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Development and Characterization of Zolpidem Tartrate Oro-Dispersible Tablets

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ABSTRACT

Zolpidem tartarate is a centrally acting potent sedative hypnotic agent used in the treatment of insomnia as well as brain disorders. In the present work an attempt has been made to prepare oro-dispersible tablet of zolpidem tartarte with a view to provide a quick onset of action and to enhance the patient compliance. FTIR, DSC studies showed that the drug and excipients were compatible. The ODTs were formulated using various superdisintegrant like Lycoat, crosspovidone, and crosscarmellose sodium in different concentration such as 5%, 7.5%, and 10%, using aspartame as a sweetener and microcrystalline cellulose as lubricant. Initially powder blend was evaluated for pre compression parameters such as bulk density, tapped density, hausners ratio, compressibility, angle of repose etc. The ODTs were prepared by direct compression and the tablets were evaluated for hardness, friability, content uniformity, in-vitro disintegration time, in vitro dissolution studies. The results were satisfactory. The drug release from ODTs increased with increasing the concentration of superdisintegrants and was found to be highest with formulation F10 containing 10% crosspovidone which released up to 98.64% in 10 min and was consider as the best formulation. Thus results conclusively demonstrated rapid disintegration of the formulated tablet in oral cavity with good mouth feel.

KeyWords: *Zolpidem tartarate, Lycoat, Superdisintegrants, Oro-dispersible Tablets,*

INTRODUCTION

Insomnia is the perception or complaint of inadequate or poor-quality sleep because of one or more of the reasons like difficulty in falling asleep, waking up frequently during the night with difficulty returning to sleep, waking up too early in the morning and un-refreshing sleep. Insomnia is not defined by the number of hours of sleep a person gets or how long it takes to fall asleep. Insomnia may cause problems during the day, such as tiredness, lack of energy, difficulty in concentrating, and irritability. Insomnia lasting from a single night to a few weeks is referred to as transient. If episodes of transient insomnia occur from time to time, the insomnia is said to be intermittent. Insomnia is considered to be chronic if it occurs on most nights and lasts a month or more [1, 2].

Zolpidem tartrate is a prescription medication used for the short term treatment of insomnia, as well as some brain disorders. It is a short-acting non-benzodiazepine hypnotic that potentiates gamma-amino butyric acid (GABA), an inhibitory neurotransmitter, by binding to gamma-amino butyric acid (GABA-A) receptors at the same location as benzodiazepines and it has a short half-life of 2–3 hours [3, 4]. It is a white crystalline powder which is sparingly soluble in water, alcohol and easily soluble in buffer solution, sulfuric acid, and hydrochloric acid solution [5-7]. To obtain quick onset of action of Zolpidem tartrate, oro-dispersible tablet is the approach taken into consideration.

Oro-dispersible Tablets (ODTs) are those which disintegrate rapidly in saliva, usually in a matter of seconds, without the need to it with water. Drug dissolution and absorption as well as onset of clinical effect and drug bioavailability may be significantly greater than those observed from the conventional dosage forms. Recently oro-dispersible tablet technology has been approved by the United State Pharmacopoeia (USP), Centre for Drug Evaluation and Research (CDER). USFDA define oro-dispersible tablets as "A solid dosage form containing medicinal substances which disintegrates rapidly usual within a matter of second, when placed upon the tongue". Recently the European pharmacopoeia also adopted the term oro-dispersible tablet as tablet that is to be placed in mouth where it disperses rapidly before swallowing. This dosage forms dissolve or disintegrates in the patient's mouth within 15 sec to 3 min without the need of water or chewing. Despite various terminologies used, Oro-dispersible tablet are here to offer unique form of drug delivery with many advantages over the conventional oral solid dosage form [8-10].

The main aim of the present work is to formulate oro-dispersible tablets of Zolpidem tartrate by direct compression method and study the effect of different super disintegrants on disintegration and dissolution time.

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MATERIALS AND METHODS

Materials:

Zolpidem Tartrate was obtained as a gift sample from Spectrum pharmaceuticals, India. Lycoat, Crospovidone, Crosscarmellose sodium, were obtained from signet chemicals, Mumbai. Microcrystalline cellulose, Magnesium stearate and aspartame were obtained from S.D. Fines (Mumbai, India). All other chemicals and solvents were of analytical grade.

Formulation of oro-dispersible tablets:

Mouth dissolving tablets of Zolpidem tartrate were prepared by direct compression method according to the formula given in the (Table 1). Nine different formulations were prepared. Zolpidem Tartrate and microcrystalline cellulose (MCC) were mixed with disintegrant for 15 minutes in porcelain mortar, passed through 60 # sieve. This blend was mixed with aspartame and magnesium stearate for 5 minutes and processed for direct compression by using 8 mm round flat-faced punch of rotary tablet machine (Rimek mini press-1, Karnavati Engineering Ltd, Mehsana, Gujarat). Compression force was kept constant for all formulations. Disintegrants were used at 5, 7.5 and10% in tablets.

Evaluation of Powder Blend:

1. Angle of repose

The mixture of powder was allowed to flow through the funnel fixed in definite height (h). The angle of repose was then calculated by measuring the height and radius of the pile of powder formed. Care was taken to see that the powder particles slip and roll over each other through the sides of the funnel [11].

$$\theta = \tan^{-1}(h/r)$$

Where, θ = Angle of repose, h = Height of the pile, r = Radius of the pile

2. Bulk density

Bulk density (ρb) was determined by pouring pre-sieved bulk powder blend into a graduated cylinder. The bulk volume (Vb) and weight of powder (M) was determined. The bulk density was calculated using the formula [12].

$$\rho b = M/Vb$$

Where, ρb = Bulk density, M = Weight of powder, Vt = Bulk volume of powder

3. Tapped density

The tapped density was determined by placing a graduated cylinder containing a known mass of powder on mechanical tapping apparatus, which was operated for a fixed number of taps (around 500) untilthe powder bed volume reached a minimum. Using the weight of powder in a cylinder and this minimum volume, the tapped density was calculated by the formula [13].

$$\rho t = M/Vt$$

Where, ρt = Tapped density, M = Weight of powder, Vt = Tapped volume of powder

4. Hausner's ratio

The Hausner's ratio is an index of ease of powder flow. Lower the value (< 1.25) indicates better flow properties. It was determined by using formula [14].

$$\text{Hausner's ratio} = \rho b/\rho t$$

Where, ρb = Bulk density, ρt = Tapped density

5. Compressibility index

The compressibility index is a measurement of free property of powder, an indication of the ease with which a material can be induced to flow is given by % compressibility that was calculated as follows [15].

$$C = (\rho t - \rho b)/\rho t \times 100$$

Where, ρt = Tapped density, ρb = Bulk density

6. Drug-Excipients compatibility Study

FTIR and DSC studies were employed, as a tool to investigate the physico-chemical compatibility between the drug and excipients.

a) FTIR spectral analysis:

Infrared spectra of Zolpidem tartarate, excipients and formulations were recorded by KBr method using Fourier Transform Infrared Spectrophotometer. In the present study, the potassium bromide disc method was employed. The powdered sample was intimately mixed with dry powdered potassium bromide. This mixture was then compressed into transparent disc under high pressure using special dies. This disc was placed in IR spectrometer and spectrums were recorded. The scanning range was 450–4000 cm^{-1} and the resolution was 1 cm^{-1}.

b) Differential scanning calorimetric (DSC) characterization:

Thermal characteristics of Zolpidem tartarate, excipients and formulations were studied using differential scanning calorimeter. DSC measurements were performed at a heating rate of 5°C/min from 25 to 200°C in aluminum sealed pan. The sample size was 2-3 mg for measurement.

Table No. 1: Composition of Zolpidem Tartarte Oro-dispersible Tablets

Ingredients (mg/tablet)	Formulation Codes								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
Zolpidem tartarte	10	10	10	10	10	10	10	10	10
Crospovidone	5	7.5	10	--	--	--	--	--	--
Croscarmellose sodium	--	--	--	5	7.5	10	--	--	--
Lycoat	--	--	--	--	--	--	5	7.5	10
Microcrystalline cellulose	83	80.5	78	83	80.5	78	83	80.5	78
Magnesium Stearate	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Aspartame	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5

Evaluation of oro-dispersible tablets:

1. Thickness:

Thickness was determined by randomly selecting six tablets from each batch using Vernier caliper. The mean values and standard deviation was calculated [16].

2. Hardness:

Six tablets were randomly selected from each batch and hardness of tablets was determined by using the Monsanto Hardness Tester. The mean values and standard deviation for each batch were calculated. The hardness was measured in terms of kg/cm^2 [17].

3. Weight variation test:

Twenty tablets were selected at random, weighed and the average weight was determined by using a weighing balance. Then individual tablets compared with the average weight. Not more than two of the individual weights deviate from the average weight by more than the 10% [18].

4. Friability test:

Six tablets from each batch were examined for friability using Roche Fribilator and the equipment was running for 4 min at 25 RPM. The tablets were taken out, de-dusted, reweighed and % friability was calculated [19].

$$\%\ \text{Friability} = (\text{loss in weight/initial weight}) \times 100$$

5. Content uniformity:

The tablets were randomly selected from each batch, weighed individually and powdered. The powder equivalent to 10mg of zolpidem was weighed and dissolved in 100 ml phosphate buffer solutions (pH 6.8), to obtain the stock solution. From this stock solution, suitable dilution was prepared and analyzed using previously validated UV method at 239 nm [20].

6. Wetting time and water absorption ratio:

A piece of tissue paper folded twice was placed in a small petridish (i.d. = 6.5 cm) containing 6 ml of distilled water, a tablet was put on the paper, and the time required for complete wetting was measured. The wetted tablet was then weighed. Three trials for each batch were performed and standard deviation was also determined [21].

Water absorption ratio, R, was determined using equation.

$$R = 100 \times (Wa - Wb)/Wb$$

Where, Wb = weight of the tablet before water absorption

Wa = weight of the tablet after water absorption

***7. In-vitro* Disintegration test:**

The disintegration time was measured using disintegration test apparatus. One tablet was placed in each tube of the basket. The basket with the bottom surface made of a stainless steel screen (mesh no. 10) was immersed in a water bath at 37± 2°C. The time required for the complete disintegration of the tablet in each tube was determined [22].

***8. In-vitro* Dissolution time:**

Dissolution study was carried using USP II dissolution apparatus. Six tablets were taken from each batch and the dissolution was carried out in a buffer solution (pH 6.8) at 75 rpm, 37± 0.5°C. 5ml sample was withdrawn from each vessel at the interval of 2 minutes initially, followed by 5 minutes till it reaches to 30 minutes. Proper dilutions were made and analyzed at 239 nm using UV spectrophotometer.

RESULT AND DISCUSSION

Pre formulation study:

Micromeretic properties of the powder, resistance to particle movement can be judged from the angle of repose. This

measurement gives qualitative and quantitative assessment of internal cohesive and frictional force. Values for angle of repose were found in the range of 24.21 to 29.68°. Carr's index of the prepared blends falls in the range of 13.23 to 19.71 % and this is also supported by Hausner's ratio values which were in the range of 1.15 to 1.24. The results of pre-formulation parameters were in the acceptable range as per the specification. Hence the prepared blends possessed good flow properties and these can be used for tablet manufacture (Table 2).

Drug-Excipients compatibility Study:

a) FTIR studies:

Compatibility study between drug and excipients were carried out using a FTIR spectrophotometer to check any possible drug interaction between them. The spectrum of selected best formulation was compared with the spectra of pure drug (Fig. 1). The characteristic peaks of pure drug remained unaffected suggesting compatibility of drug with excipients used in the formulation.

b) DSC studies:

The DSC thermogram of Zolpidem Tartarate showed endothermal peak ranging from 99^{0}C to 112^{0}C due to loss of water of hydration. It confirms salt form of drug. The DSC thermogram of Crosspovidone was characterized by a broad endothermic peak at about 177^{0}C to 198^{0}C. The DSC thermogram of best formulation showed endothermal peak at around 103^{0}C and 178^{0}C (Fig. 2). The peaks indicate that there is no physicochemical interaction between components in a formulation and selected excipients are chemically compatible.

Post compression evaluation study:

All the tablets were prepared under similar conditions with uniform thickness and drug content. The weight variation of prepared oro-dispersible tablets was 5.41 to 6.29 %. Hardness of tablets prepared by direct compression was 4.21 to 4.72 kg/cm^2. The friability of all formulations was found to be less than 1%. The results of post-compression parameters were within the acceptable range as per pharmacopoeia specified (Table 3).

Disintegration study:

Disintegration time is very important for oro-dispersible tablet which is desired to be less than 60 seconds. All the formulations showed variable results of disintegration time depending on the type and quantity of super disintegrants used as shown in Figure 3. Formulation F1 - F3 containing crospovidone as superdisintegrant showed the disintegration time in the range of 14 to 20 seconds, formulation F4 - F6 containing croscarmellose sodium as super disintegrants had disintegration time between 20 to 29 seconds which was quite lower than formulations containing crospovidone. The formulation F7 - F9 containing lycoat as super disintegrants had disintegration time between 17 to 25 seconds which was quite higher than formulations containing croscarmellose sodium. The faster disintegration of crospovidone tablets when compared to tablets with other disintegrants may be attributed to its rapid capillary activity and pronounced hydration with little tendency to gel formation. This finding is in agreement with results obtained from wetting time. Also it was observed that disintegration time decreased as a concentration of super disintegrants increased. Hence, from this (Table 4), crospovidone was found to be best among all super disintegrants employed.

Wetting time is used as an indicator for the ease of the tablet disintegration in stomach. Type of the disintegrant affects the wetting of the tablets. Wetting time of tablets was found in the range of 12 to 25 seconds. The formulation containing lycoat has more wetting time than croscarmellose sodium and Crospovidone. This may be due to the fact that lycoat is disintegrated by swelling mechanism leading to longer wetting time. Crosprovidone and croscarmellose sodium perform their disintegrating action by wicking through capillary action and fibrous structure, respectively with minimum gelling. Tablets containing Crospovidone quickly wicks water and were hydrated, but were soft as compared with tablets prepared with croscarmellose sodium and lycoat. Higher water uptake leads to faster disintegration and dissolution of tablets.

***In-vitro* dissolution study:**

Dissolution study was performed using a phosphate buffer solution (pH 6.8) as a dissolution medium in specified condition. The drug release from formulations F1, F2 and F3 which contained increasing concentrations of crospovidone have recorded drug release of 95.6%, 96.07% and 98.64% respectively, at the end of 30 minutes. Formulations F4, F5 and F6 which contained increasing concentrations of crosscarmellose sodium have recorded drug release 94.52%, 96.25% and 95.21% respectively, at the end of 30minutes. Formulations F7, F8 and F9 which contained increasing concentrations of lycoat have recorded drug release 84.35%, 89.49% and 92.04% respectively, at the end of 30 minutes. Suggesting that dissolution rate of formulation is dependent on the type and the concentration of superdisintegrants. In all the formulations the drug release was near to 100% within 30 minutes as shown in Figure 4. At 10% superdisintegrant level the drug release at the end of 10 minutes were found to be 98.64, 85.16 and 74.59 % with crosprovidone, crosscarmellose sodium and lycoat respectively. The relative efficiency of different superdisintegrants to improve the dissolution rate of tablets was in order, Crospovidone > Crosscarmellose sodium > Lycoat. This experiment proved that disintegration step is the rate limiting step for ODTs. From the observed data, it is clear that less disintegration time increases the release rate of zolpidem tartrate from ODTs.

Table No. 2: Micromeritic properties of powder blend of oro-dispersible tablets

Formulation code	Bulk density	Tapped density	Angle of repose ( )	Compressibility (%)	Hausner's ratio
F1	0.56±0.033	0.67±0.013	24.71°±0.33	16.41±0.026	1.196±0.011
F2	0.60±0.024	0.71±0.021	26.12°±0.89	17.99±0.025	1.218±0.03
F3	0.57±0.32	0.71±0.021	24.21°±0.28	13.23±1.023	1.152±0.014
F4	0.55±0.011	0.67±0.021	28.16°±1.025	15.49±0.015	1.183±0.011
F5	0.57±0.019	0.68±0.033	29.17°±1.89	16.17±0.011	1.192±0.015
F6	0.60±0.035	0.72±0.025	28.91°±1.535	15.94±0.021	1.189±0.02
F7	0.59±0.013	0.68±0.015	29.68°±1.99	19.71±0.033	1.245±0.015
F8	0.58±0.011	0.73±0.019	26.51°±0.995	16.666±0.015	1.200±0.011
F9	0.59±0.015	0.69±0.031	24.26°±0.22	14.149±0.020	1.169±0.01

Table No. 3: Evaluation of Post Compression Parameters of Zolpidem tartrate ODTs

Formulation code	Hardness (kg/cm^2)	Friability (%)	Thickness (mm)	Drug content (mg)	%Weight variation
F1	4.46±0.14	0.3493	2.49±0.03	8.855±0.146	5.76±1.712
F2	4.66±0.20	0.2451	2.55±0.01	8.988±0.022	6.29±0.671
F3	4.40±0.13	0.3291	2.62±0.03	8.933±0.023	6.29±1.183
F4	4.30±0.23	0.2647	2.47±0.01	8.965±0.136	6.31±1.121
F5	4.41±0.21	0.2834	2.53±0.04	9.215±0.061	5.41±2.531
F6	4.70±0.21	0.3261	2.51±0.05	8.977±0.023	5.64±1.663
F7	4.72±0.23	0.2888	2.65±0.03	9.585±0.125	6.01±1.225
F8	4.21±0.12	0.2537	2.55±0.01	8.945±0.067	5.43±2.133
F9	4.45±0.16	0.3123	2.47±0.01	8.953±0.021	5.62±1.60

Table No. 4. Evaluation for disintegration time, wetting time and water absorption ratio

Formulation code	Disintegration time (sec)	Wetting time (sec)	Water absorption ratio
F1	20.43±0.65	17.74±1.55	56.62±1.60
F2	17.64±1.15	15.21±1.43	57.26±1.712
F3	14.38±2.19	12.23±1.45	59.41±2.531
F4	29.63±2.13	27.28±1.25	56.64±1.663
F5	25.30±1.69	22.53±1.57	59.43±2.133
F6	20.63±1.48	17.64±1.44	62.79±0.671
F7	25.50±1.16	21.20±1.29	62.39±1.183
F8	20.53±0.61	16.01±0.37	63.31±1.121
F9	17.53±1.12	13.11±1.23	66.01±1.225

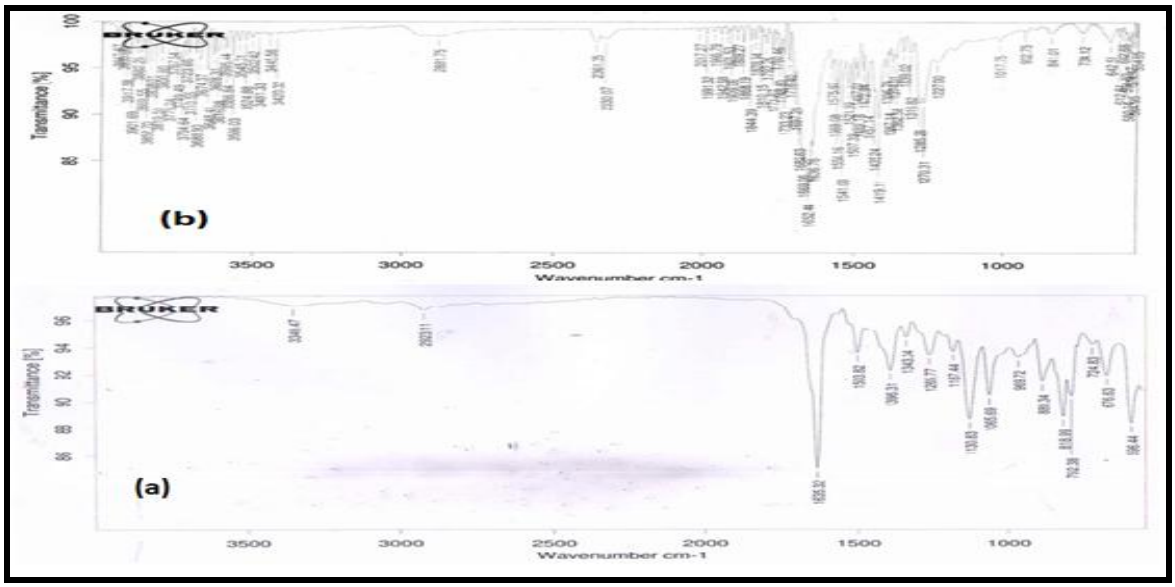

Fig. 1: FTIR Spectrum of pure Zolpidem tartrate (a) and Oro-dispersible Tablet (b)

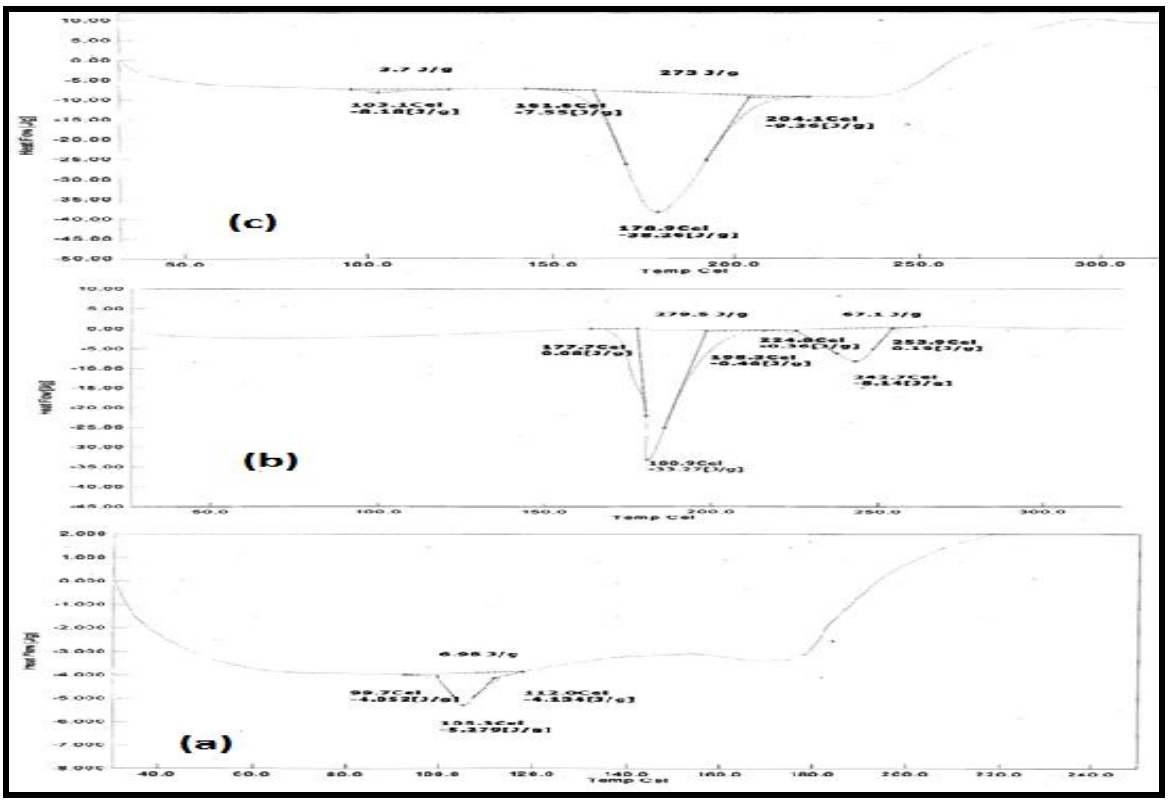

Fig. 2: DSC thermograms of pure Zolpidem tartrate (a), crospovidone (b) and Oro-dispersible Tablet (c)

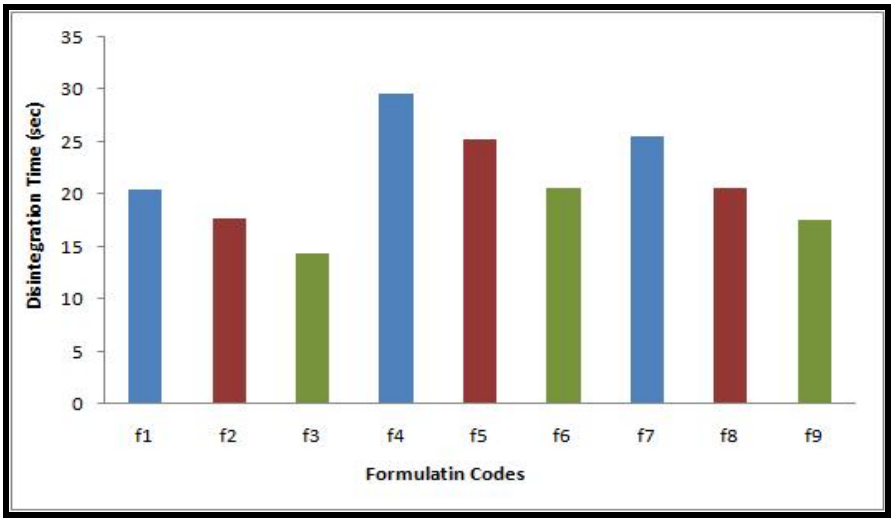

Fig. 3: Disintegration time data of Zolpidem tartrate oro-dispersible tablets

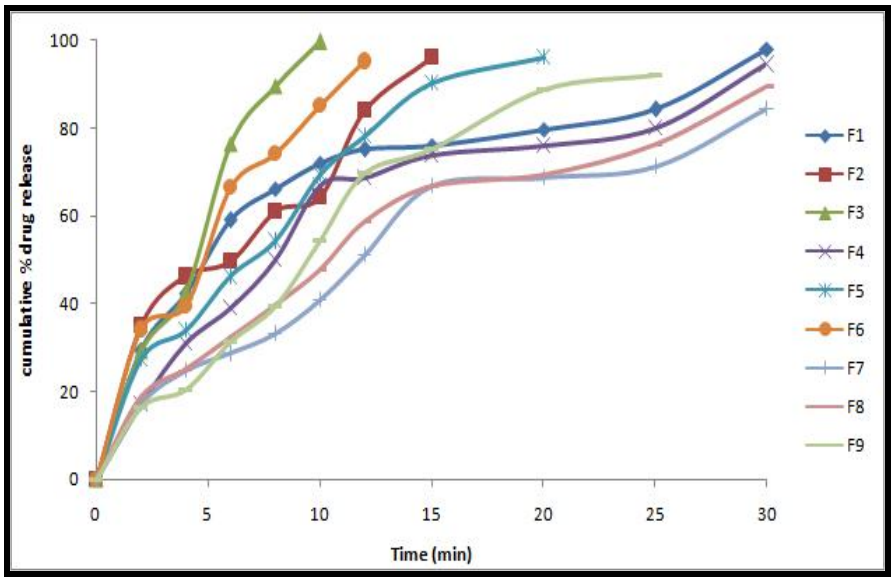

Fig. 4: *In-Vitro* Drug Release Profile of Zolpidem tartrate oro-dispersible tablets

CONCLUSION

On the basis of current investing results, it was concluded that the oro-dispersible tablets of zolpidem tartrate could be formulated by direct compression method to improve the drug release profile. The results of formulation F3 Containing 10% crospovidone as superdisintegrant matched with the required criteria with 98.64% drug release within 10 mins. It was found to disintegrate in less than 1 minute, which provides faster effect and better patient compliance.

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