. Tablets parameters like taste and colour, size, thickness, shape, hardness, friability, weight variation and drug content were carried out (Butola *et al*., 2023; Lachman and Lieberman, 2009).

In-vitro drug release study. Dis-solution tests (Farzan *et al*., 2023; Jantzen and Robinson, 1992) were performed in a USP XXII dissolution apparatus type II (electrolab Mumbai, India) at 37±0.5 °C. The paddles were rotated at a speed of 50 rpm. The prepared tablets of ondansetron HCl were placed in the dissolution vessel containing 0.1 N HCl solutions (pH 1.2) for 2 h. For the next 10 h, the dissolution was conducted in pH 6.8 phosphate buffer. 5 mL sample were withdrawn every hour for 12 h and the same volume of fresh medium was replaced every time. Sample were filtered through 0.45 µm filter paper and the content of ondansetron HCl was determined spectrophotometrically at a wavelength of 300 nm for the first two hours and 309 nm for the next 10 h.

Dissolution kinetic model. Model dependent methods Table 7 are based on different mathematical functions, which describe the dissolution profile. Once a suitable function has been selected, the dissolution profiles are evaluated depending on the derived model parameters (Farzan *et al*., 2023; Jantzen and Robinson, 1992).

Differential scanning calorimetry (DSC). Thermal properties of the pure ondansetron HCl and the physical mixture of drug and excipients were analyzed. The samples were heated in a hermetically sealed aluminum pan. Heat runs for each sample were set from 30 to 350 °C at a heating rate of 10 °C/min, using nitrogen as blanket gas (Butola *et al*., 2023).

Stability studies. The optimized tablet batch F7 was selected and wrapped in aluminum foil of thickness 0.04 mm and stored at a temperature of 40±2 °C with a relative humidity of 75±5%. The sampling was done every month and evaluation were done for appearance, thickness, hardness, friability, drug content and cumulative % drug release (Cartensen, 1995).

Results and Discussion

Procured ondansetron was evaluated for organoleptic parameters like colour, odour, taste and melting point and found to comply with the specifications given in the Indian Pharmacopoeia. Ondansetron was observed to be white powder, odourless, slightly bitter in taste with a melting point of 231 °C-232 °C. The solution of 10 µg/mL in 0.1 N hydrochloric acid and phosphate buffer pH 6.8 was prepared separately and scanned in the range of 200-400 nm and wavelength maxima was determined by using Shimandzu UV-spectrophotometer (Fig. 1 and 2) found to be 300 nm in 0.1 N hydrochloric acid and 309 nm in phosphate buffer, pH 6.8, respectively. In order to prepare standard calibration curve of ondansetron (Fig. 3) in 0.1 N hydrochloric acid and (Fig. 4) in phosphate buffer pH 6.8 absorbance values of different concentrations of ondansetron were determined Table 1 and Table 2 respectively. The solubility of ondansetron in water, 0.1 N HCl and phosphate buffer (pH 6.8) was found to be 0.25 mg/mL, 2.28 mg/mL and 8.22 mg/mL respectively (Table 3).

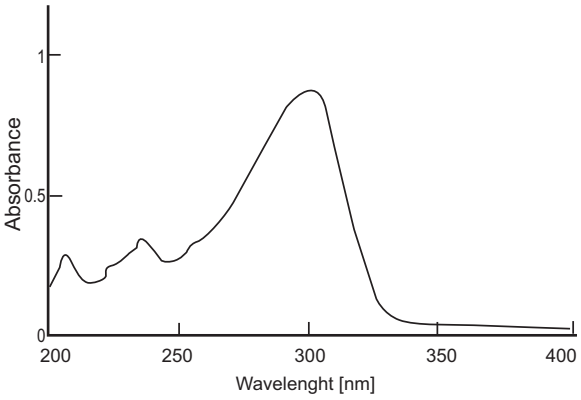

Fig. 1. Determination of wavelength maxima (λ_{max}) of ondansetron HCl in 0.1 N hydrochloric acid (Abs=absorbance).

Table 1. Absorbance values of different concentration of ondansetron in 0.1 N hydrochloric acid

Concentration (µg\mL)	Absorbance
0	0
2.0	0.076±0.04
4.0	0.147±0.02
6.0	0.221±0.07
8.0	0.301±0.05
10.0	0.379±0.02
12.0	0.456±0.03

Table 2. Absorbance values of different concentration of ondansetron in phosphate buffer pH 6.8

Concentration (µg\mL)	Absorbance
0	0
2.0	0.120±0.07
4.0	0.210±0.04
6.0	0.300±0.06
8.0	0.420±0.03
10.0	0.515±0.02
12.0	0.628±0.01

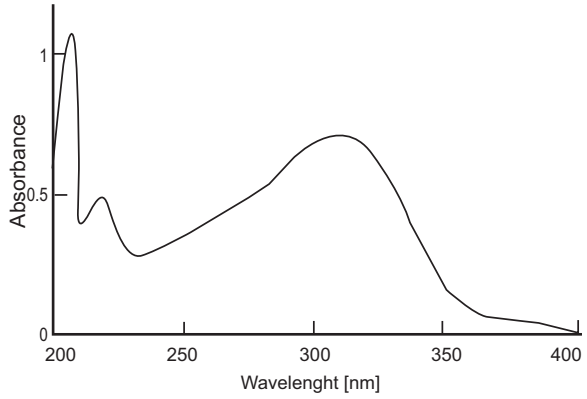

Fig. 2. Determination of wavelength maxima (λ_{max}) of ondansetron HCl in phosphate buffer pH 6.8 (Abs=absorbance).

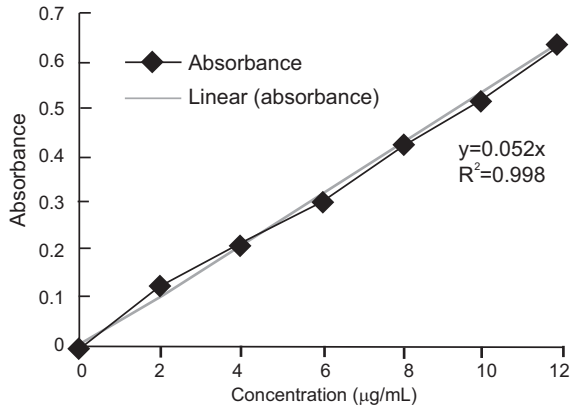

Fig. 3. Standard calibration curve of ondansetron HCl in 0.1 N hydrochloric acid (Conc.= concentration)

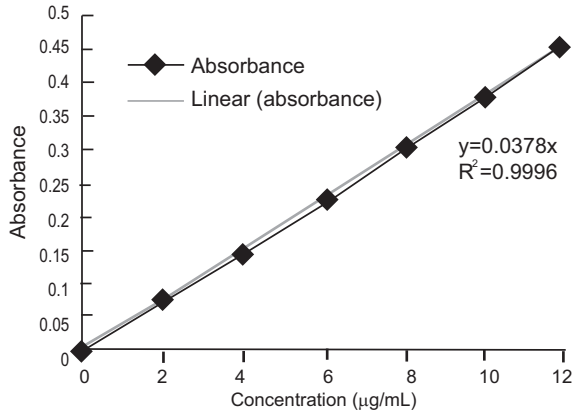

Fig. 4. Standard calibration curve of ondansetron HCl in phosphate buffer pH 6.8 (Conc.= concentration)

The FTIR interaction studies of drug (Fig. 5a) with polymers (Fig. 5b and 5c) suggest no incompatibility as retention of basic characteristics ondansetron at 3489, 3410, 2924, 1639, 1520, 1280, 756/cm due to -OH, -NH, -CH=C=O groups. Similar peaks with little alterations were also observed in the spectra of mixture of drug and polymers (Fig. 5d) indicating the chemical stability of the drug as shown in FTIR of drug and its excipients. The typical FTIR curves are shown in Fig. 5. Powder parameters were evaluated for various batches and found to pass according to the procedure given in the Indian pharmacopoeia Table 4. Matrix tablets containing ondansetron HCl were prepared by

Table 3. Solubility study of ondansetron in different solvents

Solvents	Solubility (mg/mL)
Water	0.25
0.1 N HCl	2.28
pH 6.8 phosphate buffer	8.22

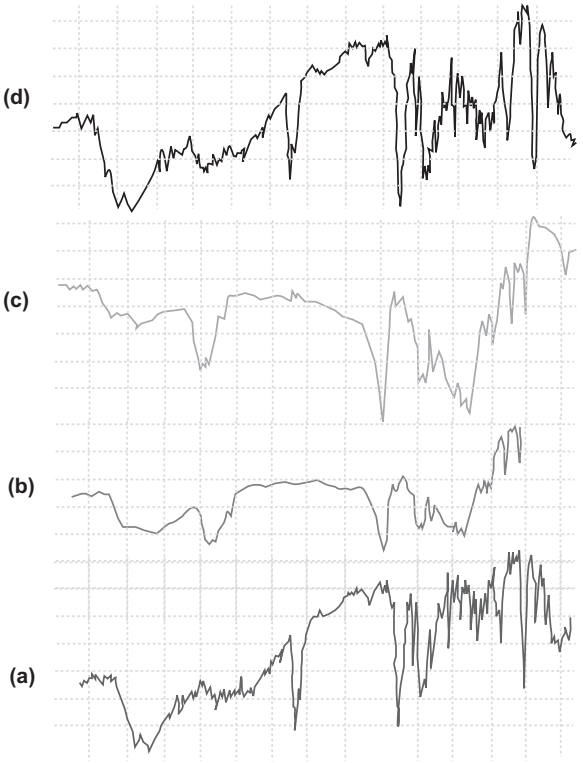

Fig. 5. FTIR of (**a**) ondansetron HCL (**b**) eudragit ®RL100 (**c**) eudragit®RS100 (**d**) physical mixture of ondansetron HCl with eudragit® RL100 and eudragit® RS100.

direct compression technique using eudragit®RL100 and eudragit®RS 100 as polymers (Table 5). Evaluation of tablets of batches F1 to F9 were carried out and found thickness in range of 2.80±0.04 to 3.05±0.02 mm; hardness 5.45±0.03 to 6.10±0.45 Kg/cm^2; friability around 0.28±0.01; weight variation about 121±0.17 mg and drug content about 98.29±0.19 which is the maximum in F7 batch (Table 6).

In vitro dissolution study of prepared tablets, namely F1-F9 (Table 7 and Fig. 6), were carried out in 0.1 N HCl solution (pH 1.2) for 2 h and in pH 6.8 phosphate buffer for the next 10 h. The results indicate that the

Table 4. Pre-formulation studies of various batches

Batches	Angle of repose ($^{\theta}$)±SD	Bulk density (g/mL)±SD	Tapped density (g/mL)±SD	Carr's index (%)±SD	Hausner's ratio ±SD
F1	29.38±0.11	0.29±0.35	0.33±0.05	11.78±0.11	1.13±0.07
F2	29.68±0.18	0.35±0.22	0.39±0.31	9.87±0.09	1.10±0.11
F3	29.66±0.19	0.30±0.09	0.33±0.07	8.92±0.62	1.09±0.01
F4	29.24±0.33	0.29±0.22	0.31±0.44	6.50±0.17	1.07±0.04
F5	27.40±0.12	0.53±0.05	0.60±0.14	12.82±0.19	1.14±0.03
F6	27.92±0.06	0.41±0.08	0.45±0.06	8.83±0.22	1.09±0.09
F7	30.00±0.45	0.49±0.03	0.57±0.40	14.03±0.21	1.16±0.09
F8	27.92±0.35	0.55±0.21	0.59±0.33	12.69±0.12	1.14±0.07
F9	27.40±0.02	0.49±0.12	0.56±0.34	13.35±0.11	1.15±0.04

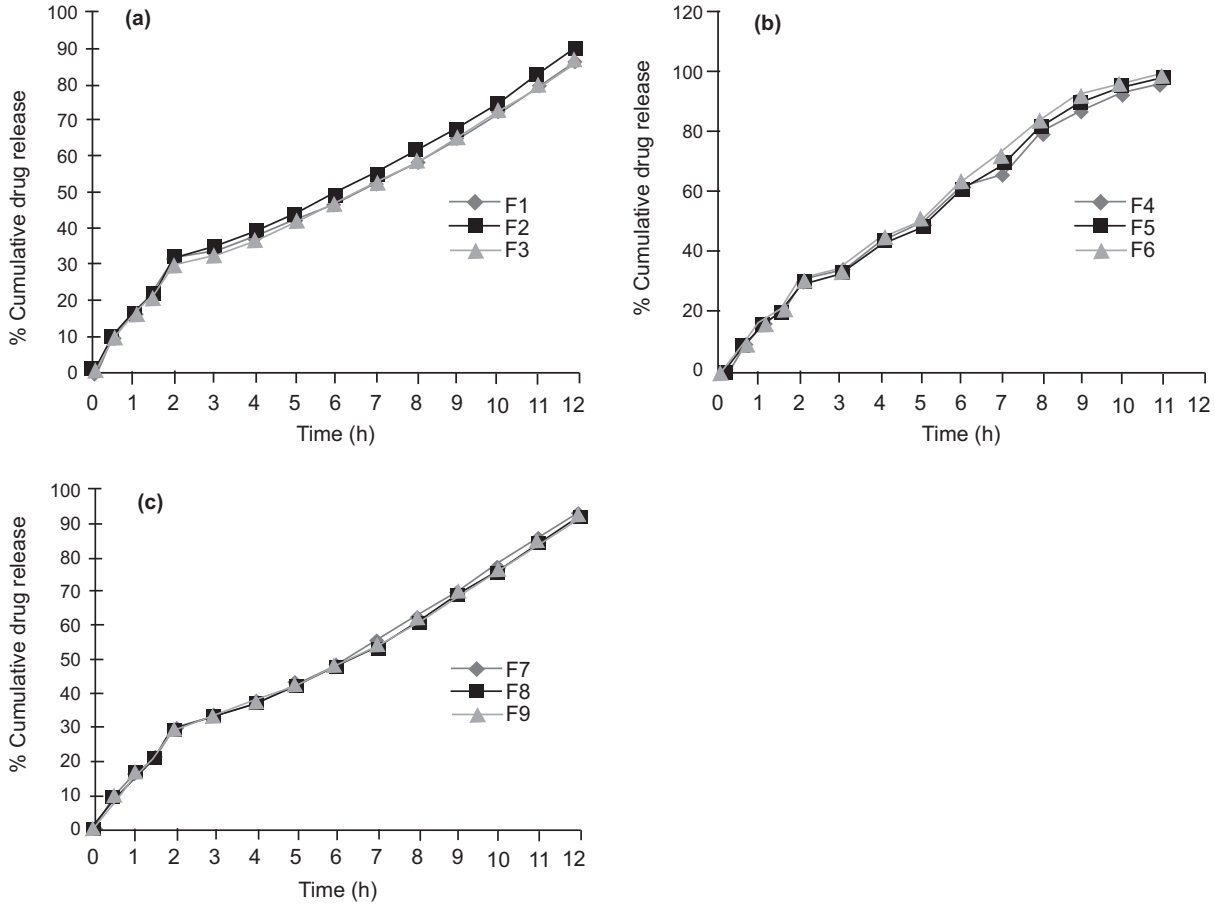

Fig. 6. % Cumulative ondensetron release from **(a)** F1-F3 **(b)** F4-F6 and **(c)** F7-F9.

Table 5. Formulation of sustained release matrix tablets

Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Ondansetron HCl	6	6	6	6	6	6	6	6	6
Eudragit RL 100	-	-	-	12	24	36	6	12	6
Eudragit RS 100	12	24	36	-	-	-	6	6	12
Avicel PH 102	101	89	77	101	89	77	101	95	95
Magnesium tearate	1	1	1	1	1	1	1	1	1
Total	120	120	120	120	120	120	120	120	120

end of 12th h. Based on the result of evaluation data from all nine (F1-F9) formulations, F7 was optimized because of its sustained release property. The *in vitro* drug release pattern of F7 showed the highest regression value (r^2=0.9922) for zero order model. The 'n' value was found to be below 0.5 suggesting that drug release follows Fickian diffusion (Higuchi Matrix) mechanism. Release kinetics may be following diffusion mechanism (Table 8 and 9).

Table 6. Physical evaluation of formulated tablet batches

Batches	Thickness (mm)±SD	Hardness (Kg/cm^2)±SD	Friability (%)±SD	Weight variation (mg)±SD	Weight variation uniformity (%)±SD
F1	2.80±0.04	5.75±0.08	0.13±0.05	119±1.15	97.22±0.25
F2	2.86±0.01	5.45±0.14	0.15±0.06	119±2.08	96.25±0.30
F3	2.83±0.06	5.80±0.09	0.12±0.09	120 ±1.52	97.29±0.25
F4	2.86±0.04	6.10±0.11	0.13±0.04	120±1.52	95.27±0.25
F5	2.87±0.01	5.45±0.03	0.28±0.01	119±0.57	96.28±0.30
F6	3.05±0.02	5.70±0.12	0.17±0.02	119 ±1.50	97.75±0.17
F7	2.83±0.02	5.75±0.17	0.13±0.09	121 ±0.17	98.29±0.19
F8	2.88±0.07	6.10±0.45	0.11±0.08	121±0.32	97.73±0.21
F9	3.03±0.03	6.00±0.40	0.10±0.04	120±1.05	97.91±0.20

Table 7. *In vitro* drug release profile of ondansetron HCl matrix tablet (F1-F9)

Time (h)	Batches								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
0.5	10.45±0.23	9.83±0.31	9.39±0.56	9.33±0.24	9.31±0.41	9.46±0.32	9.82±0.11	9.75±0.29	9.80±0.41
1	16.61±0.91	16.55±0.35	16.74±0.30	16.40±0.29	16.37±0.50	16.61±0.49	16.59±0.19	16.48±0.32	16.56±0.31
2	30.74±0.13	31.83±0.20	29.95±0.01	30.56±0.10	30.28±0.32	31.73±0.49	29.17±0.52	29.37±0.59	29.95±0.30
3	33.67±0.19	34.92±0.12	33.17±0.28	33.89±0.26	33.76±0.45	35.53±0.56	33.71±0.34	33.06±0.43	33.59±0.66
4	37.73±0.32	38.92±0.16	36.92±0.30	43.46±0.20	43.34±0.34	45.63±0.49	38.03±0.18	37.27±0.19	37.65±0.39
5	42.39±0.27	43.88±0.25	41.76±0.33	48.92±0.66	48.86±0.44	51.30±0.54	42.71±0.73	41.69±0.57	42.12±0.77
6	47.35±0.47	49.20±0.53	47.02±0.40	60.89±0.10	61.09±0.11	63.90±0.13	48.43±0.19	47.52±0.42	47.79±0.45
7	52.82±0.55	54.92±0.77	52.74±0.41	67.29±0.56	69.60±0.46	72.61±0.35	54.83±0.25	53.71±0.16	54.09±0.44
8	58.74±0.46	61.15±0.17	58.93±0.54	80.72±0.10	82.03±0.18	84.41±0.30	62.06±0.42	60.74±0.53	60.61±0.41
9	65.37±0.15	67.68±0.35	65.59±0.13	88.02±0.35	90.39±0.10	92.41±0.14	69.56±0.19	68.08±0.24	68.14±0.33
10	72.36±0.45	75.02±0.31	72.62±0.30	93.84±0.15	95.36±0.35	96.36±0.30	77.28±0.50	75.58±0.51	75.58±0.31
11	79.55±0.54	82.46±0.06	79.75±0.35	97.10±0.30	98.21±0.11	99.01±0.41	85.17±0.11	83.34±0.22	83.28±0.56
12	86.89±0.16	90.07±0.13	87.04±0.22	-------	-------	-------	92.89±0.50	91.30±0.20	91.35±0.20

prepared tablets were capable of releasing drug upto 12 h, depending upon the formulation variables, except formulations F4 to F6 releases drug early, which might be due to using a single eudragit®RL 100 polymer, which is relatively more hydrophilic than eudragit®RS 100. Among all the formulations, the F7 was optimized on the basis of its drug release profile. The tablets (F7) prepared with eudragit®RL100 and eudragit®RS 100 have shown a maximum drug release of 92.89% at the

Table 8. Mathematical models used to describe drug dissolution curves

S. No.	Models	Equation
1.	Zero order release equation	$Q_t = Q_0 + K_0 t$
2.	First order release equation	$\ln Q_t = \ln Q_0 + K_1 t$
3.	Higuchi plot equation	$Q_t = K_H t^{1/2}$
4.	Hixson – crowell equation	$Q_0^{1/3} - Q_t^{1/3} = K_s t$
5.	Korsmeyer-peppas equation	$\text{Log } (M t / M f) = \text{Log } k + n \text{ Log } t$

The DSC thermograms of ondansetron HCl (Fig. 7a) records an endothermic peak corresponding to the melting point of drug (231 °C) whereas the ondansetron HCl loaded optimized formulation, F7 (Fig. 7b), didn't show the peak at 231 °C, suggesting uniform dispersion of the drug in an amorphous form in the tablets. The optimized tablet batch F7 was selected and wrapped in aluminum foil of thickness 0.04 mm and stored at a temperature of 40±2 °C with a relative humidity of 75±5%. The sampling was done after every one month for three

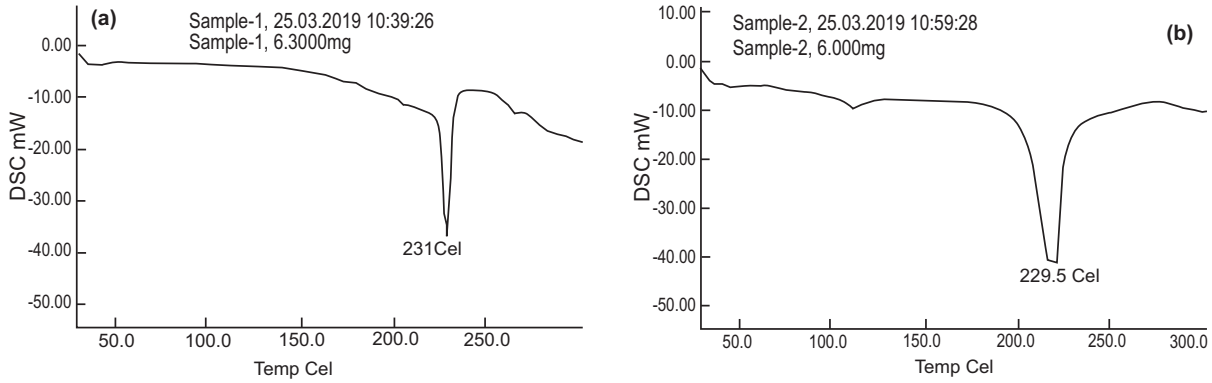

Fig. 7. DSC Thermogram of **(a)** ondansetron HCl **(b)** ondansetron HCl loaded optimized formulation.

Table 9. Kinetic treatment of data of dissolution profiles F1-F9

Batch	Variables	Zero order	First order	Hixson crowell	Korsmeyer peppas	Higuchi plot
F1	r^2	0.9879	0.7669	0.8557	0.9506	0.9831
	n	0.1064	0.0032	0.0149	0.6002	0.3084
	K	9.5183	0.7409	2.3675	-0.6170	2.5928
F2	r^2	0.9880	0.7749	0.8423	0.9417	0.9833
	n	0.1110	0.0033	0.0154	0.6368	0.2956
	K	9.5140	0.7338	2.3408	-0.6886	2.7126
F3	r^2	0.9892	0.7739	0.8600	0.9402	0.9822
	n	0.1076	0.0032	0.0149	0.6260	0.3051
	K	8.9057	0.7258	2.3088	-0.6837	2.8065
F4	r^2	0.9939	0.8104	0.9063	0.9284	0.9798
	n	0.1458	0.0036	0.0175	0.7244	0.2365
	K	6.7964	0.7065	2.1557	-0.8576	3.5849
F5	r^2	0.9940	0.8115	0.9075	0.9280	0.9781
	n	0.1491	0.0036	0.0175	0.7256	0.2309
	K	6.4100	0.7049	2.1463	-0.8613	3.7297
F6	r^2	0.9922	0.8127	0.9097	0.9285	0.9815
	n	0.1511	0.0036	0.0180	0.7413	0.2283
	K	7.3698	0.7109	2.1677	-0.8780	3.5093
F7	r^2	0.9922	0.7779	0.8675	0.9442	0.9786
	n	0.1162	0.0033	0.0152	0.6277	0.2822
	K	8.0399	0.7271	2.2996	-0.6807	3.2627
F8	r^2	0.9914	0.7751	0.8634	0.9438	0.9781
	n	0.1135	0.0032	0.0150	0.6202	0.2885
	K	8.0623	0.7267	2.3032	-0.6702	3.2187
F9	r^2	0.9908	0.7741	0.8621	0.9440	0.9790
	n	0.1132	0.0032	0.0150	0.6218	0.2894
	K	8.3704	0.7296	2.3182	0.6693	3.1200

months (Table 10), and evaluation was done for appearance, thickness, hardness, friability, drug content and cumulative % drug release in Table 11 and Fig. 8.

Table 10. Evaluation of formulation F7 kept for stability studies at 40°C/75% RH

Parameters	0 month	1 month	2 month	3 month
Appearance/Colour	White	White	White	White
Thickness (mm)	2.833	2.835	2.830	2.825
Hardness (Kg/cm^2)	5.7	5.6	5.6	5.6
Friability (%)	0.13	0.13	0.15	0.14
Drug content (%)	98.29	98.23	98.24	98.23

Table 11. *In vitro* drug release study of formulation F7 kept for stability at 40°C/75% RH

Time	Cumulative % ondansetron HCl release			
(h)	0 month	1 month	2 months	3 months
0	0	0	0	0
0.5	9.82	9.45	11.05	10.95
1	16.59	16.21	16.61	16.61
2	21.37	21.76	21.37	21.37
3	29.17	28.79	28.74	28.74
4	33.71	33.69	32.77	32.67
5	38.03	37.77	37.73	37.03
6	42.71	42.39	42.19	42.09
7	48.43	48.35	48.32	48.25
8	54.83	54.82	54.82	54.82
9	62.06	61.74	61.74	61.84
10	69.56	69.37	69.37	69.37
11	77.28	81.36	81.36	81.36
12	85.17	86.05	86.05	86.09

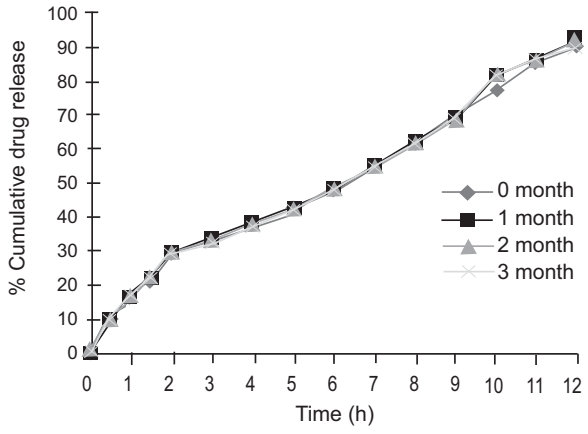

Fig. 8. *In vitro* release profiles of formulation F7 kept for stability at 40°±2°C and 75±5% RH for 3 months.

Conclusion

In present study, a sustained release matrix tablet of ondansetron HCl was prepared using eudragit®RL 100 and eudragit®RS 100 in combination as sustained release matrix forming polymers and Avicel pH 102 as a directly compressible material, which was confirmed by various characterization and evaluation studies.

It can be concluded from this study that the prepared tablets gave promising results with respect to sustained release of ondansetron from the dosage form.

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Conflict of Interest. The authors declare that they have no conflict of interest.

References

Butola, M., Bhatt, V., Nainwa, N., Jakhmola, V., Dobhal, K., Ale, Y. 2023. Preparation and evaluation of polymer fused metformin hydrochloride sustained release tablet. *Indian Journal of Pharmaceutical Education and Research*, **57:** 711-717.

Chien, Y.W. 1982. *Novel Drug Delivery System. Revised and Expanded*, 2nd edition, pp. 816, Routledge Taylor & Francis Group, UK.

Cartensen, J.T. 1995. *Drug Stability: Principle and Practice*, 2nd edition, pp. 538-550, Marcel Dekker, New York, USA.

Farzan, M., Roth, R., Schoelkopf, J., Huwyler, J., Puchkov, M. 2023. The processes behind drug loading and release in porous drug delivery systems. *Europian Journal of Pharmaceutics and Biopharmaceutics*, **189:** 133-151.

Hui, H.W., Robinson, J.R, Lee, V.H.L. 1992. Design and fabrication of oral controlled release drug delivery systems. In: *Controlled Drug Delivery Fundamentals and Applications*, Robinson J.R., Lee, V. (eds.), Vol. **2**, pp. 373-74, Marcel Dekker, New York, USA.

Indian Pharmacopoeia, 2007. Government of India, Ministry of Health and Family Welfare, pp. 177-183, Published by The Indian Pharmacopoeia Commission, Ghaziabad, India.

Jantzen, G.M., Robinson, J.R. 1992. Diffusion controlled matrix systems, In: *Treatise on Controlled Drug*

Delivery, Kydonieus, A. (ed.), pp. 172-175, Marcel Dekker Inc., New York, USA.

Lachman, L., Lieberman, H.A. 2009. *The Theory and Practice of Industrial Pharmacy*, Special Edition, pp. 430-456, CBS Publication.

Pawar, S.Y., Surawase, R.K., 2013. Formulation and evaluation of sustained release matrix tablet of valsartan. *Research Journal of Pharmaceutical Dosage Forms and Technology*, **15:** 241-247. doi:10.52711/0975-4377.2023.00039.

Remington, J.P. 2006. *The Science and Practice of Pharmacy*, pp. 772, Lippincott Williams and Wilkins, Philadelphia.

Sharma, Y.R. 2009. *Elementary Organic Spectroscopy Principal and Chemical Application*, pp.9-10, S. Chand, Company Ltd., New Delhi, India.