INTERNATIONAL JOURNAL OF PHARMACY AND ANALYTICAL RESEARCH

ISSN:2320-2831

IJPAR |Vol.7 | Issue 1 | Jan - Mar -2018

Journal Home page: www.ijpar.com

Research article *Open Access*

Fabrication and Optimization of Various Superdisintegrants to Formulate Zolpidem Tartarate Fast Dissolving Tablets

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ABSTRACT

In the general perspective, oral administration is the most popular route about 50-60% of total dosage forms are administered due to ease of ingestion, pain avoidance, versatility (to accommodate various types of drug candidates), and most importantly patient compliance. Difficulty in swallowing is also a common problem of all groups, especially the elderly and pediatrics, because of physiological changes associated with these groups. Taste of a pharmaceutical product is an important parameter governing compliance. Hence this research angled to extend towards the selection and optimization of superdisintegrants to formulate Zolpidem Tartarate fast dissolving tablets by direct compression method. The formulations F13, F14, 15 and F16 which contained increasing concentrations of combination of cross povidone with cross Croscarmellose sodium have recorded drug release 94.5%, 96.52%, 99.87% and 96.38% respectively, at the end of 25 to 30 min. From the result it has been revealed that, the disintegration and dissolution of the formulation F15 contained cross povidone (5%) with cross Croscarmellose sodium (5%) was the best formulation among the all other formulations. Consequently, the formulation of the selected drug has been successfully developed as fast dissolving tablets which might significantly improve the patient compliance.

Keywords: Fast dissolving tablets, Superdisintegrants, Zolpidem tartrate and Patient compliance.

INTRODUCTION

One important drawback of solid dosage forms is the difficulty in swallowing (dysphasia) or chewing in some patients particularly pediatric and geriatric patients. The problem of swallowing is common phenomenon in geriatric patient due to fear of choking, hand tremors, dysphasia and in children's due to underdeveloped muscular and nervous systems and in schizophrenic patients resulting in poor compliance with oral tablet drug therapy which leads to reduced overall therapy effectiveness. Difficulties in swallowing of tablet

and capsule also occur when water is not available, in diarrhea, coughing during the common cold, allergic condition and bronchial infection [9-15]. Oral fast dissolving drug delivery system (OFDDS) is one such novel approach to increase consumer acceptance by virtue of rapid disintegration, self-administration without water or chewing [3]. Orally disintegrating tablets (ODT) are solid unit dosage forms like conventional tablets, but are composed of superdisintegrants, which help them to disintegrate the tablet rapidly in saliva without the need to take it water. Orally disintegrating tablets (ODT) are not only indicated for people who have swallowing difficulties, but also are ideal for active people.

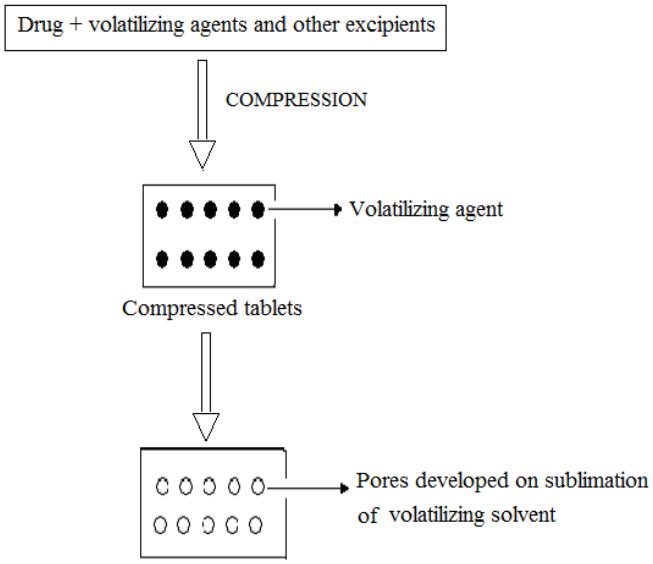

Figure 1. Steps involved in sublimation [7-9]

Porosity and capillary action (Wicking) [7-9]

Disintegration by capillary action is always the first step. When we put the tablet into suitable aqueous medium, the medium penetrates into the tablet and replaces the air adsorbed on the particles, which weakens the intermolecular bond and breaks the tablet into fine particles.

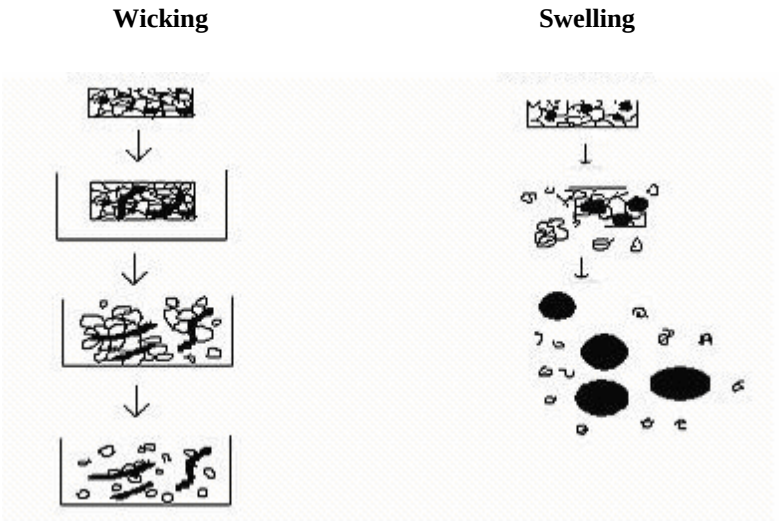

Figure 2. Disintegration of tablet by wicking and swelling

MATERIALS AND METHODS

Procurement

Zolpidem Tartarate is obtained as Gift sample from Hetero Drugs, Hyd. and all other ingredients used in formulating the tablets has been obtained as a Gift sample from Hetero Drugs, Hyd.

Drug Profile

Zolpidem tartrate is a gamma-aminobutyric acid (GABA)A agonist and selective to benzodiazepine receptors which are located on the gamma-aminobutyric acid receptors. It is classified as an imidazopyridine

- **Chemical Name:** bis[N,N-dimethyl-2-[6-methyl-2-(4-methylphenyl)imidazo[1,2-a]pyridin-3-yl]aceta mide] (2R,3R)-2,3-dihydroxybutanedioate,
- **Proprietary Name:** Ambien, Lorex, Stilnoct
- **Molecular Formula:** $C_{42}H_{48}N_6O_8$
- **Molecular Weight:** 764.88
- **Structural Formula**
- **Category**: Hypnotic and Sedative, GABA agonist.
- **Official status**: Thee drug official in B.P

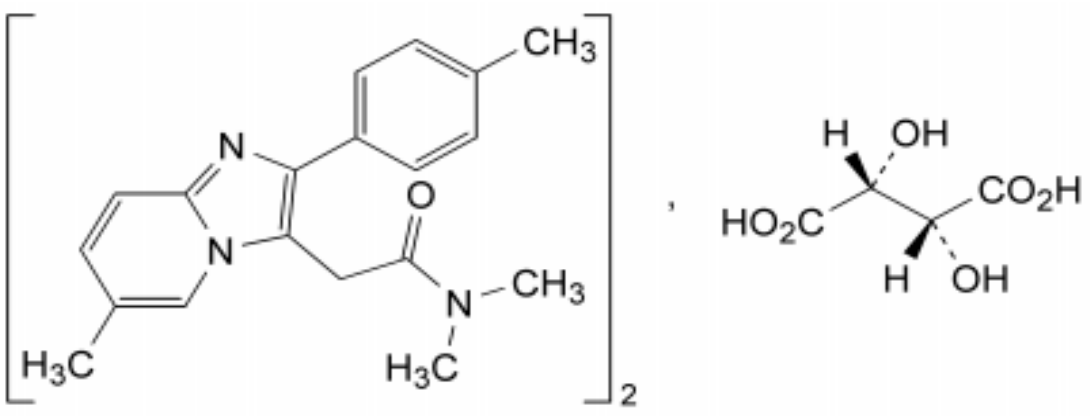

Figure 3. Structure of Zolpiedem Tartrate

Preparation of Standard Graph

A standard graph of pure drug in suitable medium was prepared by plotting the concentrations on X – axis and absorbance on Y – axis.

Table 1. Calibration curve for the estimation of Zolpidem Tartarate

S.NO.	Concentration(µg/ml)	UV Absorbance (n=5)
1	5	0.132
2	10	0.242
3	15	0.395
4	20	0.528
5	25	0.656
6	30	0.813

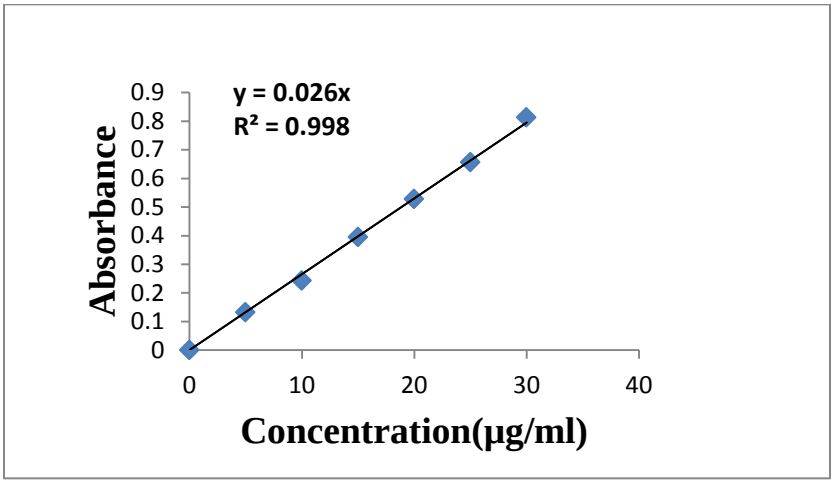

Figure 4. Calibration curve for the estimation of Zolpidem Tartarate

The present analytical method obeyed Beer's law in the concentration range of 5 – 30 µg/ml and is suitable for the estimation of Zolpidem Tartarate form different solutions.

FORMULATION AND EVALUATION OF ORAL DISINTEGRATING TABLETS OF ZOLPIDEM TARTARATE

Formulation design

Zolpidem Tartarate ODTs were prepared using direct compressiontechnique. Direct compression technique is a convenient method but the excipients used in this method are costlier when compared to the excipients used in the wet granulation technique.

Table 2. Formulation codes of ODT

Disintegrant used	Concentration (%)	Formulation code
Crosspovidone	3	F1
	6	F2
	9	F3
	12	F4
Croscarmellose sodium	3	F5
	6	F6
	9	F7
	12	F8
Sodium starch glycolate	3	F9
	6	F10
	9	F11
	12	F12
Crosspovidone + crosscarmellose sodium	6 (3:3)	F13
	8 (4:4)	F14
	10 (5:5)	F15
	12 (6:6)	F16
Crosspovidone + sodium starch glycolate	6 (3:3)	F17
	8 (4:4)	F18
	10 (5:5)	F19
	12 (6:6)	F20

PROCEDURE

All the required ingredients were passed through 40 mesh to get uniform size particles and weighed accurately. Whole amount of drug, pearlitol SD 200, Avicel pH 102, sodium saccharine and flavour except lubricant were mixed in the increasing order of their weights in a mortar. To this mixture colloidal silica and sodium stearyl fumarate were added. The final mixture was shaken manually for 5-10 minutes in a plastic bag. This powder was passed through the hopper of 16 station rotary tabletting machine and punched into tablets using 5 mm s/c. The process is similar for all the formulations, which are prepared by direct compression technique [10-16].

Evaluation of orally disintegration tablet formulations

Different quality control tests were performed for all the ODT formulations to check whether these have met the specifications given in USP along with other In *vitro* tests like wetting time and water absorption ratio.

Various *In vitro* tests performed are

- Weight variation test
- Thickness measurement
- Hardness and Friability
- Assay
- Wetting time and Water absorption ratio
- Disintegration Time
- Dissolution test

DISSOLUTION TEST

Method

Dissolution test was carried out using USP rotating paddle method (apparatus 2). The stirring rate was 50 rpm. 6.8 pH phosphate buffer was used as dissolution medium (900ml) and was maintained

at 37 ± 1^0C. Samples of 5ml were withdrawn at pre – determined intervals (2, 4, 6, 8, 10, 15, 20, 25, 30 min), filtered and replaced with 5ml of fresh dissolution medium [17-25].

RESULTS AND DISCUSSION

The collected samples were suitably diluted with dissolution fluid, where ever necessary and were analyzed for the Zolpidem Tartarate at 278 nm by using UV spectrophotometer. Each dissolution study was performed for three times and mean values were taken.

Table 3. Formulae of Zolpidem Tartarate ODTs prepared by direct compression method with various superdisintegrants

Ingredients	Super disintegrants concentration (%) of Crosspovidone/ Croscarmellose Sodium/ Sodium Starch Glycolate			
	3%	6%	9%	12%
Zolpidem Tartarate	5	5	5	5
Superdisintegrants	3	6	9	12
Avicel PH 102	69	58	49	38
Pearlitol SD200	10	10	10	10
Sodium saccharin	10	10	10	10
Orange flavor	2	2	2	2
Sodiumstearylfumerate	0.5	0.5	0.5	0.5
Talc	0.5	0.5	0.5	0.5
Total weight (mg)	100	100	100	100

Table 4. Preformulation characteristics of Zolpidem Tartarate ODTs

Formulation	Bulk density (g/cc)	Tapped density (g/cc)	Hausner ratio	Compressibilty index (%)	Angle of repose (ɵ)
F1	0.435	0.522	1.20	16.66	32.67
F2	0.429	0.518	1.20	17.18	29.08
F3	0.430	0.524	1.21	17.93	31.78
F4	0.432	0.528	1.22	18.18	30.64
F5	0.428	0.518	1.21	17.37	30.36
F6	0.420	0.510	1.21	17.64	31.05
F7	0.416	0.509	1.22	18.27	32.54
F8	0.417	0.515	1.23	19.02	29.67
F9	0.425	0.515	1.21	17.47	31.85
F10	0.421	0.509	1.20	17.28	29.56
F11	0.419	0.515	1.22	18.64	30.17
F12	0.415	0.512	1.23	18.94	32.08

Table 5. Tabletting characteristics of Zolpidem Tartarate ODTs

Formulation	Weight (mg)	Drug content (%)	Hardness (kg/cm^2)	Friability (%)	Thickness (mm)
F1	99.9±0.70	98.96±0.47	3.05±0.13	0.48	3.84±0.032
F2	99.52±0.85	99±0.65	3.10±0.15	0.53	3.85±0.028
F3	98.9±0.52	99.11±0.52	2.95±0.08	0.44	3.86±0.024
F4	100.2±1.17	99.15±0.60	2.95±0.10	0.57	3.86±0.051
F5	99.0±0.49	99.2±0.4	3.08±0.12	0.43	3.88±0.048

F6	98.8±0.58	98.85±0.58	3.11±0.14	0.56	3.90±0.052
F7	99.3±0.54	99.31±0.24	2.92±0.08	0.53	3.92±0.038
F8	100.4±1.0	98.96±0.28	3.0±0.09	0.45	3.91±0.042
F9	99.6±0.95	99.3±0.38	2.9±0.07	0.6	3.90±0.040
F10	99.2±0.97	99.36±0.29	3.05±0.08	0.49	3.89±0.042
F11	99.4±0.86	98.75±0.40	3.05±0.09	0.53	3.89±0.034
F12	98.5±0.42	99.21±0.38	2.93±0.08	0.58	3.87±0.031

Table 6. Tabletting characteristics of Zolpidem Tartarate ODTs

Formulation	Wetting time (sec)	*In vitro* dispersion time (sec)	Disintegration time (sec)	Water absorption ratio (%)
F1	24.83±0.98	221.33±1.03	116.5±1.37	58.45
F2	21.16±0.75	180.5±1.04	95.16±0.75	59.25
F3	14.66±0.51	75±0.89	56.50±1.64	58.9
F4	11.66±0.51	54±0.63	27.83±1.16	60.65
F5	57.33±0.81	244.5±1.04	168.83±1.94	59.88
F6	22.33±1.36	215.5±0.54	98±0.63	61.48
F7	28±1.09	177.83±1.16	73.16±1.47	59.55
F8	19.66±0.81	126.66±0.81	36.66±1.21	60.01
F9	37.33±0.81	259.83±1.47	171.83±1.16	64.37
F10	28.33±0.81	225.33±0.81	153±0.89	67.54
F11	26.66±0.81	186.83±0.75	81.5±1.04	65.50
F12	36.83±1.16	154.5±0.83	42.66±1.75	65.89

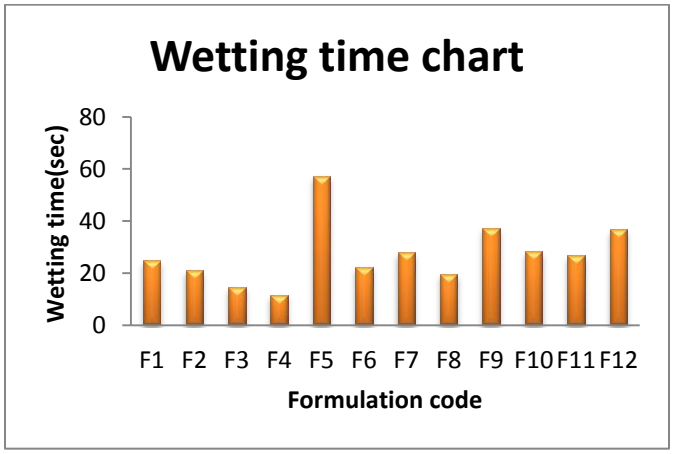

Figure 5. Graphical representation of wetting time of Zolpidem Tartarate ODTs prepared by varying concentrations of superdisintegrants

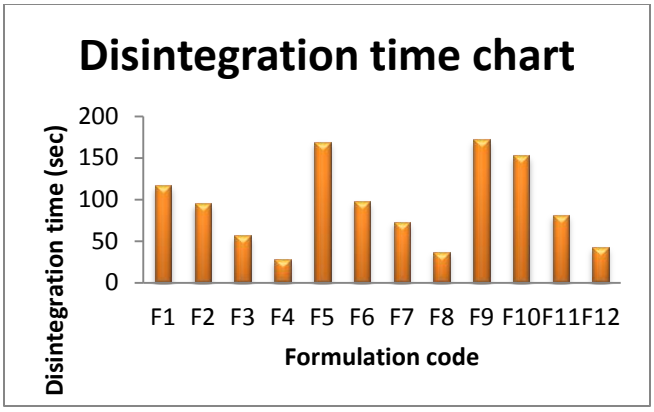

Figure 6. Graphical representation of disintegration times of Zolpidem Tartarate ODTs prepared by varying concentrations of superdisintegrants

Table 7. Cumulative percent Zolpidem Tartarate released from ODTs containing varying concentrations of different superdisintegrants (F1-F6)

	Cumulative percent (±S.D.) drug released					
Time (min)	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**
2	27.35±0.28	22.35±0.52	20.46±0.25	28.31±0.23	18.35±0.34	15.43±0.30
4	40.33±0.28	34.36±0.28	29.28±0.19	41.33±0.24	25.5±0.28	23.43±0.32
6	55.46±0.31	45.31±0.27	42.35±0.25	59.33±0.26	37.36±0.25	37.36±0.26
8	69.46±0.27	62.35±0.25	61.31±0.23	73.48±0.34	57.41±0.23	54.38±0.26
10	74.38±0.27	75.48±0.30	76.4±0.36	85.38±0.34	64.55±0.28	67.38±0.37
15	83.35±0.20	87.4±0.31	82.53±0.30	98.6±0.29	72.48±0.35	75.46±0.26
20	94.45±0.30	96.31±0.29	97.31±0.20	98.89±0.32	80.45±0.28	82.31±0.23
25	94.89±0.24	96.57±0.28	97.76±0.28	98.95±0.24	86.5±0.26	87.48±0.24
30	95.78±0.27	96.85±0.32	97.96±0.25	98.99±0.23	89.53±0.19	92.36±0.25

Table 8. Cumulative percent Zolpidem Tartarate released from ODTs containing varying concentrations of different superdisintegrants (F7-F12)

	Cumulative percent (±S.D.) drug released					
Time (min)	**F7**	**F8**	**F9**	**F10**	**F11**	**F12**
2	22.33±0.25	14.38±0.31	19.33±0.20	23.43±0.16	18.48±0.33	19.4±0.32
4	33.36±0.31	22.1±0.59	28.36±0.32	35.31±0.27	27.18±0.18	27.41±0.26
6	45.46±0.26	36.43±0.30	36.45±0.25	47.36±0.29	34.43±0.23	35.28±0.29
8	62.43±0.23	55.46±0.30	49.43±0.26	53.5±0.34	45.61±0.17	52.43±0.26
10	70.28±0.20	62.46±0.25	55.48±0.26	64.45±0.30	52.41±0.36	65.41±0.33
15	78.41±0.26	75.58±0.27	68.46±0.32	72.6±0.27	61.25±0.55	78.45±0.35
20	86.28±0.24	80.4±0.26	74.58±0.27	78.41±0.14	70.46±0.21	84.51±0.24
25	90.28±0.17	83.48±0.30	78.43±0.27	83.45±0.28	75.41±0.24	88.36±0.18
30	94.46±0.25	95.43±0.19	85.4±0.22	88.45±0.18	90.4±0.33	92.38±0.19

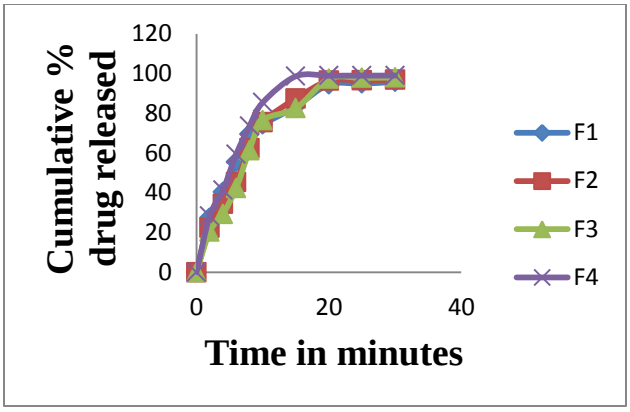

Figure 7. Graphical representation of Cumulative percent Zolpidem Tartarate released from ODTs containing varying concentrations of crosspovidone.

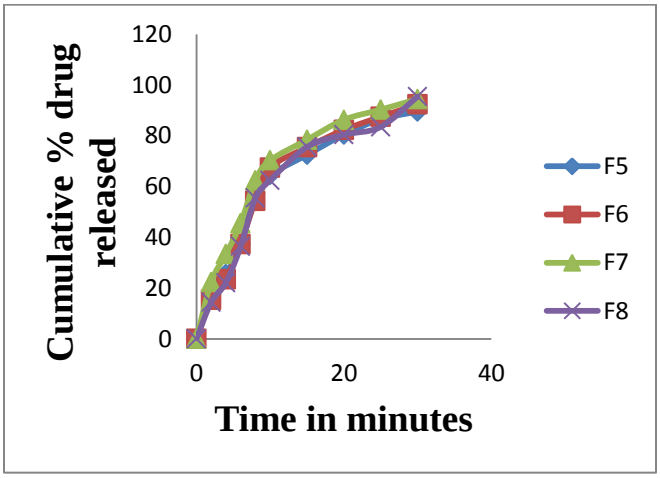

Figure 8. Graphical representation of Cumulative percent Zolpidem Tartarate released from ODTs containing varying concentrations of croscarmellose sodium.

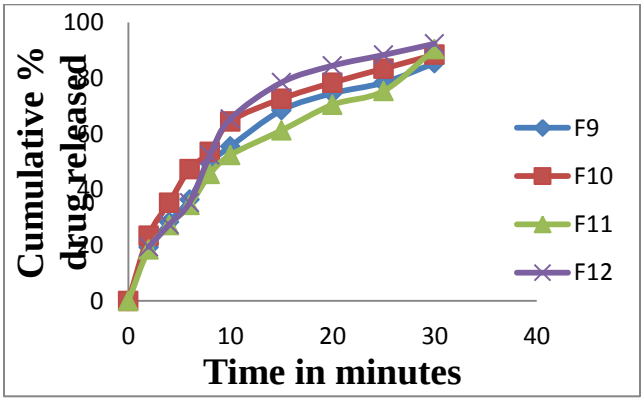

Figure 9. Graphical representation of Cumulative percent Zolpidem Tartarate released from ODTs containing varying concentrations of sodium starch glycolate.

Table 9. Formulae of Zolpidem Tartarate ODTs prepared with combination of superdisintegrants

Ingredients	CP + CCS				CP + SSG			
	6%	8%	10%	12%	6%	8%	10%	12%
Zolpidem Tartarate	5	5	5	5	5	5	5	5
Superdisintegrants	3	6	9	12	3	6	9	12
Avicel PH 102	69	58	49	38	69	58	49	38
Pearlitol SD200	10	10	10	10	10	10	10	10
Sucralose	10	10	10	10	10	10	10	10
Orange flavor	2	2	2	2	2	2	2	2
Sodiumstearyl fumerate	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Colloidal silica	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Total weight (mg)	100	100	100	100	100	100	100	100

Note: CP – Crosspovidone, CCS – Croscarmellose Sodium, SSG – Sodium Starch Glycolate

Table 10. Preformulation characteristics of Zolpidem Tartarate ODTs prepared with combination of superdisintegrants

Formulation	Bulk density (g/cc)	Tapped density (g/cc)	Hausner ratio	Compressibilty index (%)	Angle of repose (ɵ)
F13	0.420	0.520	1.23	19.23	29.67
F14	0.423	0.512	1.21	17.38	29.54
F15	0.435	0.520	1.20	16.34	31.76
F16	0.422	0.512	1.21	17.57	32.04
F17	0.425	0.523	1.23	18.73	30.56
F18	0.434	0.526	1.21	17.49	31.23
F19	0.426	0.512	1.20	16.79	29.52
F20	0.420	0.519	1.23	19.07	29.32

Table 11. Tabletting characteristics of Zolpidem Tartarate ODTs prepared with combination of superdisintegrants

Formulation	Weight (mg)	Drug content (%)	Hardness (kg/cm^2)	Friability (%)	Thickness (mm)
F13	100.3±1.18	98.56±0.49	3.19±0.05	0.47	3.86±0.034
F14	99.3±0.53	98.61±0.60	3.16±0.04	0.52	3.86±0.023
F15	100.1±0.75	98.98±0.56	3.10±0.10	0.63	3.87±0.044
F16	100.3±0.86	99.03±0.58	3.05±0.09	0.58	3.89±0.051
F17	99.1±0.84	97.75±0.69	3.15±0.04	0.58	3.85±0.029
F18	98.8±0.56	98.76±0.56	2.92±0.08	0.53	3.88±0.046
F19	99.6±0.60	99.08±0.29	3.00±0.09	0.51	3.86±0.025
F20	100.0±0.75	98.86±0.39	3.12±0.12	0.55	3.84±0.034

Table 12. Parameters of Zolpidem tartrate

Formulation	Wetting time (sec)	*In vitro* dispersion time (sec)	Disintegration time (sec)	Water absorption ratio (%)
F13	19.33±0.51	91.66±1.21	82.5±1.04	59.49
F14	14.33±0.51	49.33±1.03	46±0.89	56.59
F15	**11.16±0.75**	**30.66±0.81**	**17.66±0.51**	**57.08**
F16	12.5±0.54	35.16±0.75	20.33±0.81	58.72
F17	19.1±0.75	96.83±0.40	86.16±0.75	57.95

F18	14.83±0.75	54.16±1.72	47.5±1.04	60
F19	11.5±0.54	46.66±0.81	23.66±0.51	61.50
F20	13±0.89	43.83±0.75	20.83±1.16	58.24

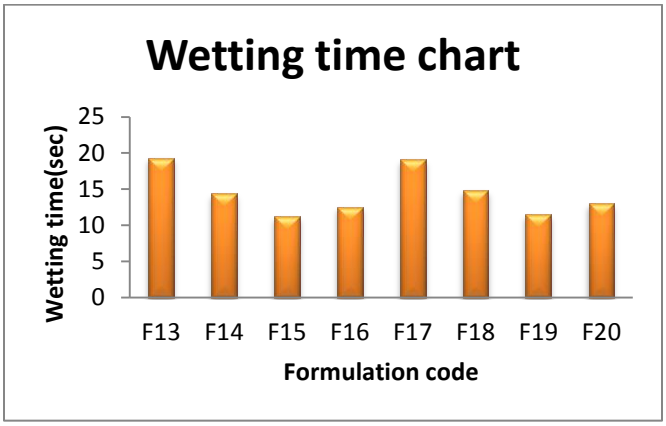

Figure 10. Graphical representation of witting time of Zolpidem Tartarate ODTs prepared by varying concentrations of combination of superdisintegrants

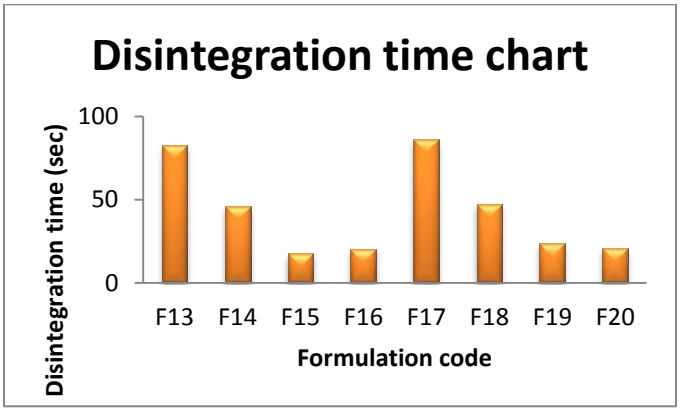

Figure 11. Graphical representation of disintegration times of Zolpidem Tartarate ODTs prepared by varying concentrations of combination of superdisintegrants

Table 13. Cumulative percent Zolpidem Tartarate released from ODTs prepared by varying concentrations of combination of superdisintegrants (F13-F16)

	Cumulative percent (±S.D.) drug released			
Time (min)	**F13**	**F14**	**F15**	**F16**
2	17.41±0.26	26.21±0.17	25.43±0.29	21.4±0.24
4	25.43±0.25	32.38±0.21	37.41±0.31	31.43±0.33
6	37.43±0.33	45.31±0.27	51.36±0.28	40.25±0.18
8	53.45±0.26	60.25±0.15	68.35±0.31	64.45±0.28
10	66.43±0.24	75.31±0.29	77.35±0.28	71.53±0.26
15	78.45±0.24	87.48±0.24	89.4±0.2	79.46±0.22
20	83.45±0.24	89.31±0.17	93.38±0.24	84.53±0.25
25	85.35±0.25	96.52±0.19	99.87±0.18	89.55±0.16
30	94.5±0.21	------	------	96.38±0.24

Table 14. Cumulative percent Zolpidem Tartarate released from ODTs prepared by varying concentrations of combination of superdisintegrants (F17-F20)

	Cumulative percent (±S.D.) drug released			
Time (min)	**F17**	**F18**	**F19**	**F20**
2	13.48±0.27	24.55±0.32	24.35±0.30	26.3±0.28
4	25.35±0.30	35.3±0.28	31.41±0.25	38.3±0.28
6	33.4±0.20	42.4±0.31	43.53±0.21	50.36±0.24
8	50.38±0.18	53.38±0.27	57.43±0.33	61.48±0.21
10	61.4±0.30	65.43±0.35	69.53±0.24	69.35±0.28
15	75.55±0.32	76.5±0.28	77.48±0.34	76.51±0.17
20	77.43±0.29	82.45±0.30	85.38±0.23	81.48±0.24
25	82.45±0.18	86.5±0.26	91.45±0.18	84.45±0.27
30	88.56±0.21	92.5±0.14	95.48±0.18	94.51±0.19

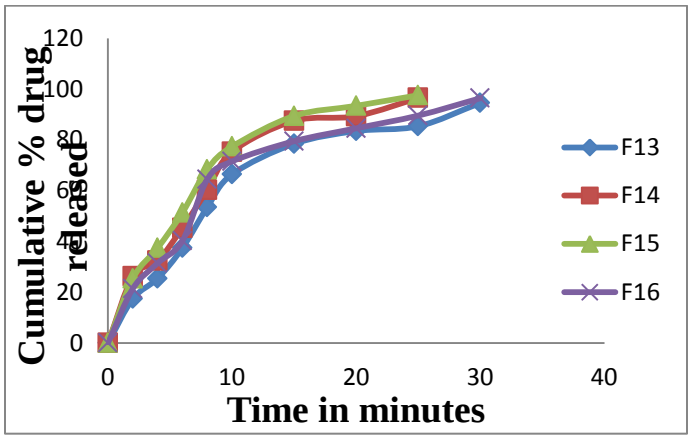

Figure 12. Graphical representation of Cumulative percent Zolpidem Tartarate released from ODTs containing varying concentrations of CP + CCS

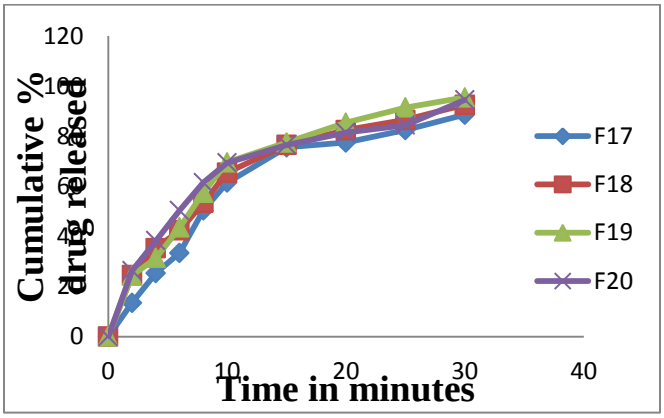

Figure 13. Graphical representation of Cumulative percent Zolpidem Tartarate released from ODTs containing varying concentrations of CP + SSG

FTIR studies

FTIR spectra of IR spectrum of pure Zolpidem Tartarate, croscarmellose sodium, crosspovidone, sodium starch glycolate and combination thereof were recorded on Perkin Elmer spectrophotometer. The scans were evaluated for presence of principal peaks of drug, shifting and masking of drug peaks due to presence of polymer. The FT – IR spectra of pure Zolpidem Tartarate.

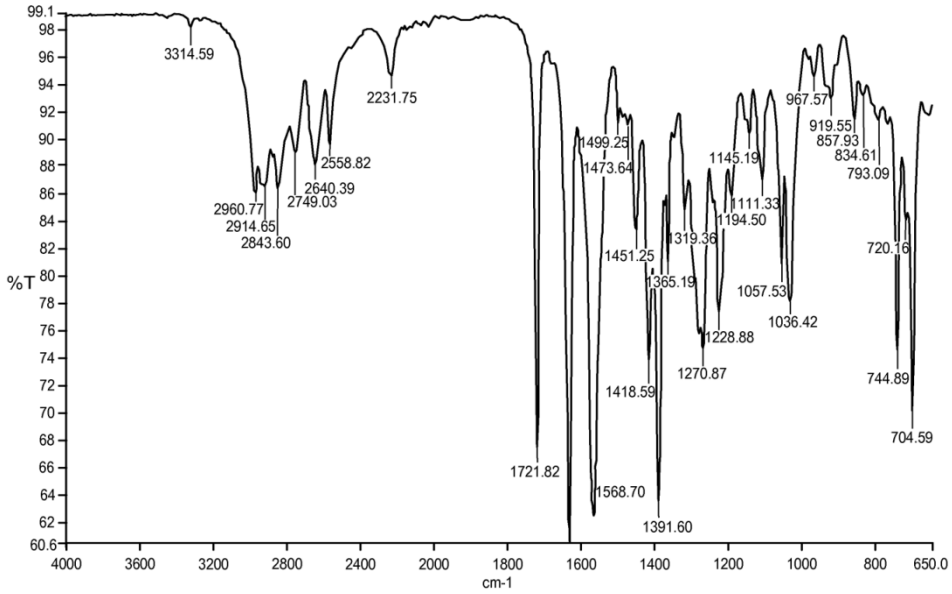

Figure 14. FTIR spectra of Zolpidem Tartarate

The above peaks are considered as characteristic peaks of Zolpidem Tartarate. These peaks were not affected and prominently observed in IR spectra of drug and excipients. This indicates there is no interaction between drug and excipients.

The overall objective of this study was to design oral disintegrating Zolpidem Tartarate tablets and films that disintegrate or disperse in the saliva within a matter of seconds.

Oral Disintegrating Tablets

Using various disintegrants like Crosspovidone, Croscarmellose sodium, Sodium starch glycolate tablets were prepared along with other additives. Direct compression method was used for the preparation of tablets. A total number of 20 formulations were prepared and evaluated.

Disintegration time is considered to be important criteria in selecting the best ODT formulation. The *in vitro* disintegration time for all the twenty formulations varied from 17.66±0.51 to 171.83±1.16 seconds. The rapid disintegration was seen in the formulations containing crosspovidone and formulations containing combination of superdisintegrants (CP + CCS, CP + SSG). This is due to rapid uptake of the water from the medium, swelling and burst effect. It is also noticed that as the disintegrant concentration was increased from 9 to 12% the time taken for disintegration was reduced. The disintegration time of formulation (F15) containing 5% CP + 5% CCS was found to be lower (17.66±0.51) and was selected as the best ODT formulation among all the 20 formulations.

The development of dissolution method for ODTs is almost similar to the approach taken for conventional tablets until they utilize the taste masking. The taste masking aspect greatly influences dissolution method development, specifications, and testing. Several factors like varied thickness and pH dependent solubility of drug particle coating influence dissolution profiles of ODTs containing taste masked actives. Since Zolpidem Tartarate is not bitter in taste, the metallic taste of drug was masked by using sweeteners and flavors. It has been reported that USP type II apparatus with a paddle speed of 50 rpm is commonly used for ODT formulations. Slower paddle speeds are utilized to obtain good profiles as these formulations disintegrate rapidly.

In *vitro* dissolution studies of the prepared ODTs was performed in pH 6.8 phosphate buffer using USP dissolution apparatus type 2. The dissolution rate was found to increase linearly with increasing concentration of superdisintegrant. Formulations F1, F2, F3 and F4 which contained increasing concentrations of crosspovidone have recorded drug release 95.78%, 96.85%, 97.96 and 98.99% respectively within 20 to 30 min. Formulations F5, F6, F7 and F8 which contained increasing concentrations of croscarmellose sodium have recorded drug release 89.53%, 92.36%, 94.46% and 95.43% respectively, at the end of 30 min. Formulations F9, F10, F11 and F12 which contained increasing concentrations of sodium starch glycolate have recorded drug release 85.4%, 88.45%, 90.4% and 92.38% respectively, at the end of 30 min.

Formulations F13, F14, 15 and F16 which contained increasing concentrations of combination of CP + CCS have recorded drug release 94.5%, 96.52%, 99.87% and 96.38% respectively, at the end of 25 to 30 min. Formulations F17, F18, F19 and F20 which contained increasing concentrations of combination of CP + SSG have recorded drug release 88.56%, 92.5%, 95.48% and 94.51respectivel, at the end of 30 min.

CONCLUSION

In this contemporary investigation, the oral Disintegrating Tablets of Zolpidem Tartarate were formulated with an aim to improve the versatility, patient compliance and accurate dosing. The formulations ere developed with an objective to use by the pediatric and geriatric patients. Zolpidem Tartarate Oral Disintegrating Tablets were prepared by direct compression method using crosspovidone, croscarmellose sodium, sodium starch glycolate. The formulation F15 was found to be the best among the all twenty Zolpidem Tartarate ODT formulations because it has exhibited faster disintegration time (17.66 sec) when compared to the other formualaions and it showed 99.87±0.18%drug release at the end of 25 min.. Based on disintegration and dissolution results it was concluded that the formulation F15 contained CP 5% + CCS 5% was the best formulation among the all other formulations. The metallic taste of the drug was masked effectively by suitable ingredients.

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