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# FORMULATION AND EVALUATION OF ZOLPIDEM TARTRATE FAST DISSOLVING ORAL THIN FILMS

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**ABSTRACT**

Developing orally films is an innovative way to create dose forms that dissolve orally. They have a thin appearance and may be shaped into many different sizes and shapes, such circles or rectangles. The strips may be translucent or opaque, brittle or flexible. Oral films are made of a variety of hydrophilic and hydrophobic polymers that dissolve rapidly on the tongue without the need for water with the objective to enhance the drug's dispersion in the oral cavity, the current effort attempts to develop fast-dissolving oral thin films containing zolpidem tartrate. Zolpidem tartrate films were made by Solvent casting method by using various Polymers such as hydroxy propyl methyl cellulose-E15, starch 1500, and Xanthan Gum polymers. Nine Formulations were Prepared and evaluated. The thickness of the films in all formulations were found to be in the range of 0.7 ± 0.057 mm to 1.1 ± 0.100 mm., physical properties, and surface texture of the prepared films, as well as their folding endurance were found to be 112 – 208, moisture absorption, homogeneity of weight and drug content, swelling index, and in vitro disintegration was found to be 26 to 60sec and the F4 formulation attained 100% drug release with 15 minutes were all taken into consideration when evaluating them. Additionally, stability studies were conducted. Even if each formulation satisfied the evaluation requirements, it is determined that oral thin films with a polymer of 40 mg starch1500 had a superior dissolving profile.

**Key words: Zolpidem Tartrate, Oral thin Film, Insomnia, Solvent Casting, Oral Cavity**

## INTRODUCTION:

Since the past few decades there has been a tremendous change in designing various drug delivery systems to achieve rapid onset of action to overcome the limitations of oral dosage forms like tablets and capsules, oral thin films have been developed These are ultra-thin postal stamp sized films which are prepared using hydrophilic polymers with drug and other pharmaceutical excipients **[1]**. This delivery system consists of a thin film, which is simply placed on the patient's tongue or mucosal tissue and instantly gets wet by saliva to dissolve the film rapidly. The majority of the medication is ingested orally along with saliva, and the gastrointestinal tract absorbs the medication **[2]**. These are also known as quick disintegrating, orally disintegrating, rapidly disintegrating, mouth dissolving or melt in mouth dosage forms. They have benefitted such easy swallowing, quick start of action, convenient dosing, and administration without the need for water **[3]**. Zolpidem initially became available in France in 1988with the brand name Stilnox and then in the US in 1993as Ambien. For many years it has been the most widely prescribed hypnotic both in the US and internationally **[4]**. An extended-release formulation (Ambien CR) was first marketed in the US in 2005 and it remains under patent protection. Alternative delivery methods for non-benzodiazepine hypnotics have been researched over the last few years. Oral spray, nasal spray, sublingual pill, oral dissolvable, and inhalation systems have been some of these. At the time of this writing, the FDA has approved two alternative delivery formulations of immediate-release zolpidem and others remain in development **[5]** to increase patient compliance, several sweeteners and flavors were used to make the fast-dissolving films. The main objective of the present study is to develop fast dissolving oral films with rapid dissolution of drug and absorption which may produce the rapid onset of action **[6]**.

**Drug name:**

N,N-Dimethyl-2-[6-methyl-2-(4-methylphenyl)imidazo[1,2-a]pyridin-3-yl]acetamide

hemi tartrate.

**Mechanism of Action:**

It interacts with a GABA-BZ receptor complex and is pharmacologically similar to the benzodiazepine class of medications in some ways. The primary regulatory site of the GABA receptor complex, also known as the benzodiazepine (BZ) or omega (ω) receptor, is located on the alpha (α) subunit **[7]**.

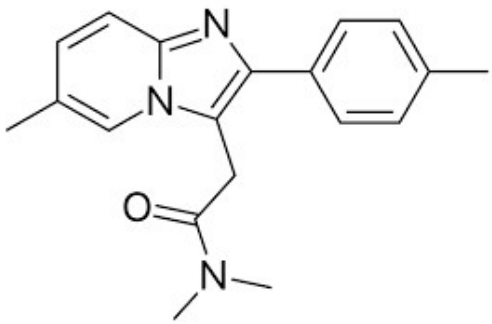


**Figure 1: Chemical structure of Zolpidem Tartrate**

**MATERIALS AND METHODS: [8]**

Zolipidem Tartrate, Hydroxy Propyl methyl Cellulose E15, Xanthan gum, Pectin, Starch 1500, Poly ethylene glycol400, Mannitol, Glycerine, cross carmellose Sodium, Citric acid, Ethanol, Tween 80, Menthol, Water.

**METHODS:**

**Characterization of Zolpidem Tartrate:**

**Solubility of Zolipidem Tartrate:** The Zolpidem has Freely soluble in Methanol (16.9 mg/mL) and insoluble in water.

**Melting Point Determination:**

The capillary tube method was used to determine the melting point of zolpidem. The medication was finely powdered and put into a glass capillary tube that had been previously sealed at one end. Temperature increases were applied to the capillary tube while it was fastened to a thermometer. As a result, the melting point of zolpidem was determined.

**Compatibility Studies:**

The drug's compatibility with polymers was investigated using FTIR analysis. Using the KBr dispersion method, the Fourier Transform Infrared spectrophotometer was used to determine the infrared spectra of Zolpidem tartrate, potassium bromide, the baseline correlation was carried out. Next, using an FTIR spectrophotometer, the spectra of a dried mixture of the drug and potassium bromide was run, and then the drug with other polymers. The wavelength ranged from 400 to 4000 cm-1.

**Calibration Curve:**

**A. Determination of absorption maxima (λmax):**

Maximum absorbance (λmax) was measured by scanning a 30 µg/mL zolpidem tartrate solution with a double beam UV-Vis spectrophotometer that had a 1 nm limit in the 200–400 nm spectral region.

**B. Preparation of standard graph Procedure:**

The 100 milligrams of zolpidem tartrate were dissolved in 5 milliliters of methanol, and 100 milliliters of pH 6.8 buffer were added to

create a stock solution. From this stock solution, 10 milliliters were added to 100 milliliters of pH 6.8 buffer, and serial dilutions of 2, 4, 6, 8, and 10 were made. At 294 nm, absorbances were measured.

**Preparation of Fast Dissolving Oral Film of Zolpidem tartrate:**

The solvent casting procedure was used to create the oral fast-dissolving film. Aqueous solution I was made by dissolving a film-forming polymer in a certain amount of distilled water, stirring for three hours, and then letting it sit for one hour to eliminate any trapped air bubbles. A particular amount of distilled water was used to dissolve the pure medication, sweetener, and plasticizer to create Aqueous solution II. For one hour, the aqueous solutions I and II were combined and swirled **[9]**. The solutions were poured onto a 64 $cm^2$ glass plate and allowed to dry for 12 hours at 45 ºC in the oven. The following ingredients as shown in **Table1**. The film was carefully removed from the glass plate's surface and sliced into the necessary measurements for the test (2 cm in length and 2 cm in width). The instances were kept in glass containers until further analysis, where they were kept at 30oC and 60% ± 5% relative humidity **[10]**.

**Table 1: Formulation Details of Fast Dissolving Films of Zolpidem Tartrate F1-F9**

| Drug: HPMC E15 | 1:16 + XG | 1:20 + XG | 1:24 + XG | 1:16 + Starch 1500 | 1:20 + Starch1500 | 1:24 + Starch1500 | 1:16 + Pectin | 1:20 + Pectin | 1:24 + Pectin |
|---|---|---|---|---|---|---|---|---|---|
| **Ingredients** | **F1** | **F2** | **F3** | **F4** | **F5** | **F6** | **F7** | **F8** | **F9** |
| **Zolpidem Tartrate** | 25 | 25 | 25 | 25 | 25 | 25 | 25 | 25 | 25 |
| **HPMC E15** | 400 | 500 | 600 | 400 | 500 | 600 | 400 | 500 | 600 |
| **Xanthan gum** | 40 | 40 | 40 | - | - | - | - | - | - |
| **Starch1500** | - | - | - | 40 | 40 | 40 | - | - | - |
| **Pectin** | - | - | - | - | - | - | 40 | 40 | 40 |
| **PEG 400 (mL)** | 0.3 | 0.3 | 0.3 | 0.3 | 0.3 | 0.3 | 0.3 | 0.3 | 0.3 |
| **Mannitol(mg)** | 6 | 6 | 6 | 1 | 1 | 1 | 1 | 1 | 1 |
| **Glycerine (mL)** | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 |
| **Cross carmellose sodium(mg)** | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| **Citric acid** | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |
| **Ethanol (ml)** | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |
| **Tween80 (ml)** | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 |
| **Menthol(ml)** | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 | 0.01 |
| **Water (ml)** | q. s. | q.s. | q.s. | q. s. | q.s. | q.s. | q.s. | q.s. | q.s. |
| **Total (mg)** | 470 | 570 | 670 | 470 | 570 | 670 | 470 | 570 | 670 |

**Evaluation of Fast Dissolving Films: [11]**

The following characteristics of the zolpidem tartrate were assessed:

**Physical Appearance and Surface Texture of the Film:**

This criterion was verified visually through film examination, and the texture of the films was assessed.

**Thickness of Film:**

A screw gauge micrometer with a minimum count of 0.01 mm was used to measure the film's thickness at various locations. Five distinct locations on the film were used to assess its thickness, and an average was calculated.

**Folding Endurance:**

The test of folding endurance involved repeatedly folding the entire film in the same spot until it broke. The folding endurance value was calculated as the number of times the film could be folded without breaking.

**Moisture Uptake:**

The films were exposed to 40 °C and 75% relative humidity for one week in order to measure the amount of moisture they could absorb. The percentage increase in weight was used to calculate the moisture uptake by the films. Moisture uptake percentage = [Final weight - Initial weight / Initial weight] × 100

**Uniformity of Drug Content:**

A 2 × 2 cm film containing zolpidem tartrate was homogenized in 100 cc of pH 6.8 phosphate buffer and shaken constantly for 30 minutes in order to assess this parameter. A pH of 6.8 buffer solution was used to dilute 10 ml to 50 ml from this. At 203 nm, the absorbance was measured using a UV spectrophotometer.

**Swelling Index:**

The swelling index of the film was examined using a phosphate buffer solution with a pH of 6.8. The film sample (surface area of 4 cm2) was weighed and then passed through a pre-weighed stainless wire sieve with 800 µm mesh. The mesh containing the film sample was dipped into 50 milliliters of pH 6.8 phosphate buffer solution that had been added to a mortar. After a set period of time, the stainless steel mesh was removed, and any residual moisture was carefully wiped away with absorbent tissue before the mesh was weighed again. The weight of the film was gradually increased until a constant weight was observed. The degree of swelling was calculated using the formula below: The swelling index is represented as SI = Wt - Wo / Wo, where Wt is the weight of the film at time t, Wo is the weight of the film at t = 0, and SI is. Weight Uniformity: The weight of the prepared films was measured with a digital balance, and the average weight of all the films was calculated.

***In-vitro* Disintegration Study:**

The Electro Lab Disintegration Tester ED-2L (USP) disintegration test apparatus was used to measure the fast-dissolving oral film's in-vitro disintegration. Place one piece of film into each of the six tubes in the basket. Use 900 milliliters of pH 6.8 phosphate buffer solution as the immersion liquid to run the apparatus after inserting the disc into each tube. For thirty cycles per minute, the assembly must be raised and lowered in distilled water maintained at 37 ± ± 0.5 ºC. It was recorded how long, in seconds, the oral film took to totally disintegrate and leave no observable mass inside the apparatus.

**In vitro Dissolution Study: [12]**

Fast-dissolving oral film of Zolpidem tartrate was released in vitro using a basket-style Electro lab tablet dissolving tester (USPXXIII). Film with 25 mg of medicine was placed into a 900ml pH 6.8 phosphate buffer (dissolution media), and the basket was rotated at 50 rpm while the temperature was maintained at 37 ± 0.5 °C. Samples are taken out and put through spectrophotometric analysis using a UV-Visible spectrophotometer. Each sample was removed, and then 5 milliliters of the same dissolving liquid were added, bringing the total volume of the dissolving medium to 900 milliliters.

**Stability Studies: [13]**

Stability testing aims to establish a retest period for the drug substance or shelf life for the drug product, as well as recommended storage conditions. It also provides evidence on how the quality of the drug substance or drug product varies with time under the influence of various factors, such as temperature, humidity, and light. The specific drug substance and product type involved determine the sort of stress test that is used. The drug material was tested for stability using a container closure method that either mimicked or matched the packing suggested for distribution and storage. For three months, the selected formulations were stored in an amber-colored bottle that was tightly sealed, blocked with cotton, and capped at 40 ± 0.5 ºC and 75.0 ± 5% Rh. At one-month intervals, the formulations' in vitro dispersion time, drug content, and physical appearance were assessed.

**RESULTS AND DISCUSSION:**

**Melting Point Determination:** It was discovered that the melting point was 171 $^0$C, which is the same as the melting point reported in published works **[13]**.

**Ultraviolet Spectroscopy:**

For phosphate buffer with a pH of 6.8, the correlation coefficient for the linear regression equation was determined to be 0.999, showing a strong positive connection between Zolpidem tartrate concentration and

the associated absorbance values. At 295 nm, it possesses its maximum absorbance (λmax). In the continuous range of 2–10 µg/mL, as indicated by a straight line with a regression coefficient (r2) of 0.999, y = 0.100x + 0.007, this analytical technique complies with Beer's law.

**Compatibility Studies**:

The medicine has not experienced any structural changes or chemical reactions with the polymers and other excipients utilized, according to FTIR measurements. As a result, it was determined that the medicine did not interact with the polymers or excipients in this experiment. Since there were no appreciable changes in the spectra of the pure drug and drug + excipients, zolpidem tartrate is compatible with the polymers used in the study. Its FTIR spectra are 1739.32 C=N stretching1631.80 C=O stretching1500.42 C=C stretching 1112.15 C-N stretching.

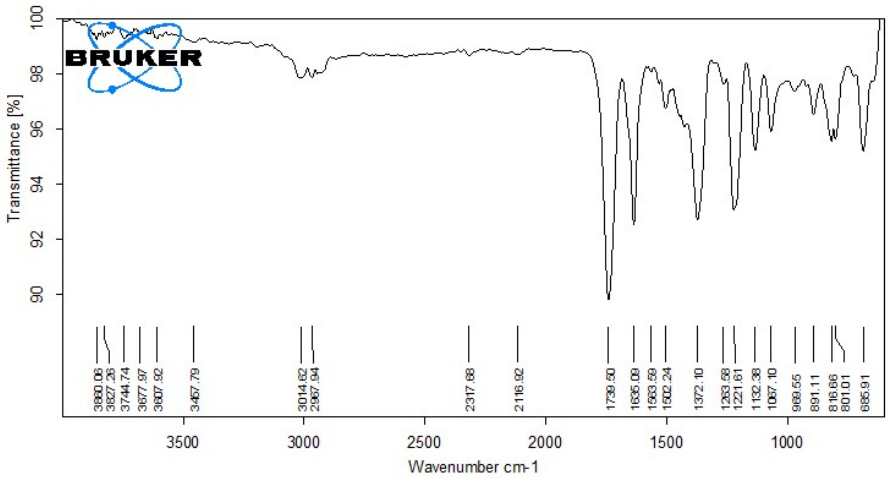


**Figure 2: FTIR study of pure drug zolpidem tartrate**

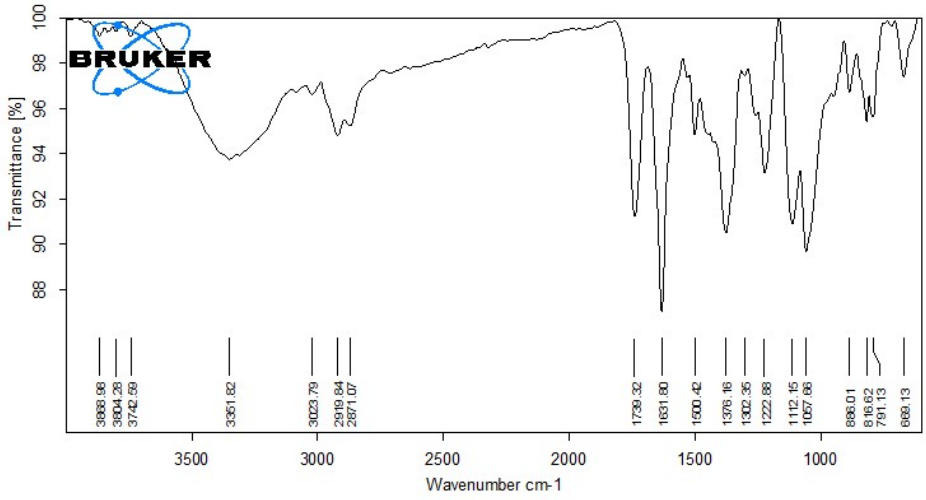


**Figure 3: Zolpidem tartrate Optimized Formulation**

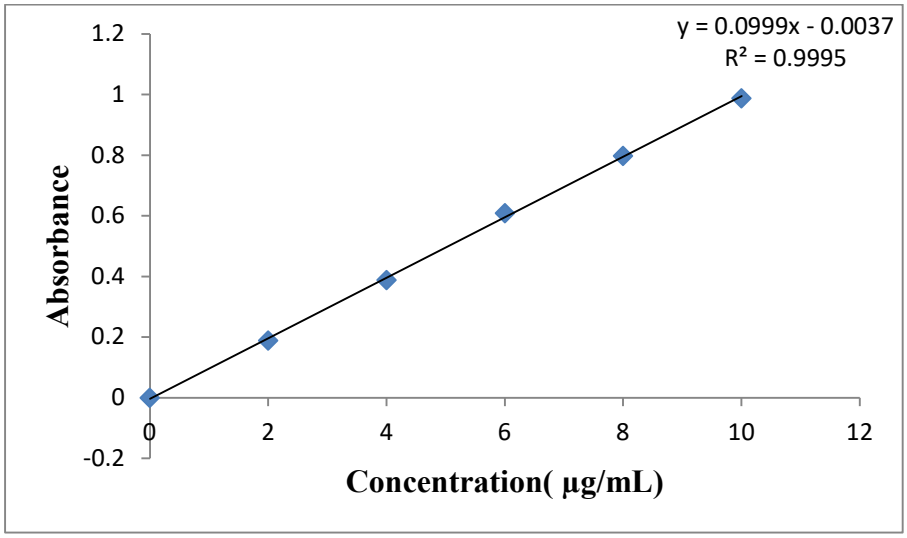


**Figure 4: Calibration curve of zolpidem tartrate**

**Evaluation of Fast Dissolving Films:** The following characteristics of the Zolpidem tartrate films were assessed as per **Table 2**.

**Thickness of Film:**

All formulations had about the same thickness, with values ranging from 0.7 ± 0.057 mm to 1.1 ± 0.100 mm. According to the standard deviation values, every formulation fell inside the given range.

**Folding Endurance:**

A tiny strip of film was folded repeatedly at the same location until it broke to determine the films' folding endurance; the results ranged from 112 to 208.

**Moisture Uptake**:

There was no sign of moisture assault in any of the produced films, and none of the films exhibited moisture uptake.

**Weight Uniformity of Films:**

Using digital balance, the weights of the prepared films were ascertained. There was a 43–57 mg range.

**Table 2: Evaluation of films for physical parameters:**

| Formulations | Appearance | Texture | Average weight *(mg) | Surface (pH) | Folding endurance* | Average thickness* |
|---|---|---|---|---|---|---|
| F1 | Transparent | Smooth | 20±0.25 | 6-7 | 239±1.86 | 0.032±0.03 |
| F2 | Transparent | Smooth | 20±0.62 | 6-7 | 270±2.32 | 0.033±0.02 |
| F3 | Transparent | Smooth | 31±0.35 | 6-7 | 251±1.25 | 0.034±0.04 |
| F4 | Transparent | Smooth | 22±0.24 | 6-7 | 223±1.42 | 0.030±0.02 |
| F5 | Transparent | Smooth | 21±0.36 | 6-7 | 250±1.32 | 0.032±0.03 |
| F6 | Transparent | Smooth | 21±0.28 | 6-7 | 205±1.22 | 0.034±0.05 |
| F7 | Transparent | Smooth | 16±0.87 | 6-7 | 250±1.65 | 0.031±0.01 |
| F8 | Transparent | Smooth | 26±0.11 | 6-7 | 230±1.85 | 0.033±0.02 |
| F9 | Transparent | Smooth | 26±0.21 | 6-7 | 235±1.68 | 0.032±0.02 |

**(*Average of 3± Standard Deviation)**

**Uniformity of Drug Content:**

For each of the nine formulations, a uniform drug content analysis was conducted. When the drug content was assessed, it ranged from 96.80 to 99.56. For formulation F3, or 96.80, the drug concentration was determined to be low, while for formulation F4, or 99.56, it was found to be higher. The drug content was confirmed to be between the 85 and 115% levels, in accordance with USP criteria **[14]**.

***In-vitro* Disintegration Study**:

This is the amount of time the film takes to completely disintegrate in vitro. It is the crucial element in OTFs. The duration in seconds that the in vitro film disintegrates upon coming into touch with saliva or water. The results are shown in **Table 3** It was discovered that every formulation disintegrated in 60 seconds or less. Formulation F9 exhibits greater disintegration, while formulation F1 exhibits less disintegration time.

***In-vitro* Dissolution Study:**

With a USP basket-style dissolving device and 6.8 phosphate buffer, in vitro drug release was performed. Formulation F4 releases a greater dose of medication in a shorter amount of time-100.5% in just 15 minutes. As the disintegration time decreases, the dissolution rate rises. Graphs from in vitro dissolving investigations are referenced in fig. Increased medication release volume signifies a quicker start of action. The results are shown in **Table 4**.

**Table 3: Evaluation of films for Drug content uniformity, *In-vitro* disintegration:**

| F Code | Drug content (%) | Disintegration (Min) |
|---|---|---|
| F1 | 98.53±0.152 | 49±1.5 |
| F2 | 99.27±0.963 | 55±0.25 |
| F3 | 96.80±0.293 | 58±0.13 |
| F4 | 99.64±0.658 | 26±0.28 |
| F5 | 98.33±0.952 | 42±0.26 |
| F6 | 97.95±0.389 | 49±0.52 |
| F7 | 99.56±0.925 | 50±1.32 |
| F8 | 98.54±0.756 | 55±1.24 |
| F9 | 97.27±0.594 | 60±0.65 |

**Table 4: *In-vitro* dissolution studies data**

| Time (min) | Cumulative % drug release | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | F1 | F2 | F3 | F4 | F5 | F6 | F7 | F8 | F9 |
| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1 | 20.8±0.05 | 28±1.2 | 27±1.12 | 30.5±0.9 | 28±0.54 | 25±0.23 | 25±0.56 | 24.5±0.51 | 22±0.69 |
| 3 | 35.6±0.2 | 50±0.9 | 40±0.6 | 52.7±0.5 | 39±0.20 | 36±0.10 | 39±0.90 | 37±0.24 | 35.9±0.28 |
| 5 | 55.9±0.1 | 65±0.3 | 68±0.9 | 78.2±0.3 | 50±0.27 | 49±0.2 | 47±0.32 | 45±0.61 | 45±0.71 |
| 7 | 69.8±0.3 | 78±0.6 | 75±0.3 | 68.1±0.4 | 69±0.58 | 62±0.61 | 58±0.41 | 56±0.12 | 54.7±0.19 |
| 10 | 75.2±0.3 | 87±1.0 | 83±1.1 | 98.7±0.02 | 75±0.38 | 73±0.15 | 69.7±0.6 | 67±1.0 | 66.9±1.05 |
| 15 | 82.8±0.2 | 95±1.5 | 89±0.01 | 100.05±0.6 | 85±0.45 | 81±0.8 | 78.5±0.2 | 76±0.2 | 77.8±0.60 |
| 20 | 98.5±0.1 | 97±1.1 | 92.9±0.2 | - | 91±0.1 | 90±0.4 | 88.9±0.2 | 87.5±0.12 | 86.9±0.7 |

Table 5: Drug release kinetic parameters for formulations 1-9 of films:

| FORMULATIONS | Zero order | First order | Higuchi | Korsmeyer Peppas |
|---|---|---|---|---|
| | $r^2$ | $r^2$ | $r^2$ | $r^2$ |
| F1 | 0.849 | 0.879 | 0.994 | 0.683 |
| F2 | 0.753 | 0.907 | 0.948 | 0.894 |
| F3 | 0.725 | 0.801 | 0.929 | 0.952 |
| F4 | 0.734 | 0.989 | 0.948 | 0.847 |
| F5 | 0.804 | 0.875 | 0.973 | 0.911 |
| F6 | 0.825 | 0.971 | 0.986 | 0.93 |
| F7 | 0.808 | 0.961 | 0.991 | 0.942 |
| F8 | 0.828 | 0.983 | 0.994 | 0.923 |
| F9 | 0.821 | 0.963 | 0.996 | 0.953 |

**Stability Studies:**

Studies on stability were carried out using the optimal release formulation, F4. Following storage, no observable alterations were found in the products. The drug content was found to be consistent and within tolerances even after three months of storage at (40 ºC ± 75% Rh), suggesting that the drug release remained mostly unchanged **[15]**. It was discovered that the product's medication release properties were consistent and stable. However, because HPMC is hydrophobic, the matrix that forms becomes extremely stiff, allowing the medication to stay intact within the polymer matrix. As a result, the film cannot stick, hydrates, and dissolves fast to release the drug for absorption inside the stomach. Release rate slows down as a result are shown in **Table 6**.

Table 6: Stability studies for optimised formulation:

| Parameters | Initial | I Month | II Month | III Month |
|---|---|---|---|---|
| Colour | White | White | White | White |
| Average weight(mg) | 22 ± 0.24 | 22.3 ± 0.28 | 22.6 ±0.27 | 22.1 ± 0.23 |
| Average thickness(mm) | 0.030±0.02 | 0.034 ± 0.05 | 0.036 ±0.04 | 0.032 ± 0.01 |
| Folding Endurance | 223 ±1.42 | 223 ± 1.54 | 223 ± 1.21 | 223± 1.56 |
| Drug content % | 99.64 ± 0.65 | 99.64 ± 0.68 | 99.63 ± 0.65 | 99.61 ± 0.64 |
| % Drug Release | 100.05±0.6 | 100.03± 0.5 | 100. 06± 0.4 | 100. 04 ± 0.3 |

**CONCLUSION:**

An agent used to induce hypnosis is zolpidem tartrate. The quick beginning of action of zolpidem tartrate fast-dissolving films makes them beneficial. The present conventional quick release dose forms have a viable replacement: fast dissolving films.

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