



## FORMULATION AND CHARACTERIZATION OF TRANSDERMAL FILM CONTAINING ONDANSETRON HYDROCHLORIDE

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### ABSTRACT

In the present study matrix type transdermal patch of Ondansetron hydrochloride was developed by using the blends of two different type of polymeric combinations viz. Ethylcellulose N20 and HPMC K4M with plasticizer polyethylene glycol (PEG-400) and Dibutylphthalate. Preformulation studies were carried out using fourier transform infrared (FTIR) spectroscopy and differential scanning Calorimetry (DSC) technique. The prepared formulations were subjected to various physiochemical evaluation tests like moisture loss, moisture absorption, flatness, drug content, thickness etc. *In vitro* diffusion study was accomplished by the utilization of diffusion cell using commercial semi permeable membrane. Stability of the formulations was also performed to determine the amount of drug present in patch. All the formulations ingredients were found to be appropriate after physiochemical uniqueness of drug and excipients used and there was no notification in major interaction between the drug and polymer used. *In vitro* release profile showed that formulation of Ethylcellulose N20: HPMC K4M showed faster release of drug from prepared formulations at laboratory. By the utilization of dibutyl phthalate retards the release where as formulations prepared with polyethylene glycol rate was not controlled. Addition of highest amount of HPMC increases thickness and weight but not controlled release but alongwith EC better controlled was observed. Formulation was found to be intact when placed at different climatic conditions. Thus, in future such therapy should be utilized which is helpful to prevent nausea and vomiting that may be caused by surgery or by medicine to treat cancer

**KEYWORDS:** Ondansetron hydrochloride; Transdermal films; *In vitro* diffusion study; Stability Study

### INTRODUCTION

The inspiration of using skin for delivery of therapeutically active agents is considering from early time that is from several hundreds years ago. The utilization of skin for delivery of local as well as systemic that has been known for several years as a route for topical application of drug. Historically, the medicated plaster can be viewed as the first development of transdermal drug delivery; this medicated plaster became very popular in Japan as over the-counter pharmaceutical dosage form. The transdermal drug delivery system gained the popularity over the fast decades the major pathway of drug molecules through stratum corneum of human skin is by diffusing through lipid envelopes of the skin cell. Transdermal drug delivery system has moved from a scientific realism to the point where it represents a practicable diagnostic tool for non-invasive diagnosis. The first challenge is to make a transdermal delivery of drugs by the utilization of drug along with several polymers because all drug will not show the release into or within skin thus effective transdermal system ultimately involves ensuring adequate drug permeability through the Stratum corneum (SC).<sup>1,2</sup>

Now-a-days pharmaceutical industries are been able to formulate the transdermal drug delivery system. Several antimicrobials, antiinflammatory are used in ointments, pastes, medicated plasters, and complex inductions in the treatment of various symptoms or disease Transdermal drug administration generally refers to topical application of agents to healthy intact skin either for localized treatment of tissues underlying the skin or for systemic therapy. For transdermal products the goal of dosage design is to maximize the flux through the skin into the

systemic circulation and simultaneously minimize the retention and metabolism of the drug in the skin.<sup>3</sup> In recent times, development of transdermal delivery system started in 1970s, and in 1979, the first transdermal film of scopolamine was approved by USFDA for the treatment of motion sickness and later on nitroglycerine patch was marketed for the management of angina pectoris.<sup>4</sup> Henceforth, numbers of drugs categories such as NSAID, antiemetics etc have been successfully delivered through transdermal route. The drug applied topically is uniformly distributed following by absorption, first into the systemic circulation and then transported to the targeted tissue, which can be relatively remote from the site of drug application to achieve its therapeutic action.<sup>3</sup>

Transdermal drug delivery systems (TDDS) can be defined as self-contained discrete dosage forms which, when applied to the intact skin, delivers the drug(s) through the skin at a controlled rate to the systemic circulation. A Transdermal Drug Delivery (TDD) System is a polymeric drug delivery system, which contains drug either in a reservoir with a rate-controlling membrane or dispersed in a polymer matrix. Drug is released from these devices through the skin and is taken up by the systemic circulation via blood capillaries. It reduces the load that the oral route commonly places on the digestive tract and liver. It enhances patient compliance and minimizes harmful side effects of a drug caused from temporary overdose. TDDS offers several advantages such as reduces the dosing frequency, easy termination of therapy, improves bioavailability, provides constant blood level in the plasma and suitable for unconscious patients.<sup>4</sup> The realization of transdermal delivery system in pharma market is evident as currently more than 35 transdermal drug delivery products are approved in the

USA for wide variety of pathophysiological conditions including hypertension, angina pectoris, motion sickness, female menopause, male hypogonadism and approx. 40% of drugs are under investigations to validate the feasibility for transdermal drug delivery.<sup>5,6</sup> A large number of fatty acids and their esters have been used as permeation enhancers. Polyethylene glycol has been shown to be effective as a permeation enhancer as well as plasticizer for many drugs, for example increasing the flux of salicylic acid 28-fold and 5-fluorouracil flux 56-fold, through human skin membranes *in-vitro*.<sup>7,8</sup> It has also been used for ketoprofen<sup>9</sup>, flurbiprofen<sup>10</sup> etc.

Ondansetron is used to prevent nausea and vomiting that may be caused by surgery or by medicine to treat cancer (chemotherapy or radiation). Ondansetron blocks the actions of chemicals in the body that can trigger nausea and vomiting. Ondansetron is not for preventing nausea or vomiting that is caused by factors other than cancer treatment or surgery<sup>11</sup>.

Hence the aforesaid mentioned advantages of TDDS, the drug were a choice for selection because nausea and vomiting was inevitable when drug is administered orally in cancer therapy.

## MATERIALS AND METHODS

Ondansetron HCL was received as a gift samples from Dishman Pharmaceuticals and Chemicals Limited, Lodariyal Taluka – Sanand, Dist. Ahmedabad, India. Hydroxy propyl methyl cellulose K4M(HPMC) was received as a gift sample from Alex Pharmaceutical Pvt. Ltd, Sanand, India. Ethylcellulose (EC) was generous gift from Loba chemicals, Pvt. Ltd., Mumbai India. Polyethylene glycol 400 was from Rankem chemicals Mumbai India. Dibutylphthalate purchased from Loba chemicals, Pvt. Ltd Mumbai India. All other materials used in the study (chloroform, methanol, dichloromethane, etc.) were of analytical grade and purchased from Jinedra scientific, Jalgaon. Doubledistilled water was used throughout the study.

### Preformulation Study

Preformulation is the first step in the design of new products. Preformulation study is the process of optimizing the delivery of drug through the determination of physicochemical properties of new compound that could affect drug performance as a stable dosage form. Confirmation of drug study was carried out by FTIR, Melting point determination by capillary method and DSC.

### Melting point determination by capillary method

In the present study melting point determination was done by Thiel's tube method. Melting point study determines the purity of drug.

### Solubility study

Solubility of Ondansetron HCL in water, Methanol, PBS pH 7.4 and 6.8 was determined. Excess amount of Ondansetron HCL powder was added in conical flask containing 10 ml of phosphate buffer solution. The solution was briefly sonicated and agitated at 32 °C on water bath shaker at 300 rev/min for 24 hours until equilibration. Aliquot was withdrawn and then filtrated through 0.45 µm Millipore filter and then diluted with solvent. The samples were analyzed by UV-spectrophotometer to determine the concentration of drug at λ<sub>max</sub> 374 nm.

### Drug-Excipients compatibility studies<sup>12</sup>

The drug-excipients compatibility study was carried out by using Fourier Transform Infra-Red spectroscopy and Differential Scanning Colorimetry. To check the possible interaction between drug and polymers utilized in the present study.

### Infrared spectroscopy (FTIR)

FTIR spectra of pure drug Ondansetron HCL and the mixture of polymers were taken to study the interaction between them. A mixture of with HPMC-K4M and Ethylcellulose N-20 were mixed separately with IR grade KBr in the ratio of 100:1 and compressed using motorized pellet press at 15 tones pressure.

### Differential scanning calorimetry (DSC)

Firstly, melting point of drug was determine by capillary method then confirmed by DSC. Thermogram of Ondansetron HCL was obtained using DSC. Drug-excipients compatibility study was performed by Differential Scanning calorimetry (DSC).

## FORMULATION OF TRANSDERMAL PATCH

TDDS composed by solvent casting method of different ratios of HPMC K4M and Ethyl cellulose (EC-N20) containing Ondansetron HCL. The formulations of Ondansetron HCL were prepared using the polymer such as Hydroxypropyl methyl cellulose K4M and Ethyl cellulose (EC-N20) with the use of plasticizer PEG-400, Dibutylphthalate. HPMC K4M was dissolved in a 5ml solvent of containing (Dichloromethane/methanol) (4:1) ratio by, which is previously dissolved by putting the solution on magnetic stirrer (Rpm 60/min). In another side, the Ethyl cellulose (EC-N20) was dissolved in a 5 ml (Dichloromethane/methanol), then both solution added and mixed throughout. The drug was dissolved added to the above polymeric solution along with PEG-400, Dibutyl Phthalate, as plasticizer, and 0.2 ml of Tween 80 as penetration enhancer, which is the-roughly mixed on magnetic stirrer (Rpm 60/min) to form a homogeneous mixture. The volume was made up to 10-ml. En-trapped air bubbles were removed by applying ultra Sonicator. The solution was poured on the mercury placed in a glass Petri dish of 36.29 cm<sup>2</sup> area and dried at room temperature for 24 h cut into the required size to deliver the equivalent dose (2 × 2cm<sup>2</sup> per patch) containing of 8 mg of drug and samples were stored in a desiccator<sup>3</sup>. (Table 1)

## EVALUATION

### Thickness uniformity

The thickness of the patch was assessed by using Digimatic Micrometer (Mitutoyo, Japan) at different points of the patch, from each formulation three randomly selected and their average was calculated. The standard deviations of thickness were computed from the mean value.<sup>13</sup>

### Weight variation

Weight variation study was carried out by individually weighing 3 randomly selected patches. Such determination should be performed for each formulation. Patches from each batch were weighed individually and the average weight and SD was calculated.<sup>13</sup>

### Folding endurance

The folding endurance was determined by repeatedly folding one patch at the same place till it broke. The number of times of Patch could be folded at the same place without breaking give

the value of the folding endurance. This test was done on all the batches.<sup>14</sup>

#### Drug content uniformity

The patches at (2x 2 cm<sup>2</sup>), were cut and added to a beaker containing 100ml of Phosphate buffered solution of pH 7.4. To check the uniformity of the drug in the patch, three patches were taken out from each batch. Each Patch was then placed in volumetric flask containing 100ml of Phosphate buffered solution of pH 7.4, and shaken to extract the drug from patch overnight period. One milliliter of above resulting solution was withdrawn, after suitable 10 ml dilution with Phosphate buffered solution of pH 7.4 and analyzed UV-spectrophotometrically at 249 nm using Phosphate buffered solution of pH 7.4. The mean and standard deviation of drug content of three randomly selected patches were calculated. The same procedure was adopted for all the batches and drug content was noted.<sup>13</sup>

#### Tensile strength

Tensile strength of the Patch was determined with "Texture analyzer" testing machine. It consists of two load cell grips. The lower one is fixed and upper one is movable. The test strip of specific size (3 x 1 cm<sup>2</sup>) was fixed between these cell grips and force was gradually applied till the patch breaks. The tensile strength of the Patch was taken directly from the dial reading. The tensile strength was calculated by applying the following equation. Same procedure was repeated for three times and standard deviation was calculated from mean values.<sup>12</sup>

$$\text{Tensile strength} = \text{Load at failure} / \text{Area of patch} \times 100$$

#### Percentage moisture loss test (Moisture content)

Percentage moisture loss was determined by keeping the Films (2 x 2 cm<sup>2</sup>) in a desiccator containing anhydrous calcium chloride. After 3 days, the Films were taken out, re-weighed and the percentage moisture loss was calculated using the following formula;<sup>14</sup>

$$\text{Percentage moisture loss} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100$$

#### Percentage Moisture uptake Test (Moisture uptake)

Percentage moisture uptake was determined by keeping the Films (2 x 2 cm<sup>2</sup>) in a desiccator. A weighed film kept in desiccators at 40 °C for 24h was taken out and exposed to saturated solution of potassium chloride in order to maintain

84% RH. After 24hrs the films are to be reweighed and determine the percentage moisture uptake from the below mentioned formula;<sup>15</sup>

$$\text{Percentage moisture uptake} = \frac{\text{Final weight} - \text{Initial weight}}{\text{Initial weight}} \times 100$$

#### In-vitro drug release study

The *in vitro* diffusion studies were carried out to get an idea of permeation of drug through barrier from the transdermal system. The *in vitro* diffusion study was carried out with the cellophane membrane (0.4μ) by using Franze diffusion cell. The cylinder consists of two chambers, the donor, and the receiver compartment. The donor compartment was open at the top and was exposed to atmosphere. The temperature was maintained at 32 ± 2° C and receiver compartment was provided with sampling port. The diffusion medium used was PBS pH 7.4. *In vitro* drug release study was performed by placing patch of known weight and dimension (2x2 cm<sup>2</sup>) into small beaker containing 10ml of phosphate buffer solution pH 7.4. The beaker was placed on magnetic stirrer at 30 rpm. At periodic interval, the samples were taken and the drug content was analyzed at 374 nm against reference standard using PBS pH 7.4 as a blank on a UV-visible spectrophotometer (Shimadzu Inc., Japan). Then immediately known amount of PBS pH 7.4 was added. The same procedure was repeated for three times. *In vitro* release data obtained was plotted and tabulated. The cell consists of sampling port and temperature maintaining jacket. The outlet and inlet was connected with latex tube so the jacket had stagnant water inside and heat was provided by hot plate. The stainless steel pin was used to stir the receiver solution using magnetic stirrer. The Cellophane membrane was placed on receiver compartment and both compartments held tight by clamps. The volume of diffusion cell was 25 ml. The *in vitro* diffusion study was carried out for 12 hours and 1 ml sample was withdrawn at an interval of 30min, 1, 2,3,4,6,8,10 and 12 hours. The same volume of phosphate buffer pH 7.4 was added to receptor compartment to maintain sink conditions and the samples were analyzed at 374 nm in UV-spectrophotometer.<sup>16</sup>

#### Stability study

Stability study was performed on F4 formulation, according to ICH guidelines by storing replicates of Patches (packaged in aluminium foil) in a humidity chamber, with a relative humidity a temperature of 40±0.5 °C 70±5 RH%. At periodic intervals, the samples were taken out at 0, 15, 45, and 90 days and the period for their degradation of the patch was checked. Samples were also analyzed for drug content<sup>17</sup>.

Table 1: Composition of formulations containing Ondansetron HCl

Ingredients	F1	F2	F3	F4	F5	F6
Drug(mg)	8	8	8	8	8	8
Hydroxypropyl methyl cellulose (HPMC- K4M) (mg)	50	50	100	150	100	150
Ethyl cellulose (EC-N20) (mg)	150	100	50	50	200	150
Tween-80 (ml)	0.2	0.2	0.2	0.2	0.2	0.2
Dibutylphalate (ml)	5%	-	5%	-	5%	-
PEG-400(ml) (% w/w of polymers)	-	5%	-	5%	-	5%
Solvent (Dichloromethane: Methanol) (4:1) (ml)	10	10	10	10	10	10

Table 2: Preformulation data for ondansetron hydrochloride

Description	white to off-white powder	Solubility determination	
Melting point	187-189°C	Media	Saturation solu (mg/ml)
$\lambda_{max}$	374 nm	Water	0.034 $\pm$ 0.04
Partition Co.(log P)	2.4	6.8pH	0.089 $\pm$ 0.05
pH	3.3	7.4pH	0.086 $\pm$ 0.09
PKa	7.34	Methanol	3.65 $\pm$ 0.9

Table 3: Characterization of Developed Formulations

Formulation Code	% Drug content	Thickness (mm)	Weight(mg)	Tensile strength (kgmm-2)	Folding endurance	Surface pH
F1	98.15 $\pm$ 0.14	0.216 $\pm$ 0.25	153 $\pm$ 0.03	0.168 $\pm$ 0.21	112 $\pm$ 0.01	5.6
F2	97.78 $\pm$ 0.15	0.187 $\pm$ 0.04	187 $\pm$ 0.04	0.194 $\pm$ 0.05	154 $\pm$ 0.03	5.7
F3	99.12 $\pm$ 0.04	0.242 $\pm$ 0.05	194 $\pm$ 0.02	0.179 $\pm$ 0.13	167 $\pm$ 0.15	5.4
F4	98.84 $\pm$ 0.01	0.312 $\pm$ 0.13	198 $\pm$ 0.04	0.263 $\pm$ 0.09	162 $\pm$ 0.04	5.7
F5	99.28 $\pm$ 0.17	0.269 $\pm$ 0.12	164 $\pm$ 0.04	0.289 $\pm$ 0.17	236 $\pm$ 0.16	6.1
F6	98.74 $\pm$ 0.18	0.346 $\pm$ 0.04	218 $\pm$ 0.11	0.196 $\pm$ 0.08	97 $\pm$ 0.24	5.6

( $\pm$ SD)= standard deviation

Table 4: Stability study of optimized batch (F5)

Evaluation parameters	At zero time	After 15 days	After 45 days	After 90 days
Drug content (%)	96.14%	94%	95.34%	97.63%
%drug dissolve pH 7.4	92.441%	91.569%	88.849%	91.667%
Weight variation	44.9 $\pm$ 0.05	44.7 $\pm$ 0.06	44.6 $\pm$ 0.09	44.5 $\pm$ 0.08
Drug release (%)	98.12%	95.38%	94.69%	92.37%

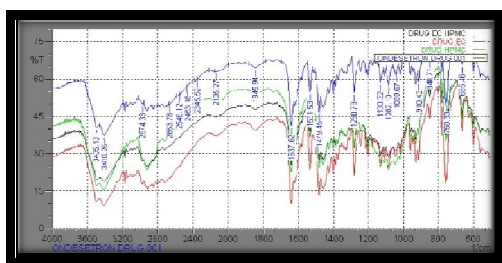


Figure 1: Infrared overlay of drug + HPMC-K4M + EC-N20

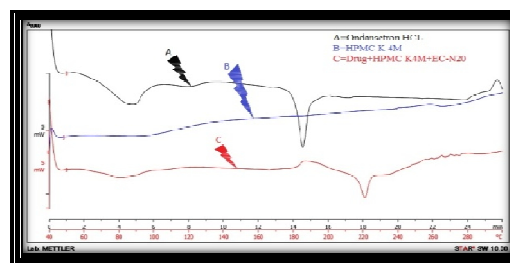


Figure 2: DSC thermogram of ondansetron HCl + HPMC + EC N20

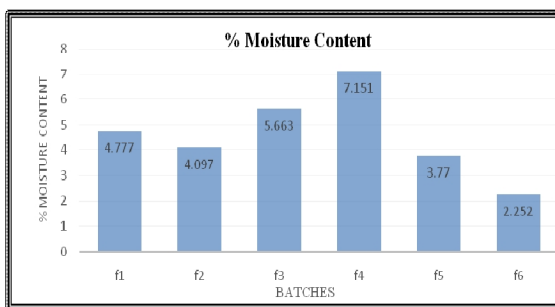


Figure 3: Percentage moisture contain

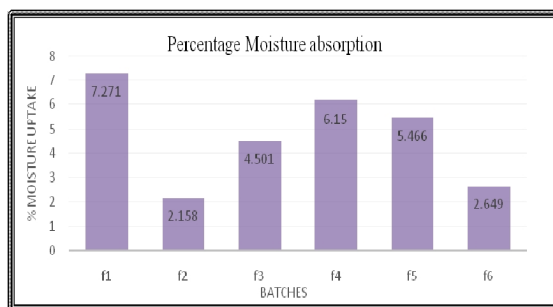


Figure 4: Percentage moisture absorption

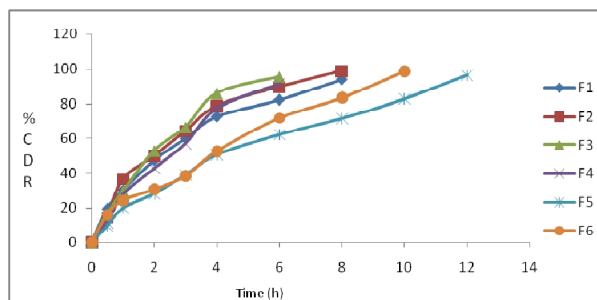


Figure 5: In- vitro drug release study of formulation F1-F6

## RESULT AND DISCUSSION

These formulations were intended to produce sustained release of drugs in the management of nausea and vomiting. (Table 2)

### Drug-excipients compatibility studies

#### Fourier transform infrared spectroscopy (FTIR)

Compatibility study was carried out by using FTIR and DSC by the use of drug & excipients. The Individual IR spectra of pure drug and polymer as well as the combination spectra of the drug and polymer are shown in the figure 1, which indicate no interaction between ondansetron HCl and polymers when compared with spectrum ondansetron HCl as all functional group frequencies were present. (Figure 1)

**Differential scanning calorimetry:** The DSC thermogram of formulation showed identical peaks correspondingly, to pure drug there was no chemical interaction between drug and polymers. (Figure 2)

Thicknesses of drug-loaded patches were measured with the help of screw gauge. Film thickness was found in the range  $0.187 \pm 0.04$  (F2) to  $0.346 \pm 0.04$  (F6). It means that the concentration of polymer showed significant change in the thickness of the film. The concentration of plasticizer did not alter the change in the thickness of patch. The weight of the patch was found to be in the range of  $153 \pm 0.03$  (F1) to  $218 \pm 0.11$  mg (F6). Weight uniformity of the patches shows the good distribution of the excipients. As the increasing polymer concentration weight of patch also increases. Drug content for varies formulation was found to be in the range of  $97.78 \pm 0.15$  (F2) to  $99.28 \pm 0.17\%$  (F5). For the uniform dispersion of drug in patch, the drug content study was performed. The aforesaid values indicated that the drug was uniformly dispersed within the formulations.

The folding endurance of the patch was found to be in the range of 97 to 236. The number of times the film could be folded at the same place without breaking gave the value of folding endurance. Folding endurance was found to be highest for F5 and lowest for F6 as shown in table. The change in the concentration of polymers and plasticizer showed the difference in the folding endurance of patch. The value of folding endurance shows, the developed formulations exhibited good physical and mechanical properties. The mechanical properties of patches were evaluated using a CT3 texture analyser. The peak load was used to evaluate by the help of probe dual grip. The texture expert software recorded the data when the probe started withdrawing from the Patch. The peak load and the area under load distance curve obtained from the texture profile were used to assess the tensile strength of the Patches. The tensile strengths of drug loaded patches are in the order of  $F5 > F4 > F6 > F2 > F3 > F1$ . Each measurement was repeated three times. The concentration of polymer and plasticizer shows higher effect on tensile strength of patch. When the concentration of HPMC-K4M increases accordingly then the tensile strength also increases. (Table 3)

Moisture content was found to be in the range of  $2.252 \pm 0.90$  to  $7.151 \pm 1.44$  mg. Moisture content was determined by keeping patches in a desiccator containing calcium chloride for 24 h. Percentage moisture content was calculated from the weight differences relative to the final weight. Results of moisture content study are shown in Figure 3. Moisture content was found to be increasing with increasing concentration of hydrophilic polymer. Moisture content in the patches were found to be low, low moisture content helps them to remain stable and from being completely dried and brittle. The capacity

of the Patch to take up water is an intrinsic parameter of the polymeric system in consideration to the release of drug. Moisture absorption of the patch was found to be in the range of  $2.158 \pm 0.31$  to  $7.211 \pm 1.26$  mg. Low moisture absorption protects the patch from microbial contamination and bulkiness. (Figure 3 & 4)

The in-vitro drug release profile is an important tool that predicts in advance how a drug will diffuse and targeted. In the present study, hydrophilic (HPMC K4M) and hydrophobic (EC-N20) polymers are used to prepared patches. Formulation F6 exhibited  $98.78 \pm 1.4\%$  of drug release at the end of 10 h, while formulation F1 exhibit  $94.11 \pm 3.3\%$  of drug release in 8 h. The cumulative amount of drug released from formulations containing hydrophilic polymer show release of drug at faster rate than hydrophobic polymer. (Figure 5)

*In vitro* drug release study indicated that the release of drug varied from the formulation batches according to their type and concentration of polymers utilized. As prepared the concentration of Ethylcellulose N-20 was increases gradually the release of drug was decreased. The concentration of Hydroxy Propyl Methyl Cellulose was increases the drug release showed effect increases release amount of drug. The variation of plasticizer in different formulation shows effect on release of drug. Polyethylene glycol-400 plasticizer incorporated patches shows better drug release as compared to the Dibutyl- phthalate the formulation F1, F3, F5 shows decreased in release rate because formulation without containing PEG-400 plasticizer. The F5 batch shows sustainly drug release  $96.43 \pm 2.5$  in 12 h but as compared to that batch F6, higher cumulative  $98.78 \pm 1.4\%$  in vitro release was observed which contained 150 mg. Hydroxy propyl methyl cellulose and 150mg Ethylcellulose N-20 (1:2) ratio which shows effect as increases amount of release of drug in 10 h further, 5% of plasticizer PEG concentration shows increase amount of release of drug. The drug release was controlled from the patch was ordered as  $F5 > F6 > F2 > F1 > F3 > F4$ .

Stability results are showed in following table major differences was not found between evaluated parameters before and after ageing/storing and all were found to be in acceptable limits. Based on the results of initial characterization batch F5 were thought to be the superior formulation and hence further subjected to accelerated stability study for 3 months. There was no significant reduction of release & drug content, weight etc. (Table 4)

In conclusion, local application delivery of drug has prospective return of avoiding hepatic first pass metabolism, reduction of dosing frequency and decreased gastrointestinal irritation hence reduces the nausea and vomiting problem that occur due to administration of drug taken by orally and irritate the gastric mucosa and hence improved patient compliance. The urge to develop such a transdermal patch for patient who suffered from cancer treatment, the delivery also reduces the felling of uncomftrness of bitter doses of drug. The use of polymer such as HPMC and EC showed their positive effect on release pattern. Plasticizer PEG-400 markedly increase the delivery where as dibutyl phthalate controlled the rate. the permeation enhancer tween 80 also showed their effect on release of drug at the end of 12 h. Hence, in near future transdermal delivery may increase the market for to treat nausea and vomiting.

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