

A RESEARCH ON “FORMULATION AND EVALUATION OF TRANSDERMAL PATCH OF ONDANSETRON HYDROCHLORIC ACID (HCL)”

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ABSTRACT

The primary theme of this research is to design the formulation and evaluation of a transdermal patch of Ondansetron hydrochloric acid (HCL), used in the prevention and management of chemotherapy-induced nausea and vomiting (CINV), post-operative nausea and vomiting (PONV), radiotherapy as well as surgery through acting upon a serotonin receptor i.e. 5-HT (5-hydroxytryptamine) and subtype-3 (5-HT₃) receptor as agonist. 5-HT₃ receptors, located centrally in the chemoreceptor trigger zone of the area postrema as well as peripherally on vagal nerve terminals, are key receptors in the nausea and vomiting response. With the controlled release of this patch directly into the bloodstream and without liver metabolism, this approach provides therapeutic benefits with improved drug efficacy, bioavailability, cost effective, enhanced drug safety, easy and painless administration lead to increase in patient compliance compare to other doses form of drug. In this study, transdermal patch formulations were prepared containing different ratio of hydrophobic i.e. ethyl-cellulose (EC) and hydrophilic polymeric i.e. Hydroxypropyl methylcellulose (HPMC) systems using the Solvent Evaporation Method in 50:50 ratio of ethanol and water as solvent. All the formulated transdermal patches were tested using several physicochemical analyses, including changes in weight, thickness, drug content, and so forth.

KEYWORDS: Transdermal patch, Ondansetron HCL, serotonin receptor, bioavailability, compliance, painless, polymer.

INTRODUCTION

The Skin

The skin is the human body's largest organ. It is made up of several biological layers that serve the body in numerous ways, acting as a permeability barrier and preventing the body from being exposed to the environment. Skin consists of three distinct layers: the nonviable epidermis, the viable epidermis, the dermis, and the hypodermis. The outer layer of the skin is called the stratum corneum, which provides the skin's barrier function. The nonviable epidermis has long been thought to be the rate-limiting step in the penetration of most molecules into the skin. Fick's Law of Diffusion can be used to regulate percutaneous absorption.^[1-8]

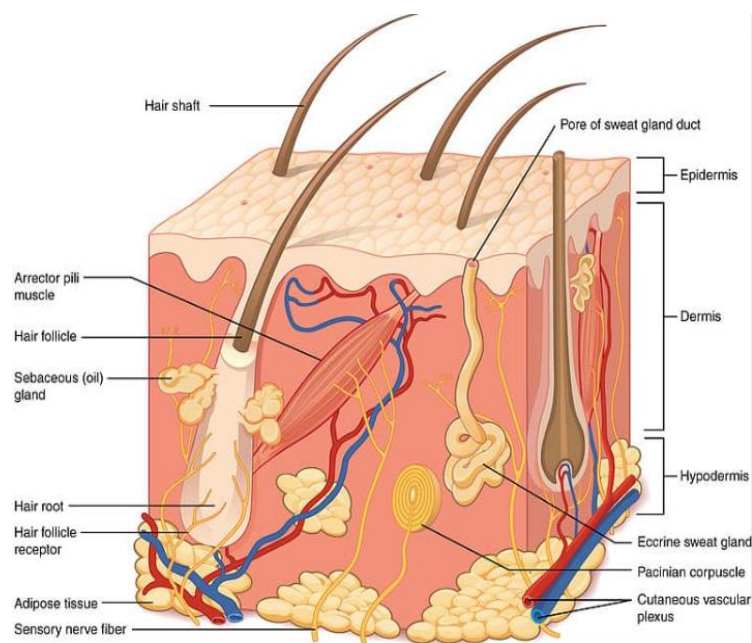


Figure 1: Different layers of the Skin.

Transdermal Drug Delivery System (TDDS)

At the extreme, pharmaceutical delivery systems exist, called Transdermal Drug Delivery Systems (TDDS). In this way, they can let the drugs pass directly through the skin into the blood. Thus, this route avoids the liver, resulting in a longer duration of the drug in circulation. The method delivers the right amount of medication through the skin and is often applied as patches, helping patients take their medication easily. Does not coerce them into taking medicines every day. These systems are tailored to each patient, helping them achieve the correct drug dosage with the same therapeutic effect and improving compliance.

Advantages of TDDS

1. Avoidance of first pass effects
2. Controlled Drug Delivery
3. Patient compliance enhancement
4. Reduced Side Effects
5. Non-Invasive (drug is delivered via the skin)
6. Self-Administration
7. Easy Termination of Therapy

Limitations of TDDS

1. Skin Irritation and Sensitization
2. Permeability Constraints
3. Variable Skin Permeability
4. Dose Limitations

In addition, the TDD system may be used instead of oral drug administration in infants or patients with swallowing difficulties, such as elderly patients. Furthermore, TDD is particularly suitable for proteins, peptides, and other macromolecules that must not pass through the gastrointestinal tract. In addition, TDD has already proven to be a good method for high-potency drug treatment and is a controlled and sustained release drug.^[9-10]

The formulation of ondansetron HCL into transdermal patch depends on various factors such as poor bioavailability, low molecular weight, shorter half-life and good skin penetration make the ondansetron an ideal drug candidate for transdermal delivery. It offers following advantages over oral route as it facilitates easy application and termination of therapy, avoids hepatic first pass metabolism, suitable for unconscious patient, pregnant women and pediatrics, has good penetration through skin increases bioavailability. It also reduces frequency of administration, sustained drug release time, constant and prolonged drug level maintaining plasma concentration and improve drug efficacy and patient compliance in the long-term therapy.^[11-12]

Drug Profile

Ondansetron is a serotonin (5-hydroxytryptamine) subtype 3 (5-HT₃) receptor antagonists used in the management of nausea and vomiting. 5-HT₃ receptors, located centrally in the chemoreceptor trigger zone of the area postrema as well as peripherally on vagal nerve terminals, are key receptors in the nausea and vomiting response. Ondansetron has been used to prevent and control chemotherapy-induced nausea and vomiting (CINV), Ondansetron is also effective in controlling post-operative nausea and vomiting (PONV), radiotherapy and surgery. Due to its short half-life and low bioavailability, it is administered orally 3 to 4-times a day, where in the patient compliance is low.^[13]

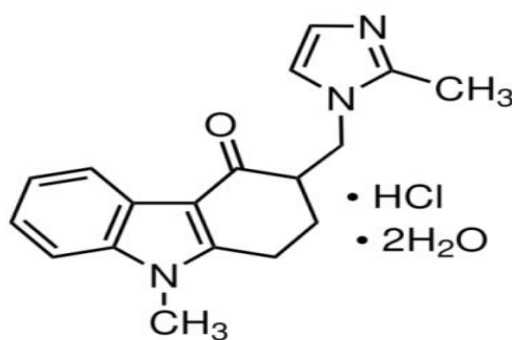


Figure 2: Structure of Ondansetron HCl.

Molecular formula: C₁₈H₁₉N₃O, HCl, 2H₂O

Molecular weight: 365.9

Colour: White to off-white crystalline powder

Odour: Odourless

Storage: Store protected from light and moisture, at a temperature not exceeding 30°C.

METHODOLOGY

1. Pre-formulation study

The pre-formulation study was performed in order to assure the accuracy of drug sample and determination of various parameters for formulation of transdermal patch.

a. Organoleptic properties of drug

The color, odor and appearance of drug sample were evaluated.

b. Determination of solubility

The solubility analysis for Ondansetron was done by solubility determination in different solvents like Methanol: Water (20: 80), Methanol: Chloroform (80:20), Chloroform: Methanol (50:50) and Ethanol: Water (50:50).

c. Linearity

Linearity of the sample was determined by preparing various concentration of Ondansetron Hydrochloride. At first, 1000 ppm of Ondansetron Hydrochloride was prepared in Phosphate buffer of pH 5.8. Main stock of 100 ppm was prepared. The stock solution was suitably diluted to obtain 4 ppm, 6 ppm, 8ppm, 10 ppm and 12 ppm. Absorbance of the solution was observed at λ_{max} 310 nm with the help of UV spectrophotometer (200-800 nm). The correlation coefficient value from 0.8 to 1 range is considered as very strong positive level of correlation.

2. Formulation

The formulation of transdermal patch of Ondansetron HCl was prepared by weighing the calculated number of polymers as per Minitab software. Total 13-different formulations were prepared i.e. from F1 to F13 and its composition is as shown in table 4.

The process of preparation of all formulations was similar. Solvent was prepared in the ratio 50:50 (Ethanol: Distilled Water) in a beaker. Then it was placed in a magnetic stirrer and Polyvinyl alcohol (PVA) was poured in the solvent and was left for stirring until it appeared transparent. Hydroxypropyl methylcellulose (HPMC) was slowly added in the solvent and left for proper mixing. Ethyl-cellulose (EC) was added in the above prepared mixture. Then API was added to the mixture following the addition of Polyethylene glycol (PEG) and glycerin. The prepared mixture was poured in five Petri dishes and left for drying by placing the Petri dishes in Hot Air Oven at 60°C for 6 hours. The dried patches were then stored between sheets of butter paper in a desiccator.^[14]

Table 1: The formulation composition of transdermal patch of Ondansetron HCl.

Formulation code	Ondansetron (mg)	HPMC (gm)	EC (gm)	PEG (ml)	PVA (gm)	Glycerin (ml)	Solvent (ml)
F1	250	1.5	1.5	30	3	1	100
F2	250	1.5	1.5	30	3	1	100
F3	250	1.5	1.5	30	3	1	100
F4	250	0.1	1.5	30	3	1	100
F5	250	1.5	1.5	30	3	1	100
F6	250	2.5	0.5	30	3	1	100
F7	250	1.5	1.5	30	3	1	100
F8	250	1.5	0.1	30	3	1	100
F9	250	2.5	2.5	30	3	1	100
F10	250	0.5	0.5	30	3	1	100
F11	250	0.5	2.5	30	3	1	100

F12	250	1.5	2.9	30	3	1	100
F13	250	2.9	1.5	30	3	1	100

3. Evaluation of patch

a. Appearance

The color, texture and shape of transdermal patch were evaluated.

b. Thickness

Vernier caliper was used for measuring the thickness of the patch by measuring at three different points and the average of the three measures was calculated.^[15]



Figure 3: Vernier caliper.

c. Weight variation

Weight variation was performed by weighing every individual patch of each batch in a weighing balance.^[16]

$$\% \text{ Weight variation} = \frac{\text{individual wt} - \text{average wt}}{\text{average wt}} \times 100$$

d. Surface pH

pH of the patches surface was determined using a digital pH-meter by keeping the patches film in the phosphate buffer (pH 5.8).^[17]

e. Percentage of Moisture content

The films were weighed individually and was placed them in the desiccator (W₀) containing silica gel at 25 °C for 24 hours. The films were weighed after 24 hours (W_t) and percentage of moisture content was calculated by the following formulae.^[17]

$$\% \text{ Moisture content} = \frac{w_0 - w_t}{w_0} \times 100$$

f. Drug content

A 5×5 cm² area of patch was cut and weighed. It was dissolved in phosphate buffer (pH 5.8) and was sonicated for about 15 minutes for complete dissolution. The solution was poured in 50 ml volumetric flask and the volume makeup was done. After that the solution was filtered and 1 ml of the filtrate was withdrawn and diluted to 100 ml with buffer solution. The content of drug present in the filtrate was determined by using double beam UV spectrophotometer at λ_{max} 310 nm and the resultant absorbance was noted and percentage of drug content was calculated using following formula.^[18]

Beer Lambert's Law: $A = EbC$,

Where,

A=Absorptivity

E= molar absorptivity,

B= length of light path,

C= concentration

g. In vitro drug release

The in vitro drug release studies were performed using IP Type II dissolution test apparatus. Buffer solution was prepared by dissolving 6.8 gm of Potassium dihydrogen orthophosphate (pH 5.8). Then 900ml of the buffer solution was kept in vessels $5 \times 5 \text{ cm}^2$ of each patch of all the formulations were cut, weighed and kept in the basket. The dissolution process was started and performed in triplicate for eight hours. In every one hour, 5 ml solution was taken and filtered from each vessel, replacing with 5 ml of buffer solution. The absorbance of the filtrate was read in double beam UV spectrophotometer and the reading was noted of every hour.^[19-20]

h. Kinetic study

Kinetic study was performed to evaluate the mechanism of drug release from the prepared formulations by subjecting all the batches to different kinetic models i.e. Zero order kinetic, First order kinetic, Higuchi model and Korsmeyer-Peppas model. The drug release kinetics of transdermal patch of all formulations was analyzed by fitting the release data into various kinetic models.

RESULTS AND DISCUSSION

1. Pre-formulation study

a. Organoleptic properties of drug

The color, odor and appearance of the drug were evaluated and results found to be as shown in *table-2*.

Table 2: Organoleptic properties of drug.

S. No.	Organoleptic properties	Inference
1.	Color	White or off- white
2.	Odor	Odourless
3.	Appearance	Crystalline powder

b. Determination of solubility

The solubility study revealed that the drug sample was freely soluble in Water: Ethanol (50:50) and sparingly soluble in Methanol: Water (20:80), Methanol: Water (80:20) and Methanol: Chloroform (50:50).

c. Linearity

The evaluation of linearity was done by plotting Concentration VS absorbance graph in X and Y- axis respectively at max 310 nm and regression line was drawn as shown in *figure-4* and data in *table-3*. The regression coefficient (r^2) was found to be 0.997 and hence the method was considered linear. This result demonstrates that Ondansetron displays a good correlation coefficient between the concentration range of 4 ppm to 12 ppm in phosphate buffer.

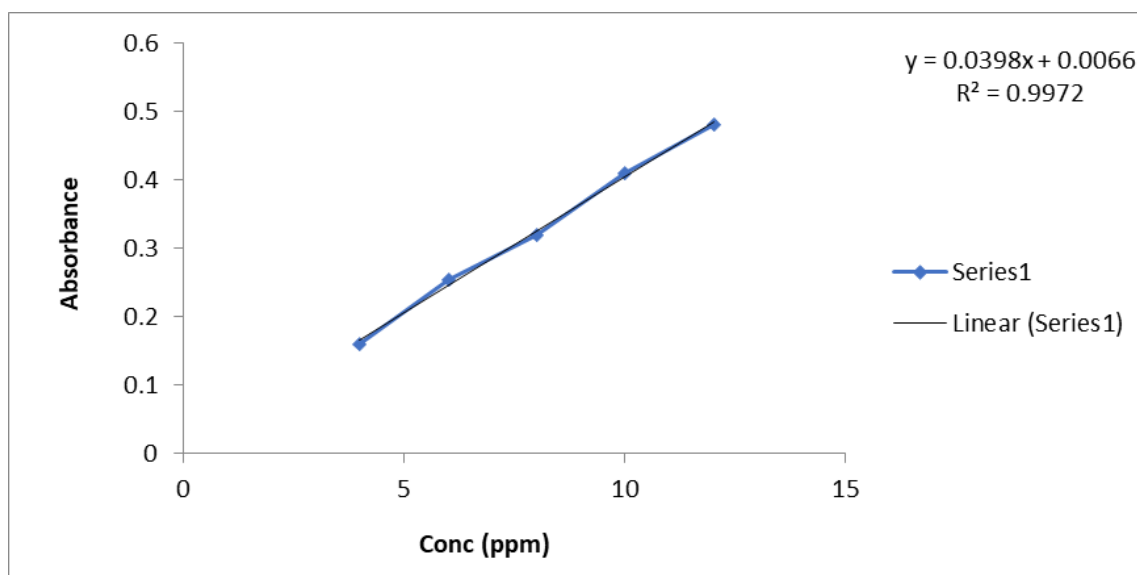


Figure 4: Standard calibration curve of Ondansetron HCl at max 310 nm.

Table 3: Absorbance of standard at different concentration.

S. No.	Concentration	Absorbance
1.	4 ppm	0.160
2.	6 ppm	0.255
3.	8 ppm	0.320
4.	10 ppm	0.409
5.	12 ppm	0.481

2. Evaluation of transdermal patch

Table 4: Evaluation Parameters of transdermal patch of Ondansetron HCL.

Formulation Code (FN)	Thickness index (mm)	Weight variation (mg/cm ²)	Surface pH	Moisture content (%)	Drug content (%)
F1	0.42±0.21	3.836±0.13	6.41±0.47	4.62±2.69	93.64±0.05
F2	0.31±0.03	3.83±0.179	6.67±0.15	3.87±2.59	93.89±0.05
F3	0.27±0.05	3.87±0.209	6.39±0.29	3.91±1.84	95.63±0.05
F4	0.33±0.02	3.84±0.147	6.32±0.16	8.90±2.91	92.66±0.05
F5	0.29±0.05	3.80±0.216	6.38±0.45	5.66±2.47	96.34±0.01
F6	0.43±0.48	3.87±0.146	6.31±0.35	6.12±2.04	94.13±0.05
F7	0.63±0.34	3.92±0.180	5.81±0.34	5.32±1.91	91.19±0.01
F8	0.35±0.15	3.84±0.18	6.42±0.39	6.51±3.44	92.42±0.003
F9	0.26±0.20	4.13±0.817	6.27±0.47	4.04±1.87	97.69±0.11
F10	0.34±0.05	4.24±0.3	7.12±0.28	8.43±5.20	101.47±0.01
F11	0.57±0.29	4.37±0.704	6.13±0.55	6.33±3.27	97.55±0.04
F12	0.51±0.35	3.83±0.127	6.69±0.59	3.91±1.57	108.07±0.04
F13	0.48±0.18	3.87±0.102	6.89±0.62	5.70±3.24	99.24±0.05

Data presented as Mean ± SD (n = 5)

a. Appearance

The color, texture and shape of transdermal patch were found to be clear and white, smooth and circular respectively.



Figure 5: Transdermal patch of Ondansetron HCL.

b. Thickness

The thickness of the patch was found to be between the ranges 0.22 ± 0.06 to 0.706 ± 0.36 . The variation in the thickness of the patch is due to the variation in the concentration of polymers. The thickness of all the formulations is as shown in the figure-6.

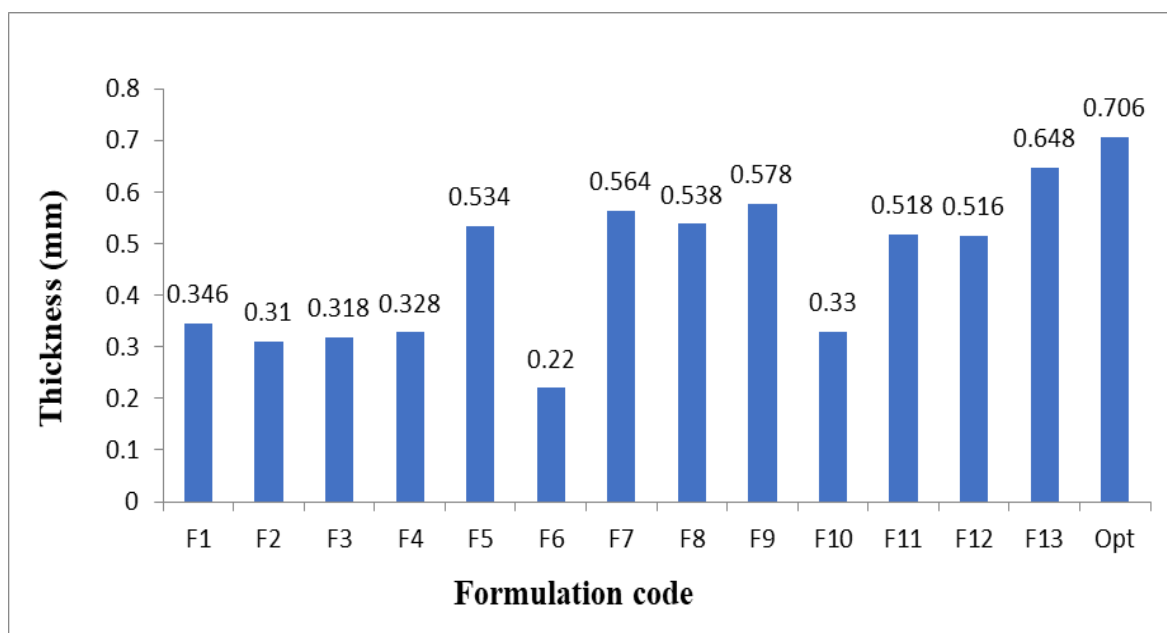


Figure 6: Bar diagram showing thickness of transdermal patches of different formulation.

c. Weight variation

The weight variation of the transdermal patch was found to be between the ranges of 3.80 ± 0.22 to 4.37 ± 0.704 . The variation in the weight variation of the patch is due to the variation in the concentration of polymers as shown in figure-7.

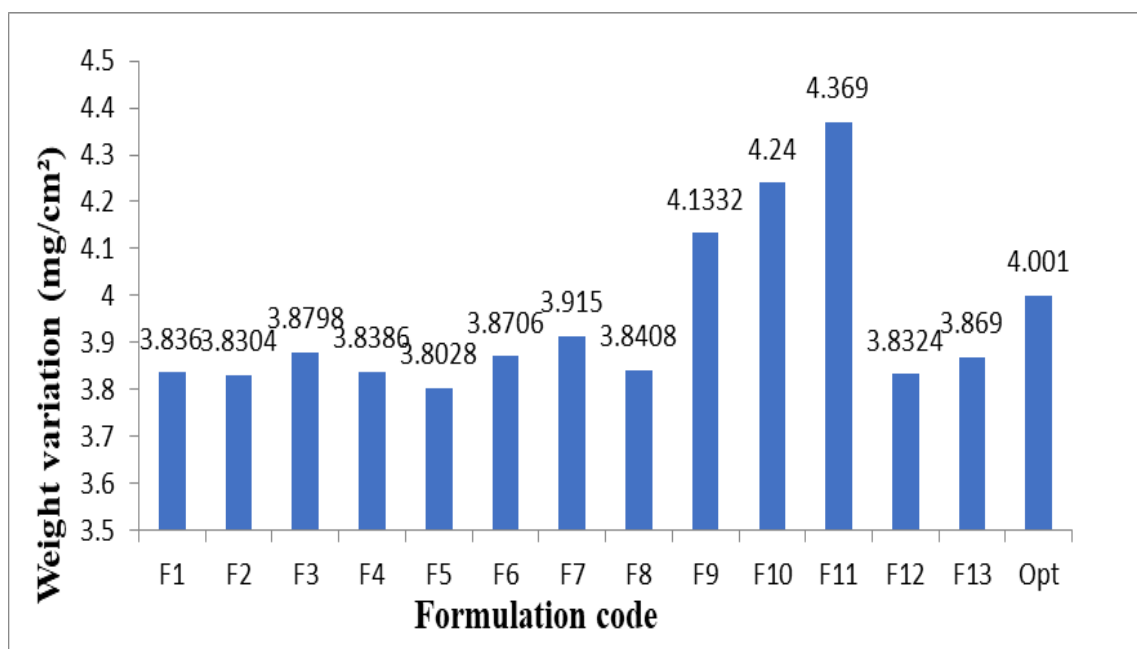


Figure 7: Bar diagram showing weight variation of transdermal patches of different formulation.

d. Surface pH

The surface pH of transdermal patch was found between 5.58 ± 0.44 to 7.12 ± 0.28 whereas highest in the formulation F10. Hence, the pH of the patch surface was within the acceptable ranges. The surface pH of the patch is shown in the figure-8.

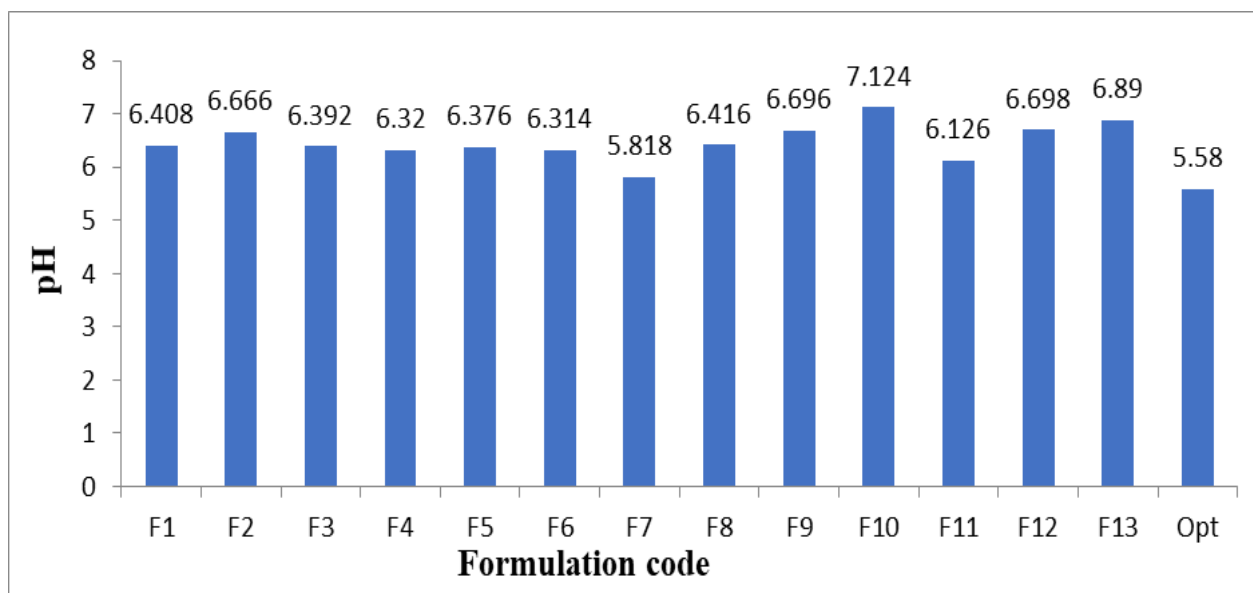


Figure 8: Bar diagram showing surface pH of transdermal patches of different formulation.

e. Percentage of moisture content

The result of the percentage of moisture content was evaluated and found to be between the range 3.60 ± 1.58 to 8.90 ± 2.91 . The moisture content of all the formulations was within the acceptable limits i.e. 2 to 10 %. The % moisture content of all the formulations is shown in the figure-9.

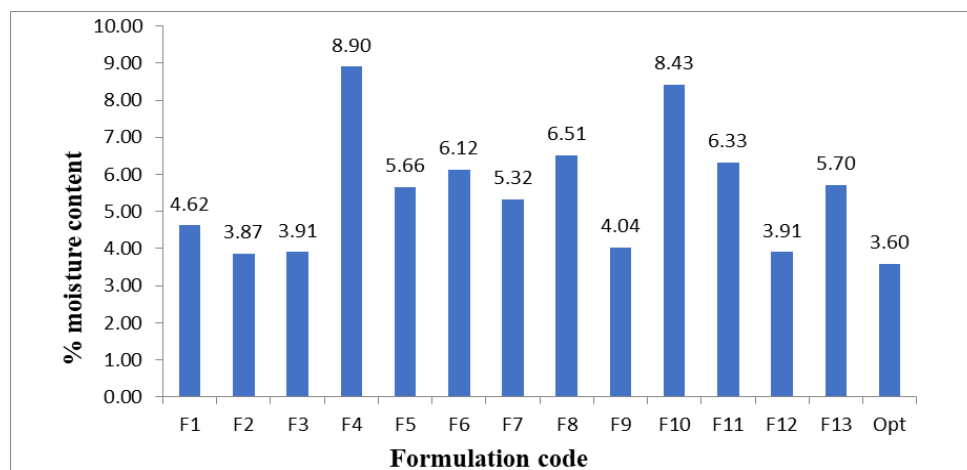


Figure 9: Bar diagram showing % moisture content of patches of different formulation.

f. Drug content

The drug content was observed to be in the range of 91.198 ± 0.047 to 108.069 ± 0.043 %. The result obtained as shown in figure-10. The content of drug of all formulations was found to be within the limit i.e. 90 to 110 % and hence passed the assay according to IP. The percentage of drug content was calculated by using formula as

$$\% \text{ Assay} = [\text{Spl Abs} / \text{Std. Abs} \times \text{std. wt.} / \text{std. dil} \times \text{spl. dil} / \text{spl. Wt.}] \times \text{Average weight} / \text{label claimed} \times 100 \%$$

Where,

Spl Abs = sample absorbance

Std. Abs = standard absorbance

Std. wt. = weight of standard

Std. dil = standard dilution

Spl. dil = sample dilution

Spl. Wt. = sample weight

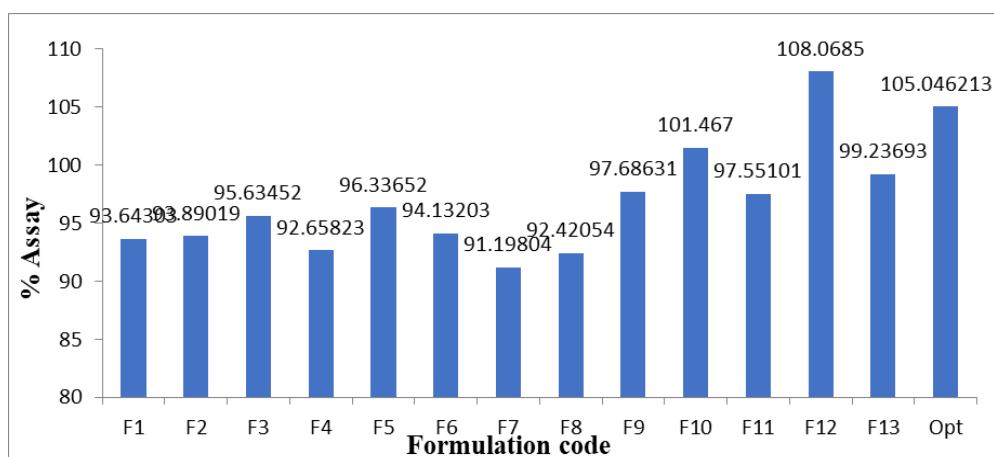


Figure 10: Bar diagram showing % assay of transdermal patches of different formulation.

g. In vitro drug release

The in vitro drug release was evaluated and observed that all the formulations exhibited slow and controlled release up to 8 hours. The in-vitro drug release of all the formulation gave different drug release profile ranging from 32.64% - 67.77% in first hour to 81.22 to 100.51% in 8 hours. Hence, the transdermal patches of all the formulations are considered to be of sustained release. The cumulative percent release of Ondansetron HCl from all the transdermal

patches is given in annex 2 and represented in Figure 8. The percent of in vitro drug release was calculated using following formula:

$$\% \text{ Assay} = [\text{Spl Abs} / \text{Std. Abs} \times \text{std. wt.} / \text{std. dil} \times 900 / \text{spl. Wt.}] \times \text{Average weight} / \text{label claimed} \times 100 \%$$

Where,

Spl Abs = sample absorbance

Std. Abs = standard absorbance

Table 5: In vitro drug release.

FN	1 hr	2 hr	3 hr	4 hr	5 hr	6 hr	7 hr	8 hr
F1	53.55	57.36	59.90	62.18	64.47	77.66	84.26	86.04
F2	52.99	56.89	59.86	61.97	63.46	76.23	83.10	85.23
F3	53.02	56.76	59.71	62.18	63.99	75.44	82.94	84.39
F4	60.66	73.10	86.04	100.02	102.36	101.14	100.08	100.51
F5	53.75	57.66	59.23	63.18	65.01	71.46	79.99	84.54
F6	44.92	51.52	56.35	62.18	64.47	77.66	84.26	93.15
F7	52.88	56.95	58.31	62.18	65.49	73.68	80.06	84.76
F8	67.77	81.73	88.58	101.02	102.36	104.14	105.08	100.51
F9	32.64	36.35	54.72	65.74	72.59	84.52	93.15	93.91
F10	36.55	54.31	54.82	60.91	63.20	74.11	82.74	78.17
F11	62.18	62.18	62.94	64.97	70.81	74.37	81.73	82.74
F12	47.72	50.76	61.17	65.23	70.56	84.77	86.04	91.12
F13	33.55	47.72	50.76	52.79	56.35	73.60	80.96	81.22

Data presented as Mean $\pm$ SD (n=3)

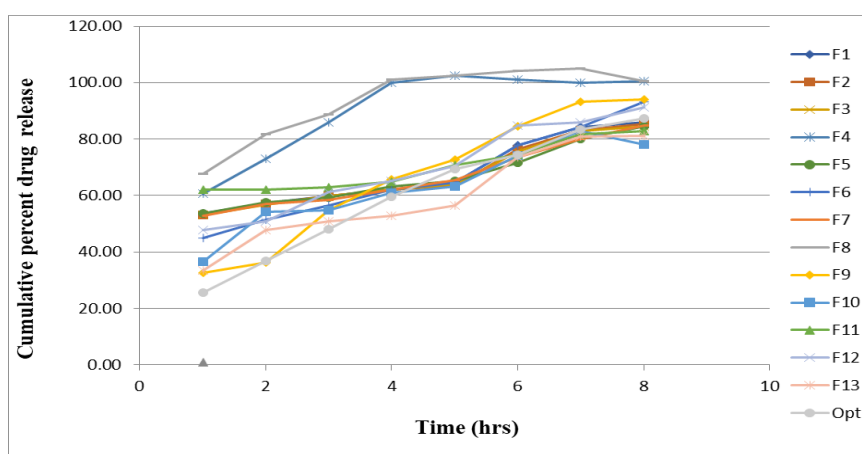


Figure 11: % Cumulative release profile of formulations in phosphate buffer solution.

h. Kinetics

The drug release kinetics was studied for Zero order, First order, Higuchi Model and Korsmeyer Peppas Model. The correlation coefficient (r^2) values of all formulations for each order are given in the table-6 as given below. It was observed that the drug release kinetic of all the formulations did not fit to first order kinetics but for the formulations F1, F2, F3, F5, F6, F7, F11, F12, F13, the r^2 values were higher when fitted to Zero order kinetics which states that the drug release rate from the formulation is independent of the concentration of the drug.

Whereas the formulation F9 followed Higuchi model. This model proposed that the initial drug concentration in the matrix is much higher than drug solubility. The r^2 value of korsmeyer-peppas model was higher for formulation F4, F8, F10 and optimized with the value of n i.e. 1.798, 1.846, 1.579 and 1.648 respectively indicates that the formulations

follow non Fickian diffusion as the value of $n > 0.45$ is considered to be optimum value for non Fickian diffusion. Non Fickian diffusion means that the formulations are of sustain release. Hence, the optimized formulation also fitted to Korsmeyer peppas model. The optimized formulation was observed to follow korsmeyer peppas model as the value of r^2 was 0.913 with the value of $n = 1.648$ and therefore the value of n is greater than 0.85 which proved that the optimized formulation has sustain release.

Table 6: Drug release kinetic of transdermal patches.

F.N.	Zero order	First order	Higuchi	Korsmeyer peppas	
	r^2	r^2	r^2	r^2	n
1	0.928	0.881	0.867	0.81	1.693
2	0.929	0.882	0.869	0.814	1.69
3	0.938	0.889	0.879	0.826	1.691
4	0.724	0.755	0.828	0.904	1.798
5	0.95	0.884	0.886	0.832	1.7
6	0.975	0.852	0.929	0.909	1.616
7	0.962	0.906	0.901	0.846	1.691
8	0.736	0.757	0.839	0.914	1.846
9	0.969	0.946	0.975	0.958	1.466
10	0.912	0.896	0.933	0.943	1.579
11	0.915	0.881	0.833	0.732	1.759
12	0.975	0.938	0.956	0.929	1.639
13	0.938	0.908	0.919	0.923	1.519

Response Surface Regression

Response Surface Regression: 1 versus HPMC, EC

$$1 = 34.3 + 22.7 \text{ HPMC} + 12.3 \text{ EC} - 5.31 \text{ HPMC} * \text{HPMC} + 0.01 \text{ EC} * \text{EC} - 9.48 \text{ HPMC} * \text{EC}$$

Response Surface Regression: 2 versus HPMC, EC

$$2 = 65.7 + 5.2 \text{ HPMC} - 1.9 \text{ EC} - 1.54 \text{ HPMC} * \text{HPMC} + 1.38 \text{ EC} * \text{EC} - 5.76 \text{ HPMC} * \text{EC}$$

Response Surface Regression: 4 versus HPMC, EC

$$4 = 103.3 - 17.0 \text{ HPMC} - 24.4 \text{ EC} + 3.03 \text{ HPMC} * \text{HPMC} + 6.39 \text{ EC} * \text{EC} - 0.13 \text{ HPMC} * \text{EC}$$

Response Surface Regression: 8 versus HPMC, EC

$$8 = 94.9 - 1.2 \text{ HPMC} - 9.5 \text{ EC} + 0.82 \text{ HPMC} * \text{HPMC} + 3.30 \text{ EC} * \text{EC} - 0.95 \text{ HPMC} * \text{HPMC}$$



Figure 12: Response surface regression curve.

CONCLUSION AND RECOMMENDATION

CONCLUSION

The transdermal patches of Ondansetron HCl were successfully prepared by solvent casting method using different polymers. We confirmed that formulations are suitable for transdermal drug delivery system (TDDS) by the in vitro test of drug release using dissolution apparatus and hence sustained release was obtained. With the increment of concentration of polymers, sustained release was found to be enhanced and sustained release is obtained.

The drug release from the transdermal patch has been affected by different concentrations of polymers. It can also be concluded from the results that the drug Ondansetron HCl with shorter half-life which undergoes hepatic first pass metabolism is a suitable candidate for transdermal delivery system. This delivery is easy to apply and removal of therapy, especially suitable for pregnant women, unconscious patients and pediatrics as well. It overcomes the problem of oral or parenteral route of administration making it most convenient form of delivery system in today's competitive world.

RECOMMENDATION

Further study can be carried out by increasing the concentration of polymers and can enhance the sustained release for 24 hours. Drug like Ondansetron which have short biological half-life has high dosing frequency can be overcome by the use of sustained release transdermal patch, which leads to enhance patient compliance reducing dosing frequency.

Further studies can be carried to prove its therapeutic utility by conducting pharmacokinetic and pharmacodynamic studies.

Conflict of interest statement: "The authors declared no conflict of interest" in manuscript.

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