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Research Article

DESIGN AND DEVELOPMENT OF RIZATRIPTAN BENZOATE ORAL DISPERSIBLE FILMS

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ABSTRACT

Aim: The present work was to formulate and evaluate the Rizatriptan benzoate oral dispersible films by using solvent casting method. Materials and methods: The formula was optimised with different polymers like sodium CMC, HPMC and sodium alginate by using different plasticizers like propylene glycol, N-dibutyl phthalate, PEG400 and PEG 200 by using different concentrations of optimised plasticizer i.e PEG 200 like 15%, 20%, 25%, 30% and 35% at different temperatures like 55˚c, 60˚c, 65˚c, 70˚c and finally by different base levels of film casting machine i.e 0.5, 1, 1.5, 2 mm by solvent casting method. The formulations were characterized for weight variation, thickness, folding endurance, disintegration time, content uniformity and in vitro drug release studies and drug polymer interactions were studied by using Fourier transform infrared spectroscopy. Results: The films prepared with 8% sodium alginate with plasticizer PEG 200 at 30% at 60˚c with 0.5mm base level dispersion shown the best results compared to different polymers and conditions by obtaining 97% of drug release. Conclusion: Based on the evaluation of different parameters it was concluded that formulation of Rizatriptan benzoate oral dispersible films was successfully done and F12 shows 97.5% drug release at 60˚c temperature.

Keywords: Rizatriptan benzoate, oral dispersible films, N-dibutyl phthalate, PEG200, PEG 400, Propylene Glycol.

INTRODUCTION

The oral cavity has been investigated as a site for drug delivery for a long period of time. In 1847 Sombrero found that nitroglycerine was absorbed from the oral cavity[1]. Since then various active substances have been investigated for local or systemic use[2]. Drug delivery through the oral cavity offers many advantages. The oral mucosa is conveniently and easily accessible and therefore allows uncomplicated application of dosage forms. Furthermore, the oral mucosa is robust against local stress or damage and shows fast cellular recovery after such incidents[3]. Oral dispersible film is a new drug delivery system. Oral dispersible film has gained popularity due to its availability in various size and shape**.** Oral dispersible films are intended to disintegrate or dissolve within seconds. They offer advantages such as administration without water, ease of swallowing, rapid onset of action and convenience of dosing. For fast dissolving active pharmaceutical ingredients, absorption is possible through the oral mucosa and may improve bioavailability. Oral dispersible film is an ideal dosage form for the patients who difficult to swallow the tablet. Due to its ease of usage and high acceptability, fast dissolving films were formulated in the present study.

Rizatriptan benzoate was selected as a model drug for the study which is an anti migraine drug, a selective 5 Hydroxy tryptamine $(5\text{-HT})_{1B/1D}$ agonist and used for the acute treatment of migraine attacks with or without aura. Rizatriptan benzoate has oral bioavailability of 45% due to hepatic metabolism. Rizatriptan benzoate oral dispersible film is alternative to oral dispersible tablets to eliminate the patients fear of chocking and overcome the patients impediments. This formulation was optimised by taking so many criteria i.e by studying the effect of different hydrophilic polymers (Sodium CMC, HPMC and Sodium alginate), plasticizers (Propylene glycol, N-dibutyl phthalate, PEG 400 and PEG 200) by varying the concentrations (15%, 20%, 25%, 30% and 35%) with wider temperature ranges (55˚c, 60˚c, 65˚c, 70˚c) at base levels (0.5mm, 1mm, 1.5mm, 2 mm) on film casting machines it can be effectively used in case of migraine patients as it can be administered without the intake of water.

MATERIALS AND METHOD

Rizatriptan benzoate was a gift sample from Natco pharma, Hyderabad. PEG 200, PEG 400 were obtained from Loba chemic pvt., Limited. Hydroxy propyl methyl cellulose, sodium alginate were obtained from Himedia, Mumbai. Carboxy methyl cellulose sodium 200-300 cps and N-dibutyl pthalate were supplied from S.D. Fine-Chem Ltd, Mumbai. Potassium chloride, sodium hydroxide and potassium di ortho phosphate were purchased from Qualigens, Mumbai.

Construction of calibration curve

100 mg of Rizatriptan benzoate was dissolved in 6.8 phosphate buffer in a 100 ml volumetric flask and the solution was made up to the volume with 6.8 phosphate buffer to prepare a standard solution. The standard solution of Rizatriptan benzoate was subsequently diluted with 6.8 phosphate buffer to obtain a series of dilutions containing 2, 4, 6, 8 and 10 µg of Rizatriptan benzoate per ml of solution. The absorbance of the above dilutions was measured in ELICO Double beam SL 210 Uv-visible Spectrophotometer at 227 nm using in 6.8 phosphate buffer as blank. The absorbance values were plotted against concentrations of Rizatriptan benzoate as shown in Figure 1.

Solvent Casting method for the preparation of oral dispersible films

By using different hydrophilic polymers

Films were prepared by using by solvent casting method with the help of film casting machine. The films were prepared by dissolving the rizatriptan benzoate in small quantity of water, to this add required quantity of plasticizer propylene glycol with the specified amount of hydrophilic polymers like Sodium CMC (8%), HPMC (5%) and sodium alginate (8%) which were weighed and dissolved separately in little amount of water and the composition is shown in the Table 1. Solution was kept aside for 10 minutes for swelling of the polymer. Drug and Propylene glycol were also added to the polymer solution. Finally make up the volume up to 25ml with water. The solution was mixed by using magnetic stirrer. The viscous solution was degassed under vacuum; the resulting bubble free solution was poured onto film machine of size 12 cm×10 cm. The machine was kept at a temperature of 60˚c for 10-15 minutes for drying. After drying the film was removed from machine and preserved.

By using different plasticizers and concentrations

Sodium alginate 8% was proved to be a best polymer when compared to polymers employed and results were shown in table 12. The formulation was then optimised with different plasticizers like N-dibutyl phthalate, PEG 200 and PEG 400 from which PEG 200 was selected as a plasticizer based on the results shown in table 13. Then PEG 200 was composed by varying concentrations from 15%, 20%, 25%, 30%, 35% and results were shown in table 14 by comparing with sodium alginate formulated with propylene glycol as a plasticizer. The formulation was shown in table 2 and 3.

By using different temperatures and base level polymeric dispersion

The PEG 200 at 30% was selected and this drug polymeric solution was optimised with different temperatures like 55˚c, 60˚c, 65˚c and 70˚c. The results were shown in table 15 and also with different base level polymeric dispersions like 0.5, 1, 1.5 and 2mm and results were shown in table 16. The formulation was shown in table 4 and 5.

Fourier Transform Infrared spectroscopy

The FTIR was studied on Pure drug rizatriptan benzoate, sodium alginate and their physical mixture of rizatriptan benzoate under dry conditions the transition minima of spectra obtain with this one polymer were compared and the presence of additional peaks corresponding to the functional groups was noted. [4]

Evaluation

Weight variation of the film

Two square inch film was cut at five different places in the casted film. The weight of each film strip was taken and the average weight variation was calculated. [4]

Thickness of the film

The thickness of the film was performed by screw gauge at five different positions of the two square inch film and the average thickness was calculated. [5]

Folding endurance

The folding endurance is expressed as the number of folds (number of times of film is folded at the same plain) required to break the specimen or develop visible cracks. This gives an indication of brittleness of the film. A small strip of 2 square cm was subjected to this test by folding the film at the same plane repeatedly several times until a visible crack was observed. [6]

Disintegration time

Test was performed using disintegration test apparatus. Two square inch film was placed in the basket, raised and lowered it in such a manner that the complete up and down movement at a rate equivalent to thirty times a minute. Time required by the film, when no traces of film remain above the gauge was noted. Test was performed in triplicate. [7]

Content uniformity

The films were tested for content uniformity. Films of size two square inch was cut, placed in 100 ml volumetric flask and dissolved in water, volume was made up to 100 ml with water. Solution was suitably diluted. The absorbance of the solution was measured at 227 nm. [8]

In vitro dissolution studies

Dissolution study was carried out using USP apparatus 5 (paddle over a disc type 5) with 250ml of pH 6.8 phosphate buffer, as dissolution medium maintained at 37 ± 0.5˚c. Medium was stirred at 100 rpm for a period of 10minutes. A sample of films 2×2 cm equivalent to 10 mg of Rizatriptan benzoate was used. Samples were withdrawn at every 2 minutes interval, replacing the same amount with the fresh medium. Samples were suitable diluted with buffer and analyzed for the drug content at 227nm using ELICO Double beam SL 210 UV-visible Spectrophotometer. [9]

RESULTS AND DISCUSSION

The influence of different polymers, plasticizers, and concentration of plasticizers, processing temperatures and at different base levels of polymer dispersion during preparation on performance of oral dispersible films were studied, along with physical characteristics of the film.

FTIR

The FTIR spectra revealed that the pure drug exhibited peak at wave number 793.96 and the physical mixture of Rizatriptan benzoate and sodium alginate polymer also exhibited highest peak at wave number 793.94 which indicates that there was no interaction between drug and polymer. It was shown in the figure 2, 3 and 4.

Weight variation of the film

The weight of each film strip was taken and the average weight variation was calculated and it was found to be from 39.06 mg to 52.9mg. It was shown in the table 7 to11.

Thickness of the film

The thickness of the film was performed by screw gauge at five different positions of the two square inch film and the average thickness was calculated and it was found to be in the range of 0.08 to 0.43 mm. It was shown in the table 7 to11.

Table 1: Composition of Rizatriptan benzoate oral dispersible films formulated with different polymers

S.No	Ingredients	Quantity for 12.10 cm^2 films		
		F1	**F2**	**F3**
01	Rizatriptan benzoate (mg)	300	300	300
02	Sodium Carboxyl methyl cellulose (mg)	2000	--	--
03	Hydroxy propyl methyl cellulose (mg)	--	1250	--
04	Sodium alginate (mg)	--	--	2000
05	Propylene glycol(ml)	0.29	0.29	0.29
06	Distilled water up to(ml)	25	25	25

Table 2: Composition of Rizatriptan benzoate oral dispersible films formulated with different plasticizers

S.No	Ingredients	Ingredients for 12.10 cm^2 films			
		F3	**F4**	**F5**	**F6**
01	Rizatriptan benzoate (mg)	300	300	300	300
02	Sodium alginate (mg)	2000	2000	2000	2000
03	Propylene glycol (ml)	0.29	--	--	--
04	N- Dibutyl phthalate (ml)	--	0.57	--	--
05	PEG 400 (ml)	--	--	0.52	--
06	PEG 200(ml)	--	--	--	5.3
07	Distilled water up to(ml)	25	25	25	25

Table 3: Composition of Rizatriptan benzoate oral dispersible films prepared with different concentrations of plasticizer

S.No	Ingredients	F6	F7	F8	F9	F10
01	Rizatriptan benzoate (mg)	300	300	300	300	300
02	8% Sodium alginate (mg)	2000	2000	2000	2000	2000
03	PEG 200 (30%)	0.53	--	--	--	--
03	PEG 200 (15%)	--	0.26	--	--	--
04	PEG 200 (20%)	--	--	0.35	--	--
05	PEG 200 (25%)	--	--	--	0.44	--
07	PEG 200 (35%)	--	--	--	--	0.62
08	Distilled water up to (ml)	25	25	25	25	25

Table 4: Composition of Rizatriptan benzoate oral dispersible films processed at different temperatures

S.No	Ingredients	Quantity for 12.10 cm^2 films			
		F11	**F12**	**F13**	**F14**
01	Rizatriptan benzoate (mg)	300	300	300	300
02	8%Sodium alginate (mg)	2000	2000	2000	2000
03	30 % PEG 200 (ml)	0.53	0.53	0.53	0.53
04	Distilled water up to (ml)	25	25	25	25
04	Processing temperature(˚C)	55	60	65	70

Table 5: Composition of Rizatriptan benzoate oral dispersible films processed with different base levels of polymer dispersion

S.No	Ingredients	Quantity for 12.10 cm^2 films			
		F12	**F15**	**F16**	**F17**
01	Rizatriptan benzoate (mg)	300	300	300	300
02	8%Sodium alginate (mg)	2000	2000	2000	2000
03	30% PEG 200 (ml)	0.523	0.53	0.53	0.53
04	Distilled water up to (ml)	25	25	25	25
05	Base level in mm	0.5	1.00	1.50	2.00

Calibration curve of Rizatriptan benzoate

Table 6: Calibration curve for the estimation of Rizatriptan benzoate in PH 6.8 phosphate buffer

Concentration (µg/ml)	**Absorbance at 227nm x±S.D**
2	0.021±0.02
4	0.058±0.01
6	0.09±0.03
8	0.117±0.02
10	0.137±0.02
12	0.178±0.04

Table 7: Physical characteristics of oral dispersible films formulated with different polymers

Parameters	F1	F2	F3
Weight variation	43.94±1.5	39.06±2	47.36±1.72
Thickness	0.08±0.01	0.092±0.005	0.086±0.094
Folding endurance	151 ± 2	114 ±1.2	176 ± 2.4
Content Uniformity	99.23 ±0.006	99.18 ±0.006	99.35 ± 0.008
Disintegration time	32± 2.86	30 ± 2.14	34 ± 2.7

Table 8: Physical characteristics of Rizatriptan benzoate oral dispersible films formulated with different plasticizers

PARAMETER	F3	F4	F5	F6
Weight variation (mg)	47.36 ± 2	51.56±2.43	45.76 ±2	42.17±2
Thickness (mm)	0.086±0.01	0.13 ±0.25	0.15 ±0.12	0.12±0.04
Folding endurance	213 ± 4	208 ± 4	225 ± 2	234 ± 3
Content uniformity	81.1±1.5	76.6±1.2	83.9±1.8	85.91±2.0
Disintegration time (sec)	34±2	30±1	32±2.1	29±2.7

Table 9: Physical characteristics of Rizatriptan benzoate oral dispersible films by using different concentrations of plasticizers

Parameters	F6	F7	F8	F9	F10
Weight Variation (mg)	43.82 ± 4.56	45.7±1.8	40.44±2	42.17±2	40.4±1.5
Thickness (mm)	0.12 ± 0.01	0.10 ± 0.02	0.14 ±0.04	0.14 ±0.01	0.12 ± 0.02
Folding endurance	212 ± 2	208 ±2	201 ±1.5	227 ±3	216 ± 1
Content uniformity	79±0.12	84±2.3	88±1.12	82±1.8	84±2.4
Disintegration (sec)	27±2	30±2.5	30±1.8	34±2.1	34.7±1.5

Table 10: Evaluation parameters of Rizatriptan benzoate oral dispersible films formulated by PEG 200 at different temperatures

Parameter	F11	F12	F13	F14
Weight variation (mg)	51.38± 1.25	51.45±1.9	48.28±1.72	52.9±2.1
Thickness (mm)	0.13±0.01	0.16±0.003	0.13±0.04	0.14±0.03
Folding endurance	219±3	202±2	226±4	214±2.1
Content uniformity	90.3±1.9	85±2	88±2	82±1.4
Disintegration (sec)	25±3	21±2	17±2.2	29±1

Table 11: Evaluation parameters of Rizatriptan benzoate oral dispersible films formulated by using different base levels of polymeric dispersions

S.No	PARAMETER	F12	F15	F16	F17
01	Weight variation (mg)	20.38±0.05	40.06±1.2	52.7 ± 1.3	31.16 ± 1.8
02	Thickness (mm)	42.83±0.07	0.43 ± 0.02	0.12 ± 0.08	0.18 ± 0.03
03	Folding endurance	60.71±0.08	196±2.3	205±2.1	212±1.7
04	Content uniformity	91.04±0.02	83±1.8	98.±1.5	86 ±2
05	Disintegration time (sec)	97.5±0.04	26 ± 2.4	20 ± 2.6	29.2± 2

Table 12: Invitro release data of Rizatriptan benzoate oral dispersible formulated by using different types of polymers

Time (min)	Cumulative % Rizatriptan benzoate drug release (mean ± S.D)		
	F1	**F2**	**F3**
0	0	0	0
2	17.26±0.02	35.66±0.06	38.92±0.05
4	29.02±0.04	39.17±0.09	59.26±0.07
6	33.58±0.07	61.28±0.07	71.49±0.02
8	38.20±0.1	71.76±0.03	90.7±0.03

Table 13: Invitro release data of Rizatriptan benzoate oral dispersible films formulated with different plasticizers

Time (min)	Cumulative % Rizatriptan benzoate drug release (mean ± S.D)			
	F3	**F4**	**F5**	**F6**
0	0	0	0	0
2	38.92±0.05	17.83 ± 0.06	20.54 ± 0.7	24.72 ± 0.06
4	59.26±0.07	24.04±0.04	33.82 ± 0.03	29.57 ± 0.09
6	71.49±0.02	29.64±0.08	42.94 ± 0.06	66.99 ± 0.03
8	90.7±0.03	47.34 ± 0.03	69.06 ± 0.01	87.78 ± 0.07
10	97±0.02	97.53 ± 0.01	87.34 ± 0.09	94.93 ± 0.05

Table 14: In vitro release data of Rizatriptan benzoate oral dispersible films formulated by different concentrations of PEG 200 with sodium alginate

Time (min)	Cumulative % of Rizatriptan benzoate dissolved (mean±S.D)				
	F6	**F7**	**F8**	**F9**	**F10**
0	0	0	0	0	0
2	20.90±0.06	36 ± 0.05	57.11±0.03	24.72 ± 0.2	23.08± 0.05
4	23.48±0.04	46.08 ± 0.03	61.05±0.09	29.57±0.05	25.54± 0.07
6	33.61±0.08	51.08 ± 0.02	68.29±0.04	66.99±0.01	44.57± 0.03
8	43.71±0.03	58.07 ± 0.02	75.50±0.06	87.78±0.09	70.49± 0.02
10	66.71±0.01	65.20 ± 0.01	83.39±0.04	94.93±0.03	84.82± 0.07

Table 15: In vitro release data of Rizatriptan benzoate oral dispersible films formulated by using PEG 200 at different temperatures

Time (min)	Cumulative % Rizatriptan benzoate drug release (mean ± sd)			
	F11	**F12**	**F13**	**F14**
0	0	0	0	0
2	47.13 ±0.03	20.38 ±0.05	62.77 ±0.09	21.91 ±0.02
4	57.12 ±0.04	42.83 ±0.07	69.41 ±0.01	44.06 ±0.04
6	63.45 ±0.01	60.71 ±0.08	77.14 ±0.06	46.76 ±0.05
8	84.14 ±0.06	91.04 ±0.02	82.91 ±0.09	62.21 ±0.05
10	97.34 ±0.05	97.5 ±0.04	93.63 ±0.07	82.72 ±0.07

Table 16: In vitro release data of Rizatriptan benzoate oral dispersible films formulated by using different base levels of polymer dispersion

Time (min)	% cumulative Rizatriptan benzoate drug release (mean ±sd)			
	F12	**F15**	**F16**	**F17**
0	0	0	0	0
2	20.38 ±0.05	23.8 ±0.09	26.0 ±0.07	39.49 ±0.05
4	42.83 ±0.07	31.65 ±0.07	28.37 ±0.03	41.97 ±0.06
6	60.71 ±0.08	55.38 ±0.03	53.13 ±0.06	56.95 ±0.08
8	91.04 ±0.02	65.0 ±0.05	77.73 ±0.04	64.02 ±0.03
10	97.5 ±0.04	77.54 ±0.03	86.6 ±0.02	77.34 ±0.08

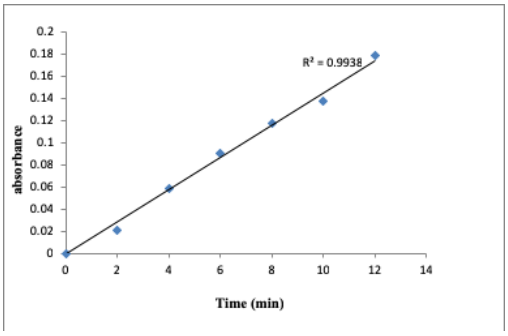

Figure 1: Calibration curve for the estimation of Rizatriptan benzoate at 227nm

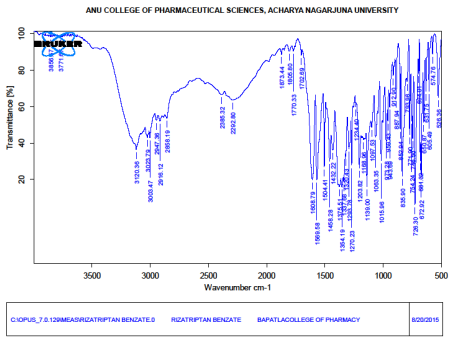

Figure 2: FTIR spectra for pure drug Rizatriptan Benzoate

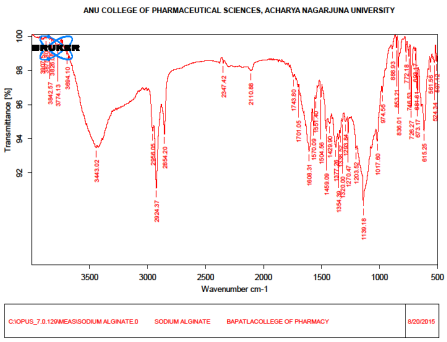

Figure 3: FTIR spectra for sodium alginate

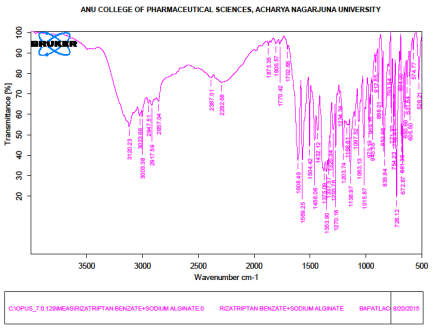

Figure 4: FTIR spectra for physical mixture of Rizatriptan benzoate and sodium alginate.

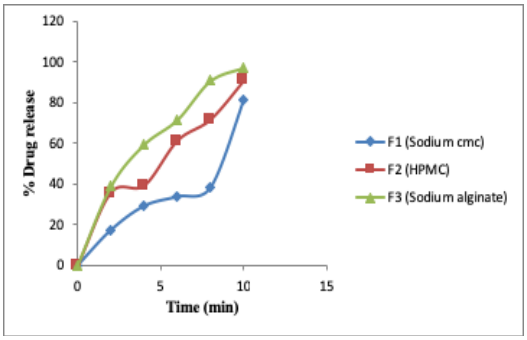

Figure 5: In vitro release plot of Rizatriptan benzoate oral dispersible films formulated by using different types of polymers

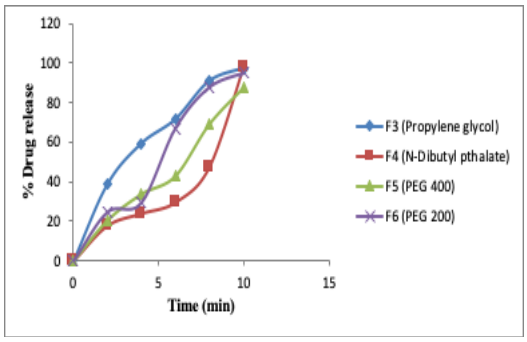

Figure 6: In vitro release plot of Rizatriptan benzoate oral dispersible films formulated by using different plasticizers.

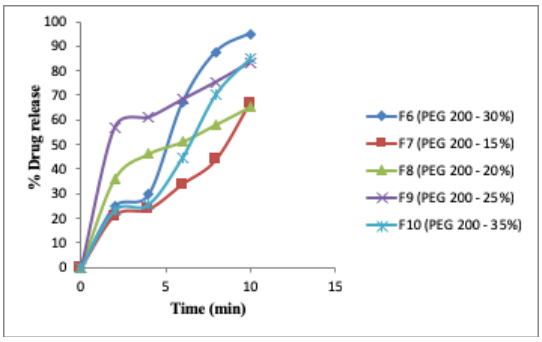

Figure 7: In vitro release plot of Rizatriptan benzoate oral dispersible films formulated by using different concentrations of PEG 200

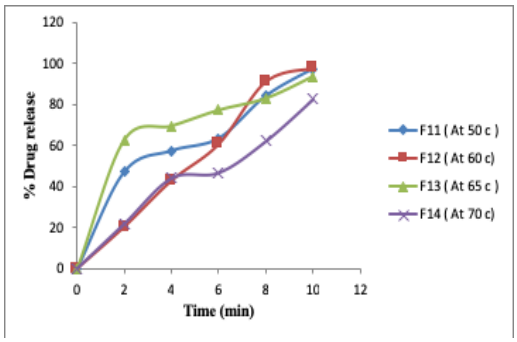

Figure 8: In vitro release plot of Rizatriptan benzoate oral dispersible films formulated by using PEG 200 at different temperatures

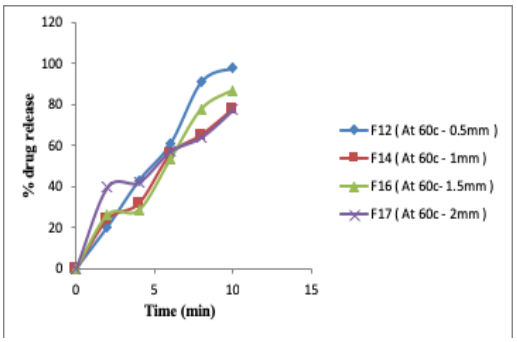

Figure 9: In vitro release data of Rizatriptan benzoate oral dispersible films formulated by using different base levels of polymer dispersion.

Folding endurance

A small strip of 2 square cm was subjected to this test by folding the film at the same plane repeatedly several times until a visible crack was observed and it was found to be in the range of 60.71 to 226. It was shown in the table 7 to11.

Disintegration time

Two square inch film was placed in the basket, raised and lowered it in such a manner that the complete up and down movement at a rate equivalent to thirty times a minute. Time required by the film, when no traces of film remain above the gauge was noted. Test was performed in triplicate and it was found to be in the range of 17 to 34.7 seconds. It was shown the table 7 to11.

Content uniformity

The films were tested for content uniformity and it was found to be in the range of 79 to 98%. It was shown in the table 7 to11.

***In vitro* dissolution studies**

A sample of films 2×2 cm equivalent to 10 mg of Rizatriptan benzoate was used. Samples were withdrawn at every 2 min interval, replacing the same amount with the fresh medium. Samples were suitable diluted with buffer and analyzed for the drug content at 227nm using ELICO Double beam SL 210 Uv-visible Spectrophotometer and it was found to be in the range of 65.20% to 97.5%. It was shown on the table 12 and 14. The optimised composition of the film prepared with different base levels like 0.5mm, 1mm,1.5mm and 2mm was studied and it was shown that preparation with 0.5mm proved as best formula with 97.5% drug release in the table 16.

Effect of polymer

The influence of polymer on physical characteristics and performance of film was studied with three different polymers like sodium alginate, sodium CMC and HPMC. From which it was shown that the films prepared with sodium alginate showed optimised drug release 97% at 10mintues. Based on the dissolution rate, the polymers can be ranked as

Sodium alginate > HPMC > sodium CMC.

It was shown in table 12 and figure 5.

Effect of plasticizers

The effect on the performance of film was studied with different plasticizers. The plasticizers like propylene glycol, N-dibutyl phthalate, PEG200 and PEG400. The films prepared with the plasticizers PEG 200 offered highest drug release compared with other plasticizers and were selected by optimising the concentration of PEG 200 with 30% when compared to 15%, 20%, 25% and 35%. Based on the dissolution rate, the plasticizers can be ranked as

PEG 200 > Propylene glycol > N – dibutyl phthalate > PEG 400.

It was shown in table 13&14 and figures 6&7.

Effect of temperature and base level polymer dispersion:

The mechanical strength, percent elongation, drug release and other performance parameters are also influenced by the processing temperature. To study the influence of temperature on physical characteristics and performance of film, the films were processed at four different temperatures 55°C, 60°C, 65°C, and 70°C. The films prepared at 60˚c offered highest drug release observed by adjusting the different base level polymer dispersions at 0.5mm, 1mm, 1.5mm and 2mm.the difference in the dissolution rate may be due to difference in thickness of film.

The films prepared at 0.5mm base level dispersion optimised drug release. It was shown in table 15&16 and figure 8&9.

CONCLUSION

The present study demonstrated the Preparation , optimisation and evaluation of Rizatriptan benzoate oral dispersible films and The FTIR spectra revealed that there was no interaction between drug and polymer. The formulation were also evaluated for its Weight variation , Thickness , Folding endurance, Disintegration time showed the optimised results. The films were tested for content uniformity and it was found to be in the range of 79 to 98%..From above results, Formulation (F12) which consists of 8% sodium alginate as polymer, PEG 200 of 30% concentration as plasticizer at 60℃ working temperature of 0.5mm base level polymeric dispersion showed the drug release of 97.5 % and it was considered as an optimised formulation.

ABBREVIATIONS

FTIR = Fourier transform infrared spectroscopy
PEG = Polyethylene glycol
UV = Ultraviolet
SD = Standard deviation
F = Formulation
Sec = seconds
Mg = Milligrams
Sodium CMC = carboxy methyl cellulose sodium

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