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Original Research Article

Development of fast release tablet of talinolol using fourth generation carrier of solid dispersion technique

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ABSTRACT

Talinolol is a beta1-selective adreno receptor antagonist well known for its Cardio protective and antihypertensive activity. Talinolol is a beta blocker. In biopharmaceutical classification system the drugs which come under class II are characterized by more membrane permeability, less dissolution rate. Talinolol is a poor aqueous solubility drug leads to poor bioavailability. So, the aimed of this study was to develop immediate release tablet of talinolol by solid dispersions technique using poloxamer 407 as a carrier. Poloxamer 407 is a hydrophilic synthetic block copolymer widely used as a solubility enhancer. Basically there are three methods used for solid dispersion. Melting or fusion method solvent evaporation method. Melting solvent method. Solvent Evaporation Method In this method a suitable solvent is selected which can capable of solubilizing both drug and hydrophilic carrier. The solvent evaporation technique is one of the most commonly used methods to prepare polymeric nanoparticles, more specifically drug-loaded polymeric systems, for pharmaceutical formulations. The prepared solid dispersions were evaluated for production yield percent, drug content, solubility, FTIR, and DSC study analysis. The prepared formulation of Talinolol with P407 in the ratio of 1:5 gave highest dissolution rate of 75.28% at 30min.So it can be concluded that the combination of solid dispersion technology as well as using superdisintergrants an encouraging and effective technique to prepare efficient fast dissolving tablets of Talinolol.The outcome of this investigation presents poloxamer 407 solid dispersion mediated fast dissolving tablets successfully resolve problem of slow rate of dissolution of talinolol.

1. Introduction

The most of the newly discovered drugs are comes under BCS class II category. But the dissolution is acting as a rate-limiting step for poorly aqueous soluble class II drugs. Hence, there is a need to increase the bioavailability of poorly water-soluble BCS class II drugs.[1]

Talinolol was purchased from Manus Aktteva Biopharma Ltd, Ahmedabad, Gujarat, India Talinolol is a beta blocker Adrenergic beta-antagonists are used for treatment of hypertension, cardiac arrhythmias, angina pectoris, glaucoma, migraine headaches, and anxiety. Drugs that bind to but do not activate beta-adrenergic receptors thereby blocking the actions of beta-adrenergic agonists.

In this regard, there are several methods have been reported for enhancement of dissolution rate of poorly aqueous soluble drugs. Among the different methods, micronization technique is the most common method to decrease size of the drug particle. But this method is limited by their agglomeration of particles which decreases the surface area and dissolution of the particles.[2] Solid dispersion (SD) technology can be used as one of the best and simple, easily scalable technology to improve the dissolution rate of poorly aqueous soluble drugs.[3] In

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SD technology, the drug particle size is reduced almost to a molecular level, and wettability of the drug is remarkably increased.[4] The solid dispersions (SD) consist of a hydrophilic carrier in which molecular dispersion of drug occurs. The different types of carriers is used for enhance the solubility of drugs. A drug carrier or drug vehicle is a substrate used in the process of drug delivery which serves to improve the selectivity, effectiveness, solubility or safety of drug administration.

Moreover, in a recent investigation, *wandeep bill et al., 2018, Monica Mao et al., 2017* investigated on preparation and evaluation of simvastatin surface solid dispersions has done the work on improving the solubility of Glimepride drug by using solid dispersion techniques. Poloxamer 188 and Poloxamer 407 were employed as carriers for preparing solid dispersions. The SDs which gave greater dissolution rate were formulated into tablets with superdisintegrants. In the tablet formulations the tablets having 5% croscarmellose sodium exhibits lesser disintegration time and greater dissolution rate.[5,6]

Prasad D et al., 2011, Prasanthi et al., 2013 formulated the lacidipine SDs with PEG 4000, PEG 6000, hydroxy ethyl cellulose and dextrin. were made an attempt to enhance the drug release rate of glipizide using solid dispersion technique. In this study they utilized P407 and P 188 as water soluble carriers and kneading technique was employed for preparation. The study revealed that the prepared solid dispersions had greater dissolution rate compared with pure glipizide.[7]

Newa M et al., 2008 investigated the dissolution of ibuprofen. This was performed using solid dispersion with the poloxamer 407. The greater dissolution rate was achieved by the preparation of itssolid dispersions and characterized by DSC, SEM, FT-IR. It was evaluated for its in-vitro ibuprofen release and solubility.[8]

Yusuke Shibata et al., 2008 formulated a solid dispersion of indomethacin. A twin-extruder of the kneader was utilized for the formulation along with crospovidone. The solid dispersion particles of indomethacin had an improved solubility.[9]

Alazar N.Ghebremeskel et al., 2007 investigated the effect of surfactants in the formulation of solid dispersion. The study concluded, using surfactants in solid dispersion can increase the drug release character of poorly soluble drugs.[10]

S.T. Prajapati et al., 2007 carried out study to enhance dissolution properties of Carbamezepine by solid dispersion method using PVP K 30, PEG 4000 & 6000.[11]

The present research work was to prepare poloxamer 407 mediated solid dispersion based fast release orally administered tablet dosage form of Talinolol for improving its solubility, dissolution characteristics, and subsequently the bioavailability. Poloxamer 407 was employed as to provide altered solubility and dissolution properties. The prepared solid dispersion of Talinolol was evaluated by Differential scanning calorimetry spectroscopy, drug-excipient compatibility, and excipient interference analysis. Further, the developed fast dissolving tablets were tested for hardness, friability, average weight, weight variation, content uniformity, and disintegration test. The dissolution rate investigation of Talinolol from fast dissolving tablets developed by poloxamer 407 mediated solid dispersion was further tested, and obtained data were fitted into in vitro kinetic models such as zero order, first order, Hixon-Crowell and Higuchi model.

2. Materials and Methods

2.1. Materials

Talinolol was purchased from Manus Aktteva Biopharma Ltd, Ahmedabad, Gujarat, India ethanol market are India Glycols, Bajaj Hindusthan Sugar, All other chemicals were of analytical grade and were used without further purification. The disintegrants, microcrystalline cellulose (Avicel PH-102) and croscarmellose sodium (Ac-Di-Sol) were sourced from FMC Biopolymer, PA, USA. Sodium starch glycolate (Primojel) was obtained from DFE Pharma, Goch, Germany. Crospovidone (Kollidon CL-SF) was obtained from BASF, Ludwigshafen, Germany. Magnesium stearate was purchased from Productos Metalest, Spain.

2.2. Methods

2.2.1. Solubility study of talinolol

Solubility measurements were performed according to method reported by Higuchi and Connors.[12] Talinolol drug was added to 10 ml volumetric flask containing 10%, 20%, 30%, 40% aqueous solution (ethanol, Acetone, Methanol) of carriers. The samples were allowed to shake for 48 h at 25 ± 1 °C. The solutions were filtered whatmann filter paper (0.45 μ). After 48 h, the Talinolol concentration was determined spectrophotometrically at 285 nm using Shimadzu UV 1800, Japan.

2.2.2. Precompression parameters

The prepared powder blend for core tablets was evaluated for various pre-compression parameters like angle of repose, bulk and tapped density, Carr's compressibility index and Hausner's ratio.

The *particle size* distribution of granules for tablet compression could be expressed as a function of median particle size and standard deviation with a logarithmic normal distribution. The physical properties of granules for tablet compression and tablets were significantly affected by this factor.[12]

Angle of repose has been used as indirect method of quantifying powder flow ability, because their relationship with interparticle cohesion. This is the angle θ as defined by the equation 1;

Tan θ = h/ r ——- (1)

where θ = angle of repose

h and r are the height and radius of the powder cone

Powder with angle of repose greater than 50° have unsatisfactory flow property, whereas minimum angle of repose close to 25° correspond to very good flow property.[13]

For determining *bulk density* 10 gm powder was taken and transferred into graduated 100 ml measuring cylinder. The volume occupied was determined. By using the formula the bulk density was calculated.[14]

Bulk density of powder is calculated by using the formula:

p_b= M / V_____(2)

where:

pb= bulk density

M = weight of powder and

V = volume of powder**.**

For determining *tape density* 10 gm powder was taken and transferred into graduated 100 ml measuring cylinder. The volume occupied after tapping (~ 1000) was determined. By using the formula the tape density was calculated.

Tape density of powder is calculated by using the formula;

P_t = M / V_t ———-(3)

where:

P_t = Tapped density

M = weight of powder, and

V_t =Minimum volume occupied after tapping

A simple test has been developed to evaluate the flow ability of a powder by comparing the bulk density and tape density of a powder and the rate at which it packed down. A useful empirical guide is given by *Carr's compressibility index.*[15]

Carr's index (%) = (tapped density –bulk density) / tapped×100 ———(4)

2.2.3. Method to prepare solid dispersions

In solvent evaporation method, solvents which were selected to dissolve the drug and hydrophilic carrier are ethanol. Five different ratios of drug and polymer were utilized. The employed ratios were 1:1, 1:2, 1:3, 1:4, 1:5, 1:6 for the formulation of solid dispersions of talinolol. The subsequent amount of talinolol and poloxamer 407 was dissolved in the required volume 100 ml of ethanol taken in a conical flask. After getting a completely dissolved clear polymeric solution, the above polymeric solution was stirred on magnetic stirrer (Patel Scientific Instruments Pvt. Ltd. Ahmedabad- 382415, India.) at 300 rpm for 45 minute. and compact mass was obtained. The prepared solid dispersion was dried in trey dryer (Refricon HVAC Systems) at 40°C for 30 min. The dried dispersions were then pulverized and which was then sifted through sieve no 60 and packed in airtight glass bottle.[16,17]

2.2.4. Selection of drug carrier ratio

The development of solid dispersion of talinolol using poloxamer 407 for the selection of molar ratio 1:1, 1:2, 1:3, 1:4, 1:5, 1:6 was employed and selected based on their dissolution profile. Next, talinolol solid dispersion was fabricated employing different ratio separately by employing the solvent evaporation method.[16] The solid dispersion powder blend was then hand filled in size "0" hard gelatin capsules (Bioven Ingredients, Gretaer Noida, India). Each of the solid dispersion gelatin capsules was subjected to an *in-vitro* dissolution rate study. The USP Type I dissolution apparatus (Electro lab, Hyderabad, India) were used to perform the in vitro dissolution studies at 50 rpm rotation speed, with 37 ± 0.5°C temperature.

The dissolution studies of fabricated solid dispersion granules were perfomred in 900 mL of phosphate buffer pH 6.8. Moreover, 2 mL aliquots of samples were withdrawn at different time intermissions (5, 10, 15, 30, 45, and 60 min.) and exchanged with the same amount of freshly prepared medium to retain sink conditions. The 0.45 μm membrane filter (Millipore, USA) was employed for filtration of samples and analysis of these samples performed with the help of ultraviolet spectrophotometer at 267 nm.

2.2.5. Drug content of prepared solid dispersion

The uniformity of drug content was performed for the prepared talinolol solid dispersions. The SDs equivalent to 20 mg of talinolol was taken from each batch, and it was then analyzed for uniformity of drug content in a 100 ml volumetric flask, an accurately weighed quantity of talinolol SDs was taken and dissolved with approx 10 ml of ethanol and filtration was done by whatmann filter paper grade 41. The amount of drug present in the SD was analyzed using a (Shimadzu model 1800, Japan.) UV-visible spectrophotometer at 267 nm.[18,19]

$$Theoretical amount of drug in solid dispersion$$

2.2.6. Fourier transform infrared radiation Study (FT-IR

FT-IR analysis was carried out for pure drug and prepared solid dispersion using KBr pellet and the spectra scanned on the wavelength range 400-4000 cm^{-1} method on FT-IR spectrophotometer (Shimadzu model 1800, Japan.,) in order to ascertain compatibility between talinolol and poloxamer 407. Samples of talinolol, physical mixtures and solid dispersions were ground and mixed thoroughly with potassium bromide at a 1:5 sample/KBr ratio. The KBr discs were prepared by compressing the powders at a pressure of 5 T for 5 min in a hydraulic press. The scanning range was 40 to 4000 cm–1 and the resolution was 4 cm–1

2.2.7. Differential scanning calorimetry (DSC)

All dynamic DSC studies of talinolol and solid dispersion of talinolol were carried out on DuPont thermal analyzer with 2010 DSC module. The instrument was calibrated using

Table 1: Preparation of Talinolol solid dispersions with Poloxamer 407

S. No	Batch Code	Drug: Carrier	Talinolol (Mg)	Poloxamer(407) (Mg)
1	F1	1:1	20	20
2	F2	1:2	20	40
3	F3	1:3	20	60
4	F4	1:4	20	80
5	F5	1:5	20	100
6	F6	1:6	20	120

high purity indium metal as standard. The dynamic scans were taken in nitrogen atmosphere at the heating rate of 10ºC/min heating rate of 10ºC/min.

2.2.8. Preparation of talinolol fast release tablet

The SD formulation which showed highest drug release was formulated into tablets using various proportions as super disintegrates. The SDs equivalent to 20mg of talinolol was used, and the formulations of tablets are indicated in Table 1. The SDs equivalent to 20mg are mixed thoroughly with all excipients and compressed (direct compression method) into tablets with cadmach single (Cadmach Machinery Co. Pvt. Ltd. - Cadmach Single Sided Rotary Tablet Press in WORLI, Mumbai India) punch tablet machine.[20]

2.2.9. Post compression parameters

2.2.9.1. Friability. In order to perform uniformity of weight, 33 Tablets were randomly selected, weighed (Weighing India Corporation) and the tablets weighed individually were compared with the average weight of the tablet. Roche friabilator (HMK-1601 Tablet Friability Tester) (Roche Company, Switzerland) was used to perform the friability test. Twenty tablets were selected and subjected to 100 revolutions. The speed is adjusted to 25 rotations per min and rotated for 4 min. The tablets were wiped with a clean cloth and weighed again. The friability was calculated as the percentage loss which should not exceed 1%.[21]

$$\%=F\{1-(w_t / w)\}\times 100 \quad \text{.....(6)}$$

Where, % F = % friability W = Initial weight of tablets, W_t = weight of tablets after 100 revolution.

2.2.9.2. Hardness . Place the sample tablet in the vertically holding edges of the anvil of Monsanto Hardness Tester (Vinsyst Technologies. model name VMT) Adjust the pointer at zero position on the scale by rotating the screw in forward direction. Now rotate the screw till break point of the tester. The breakage of tablet shows hardness on the scale. Repeat the procedure 8-10 times for average reading. Than Record the observation.[22]

3. Disintegration Time

For determining disintegration time water medium were used, set speed: 30cycles/minute and temperature: 37±0.5°c. One tablet was added into each of the 6 tubes of the apparatus and the assembly was suspended in a beaker containing water and time required to disintegrate each tablet was noted. From this average disintegration time was determined.

3.1. Drug content

The drug content was analyzed by selecting ten tablets and each tablet was undergone for determination of drug content. Accurately weighed amount of sample was dissolved in 10 ml of ethanol and stirred on magnetic stirrer for 10 min. The solution was filtered whatmann filter paper filter (0.45 μm), diluted suitably and assayed for Talinolol content spectrophotometrically.[23]

3.1.1. In-vitro drug release study

The release rate of talinolol fast release tablets was determined using USP dissolution testing apparatus II. (S- 9500 Microprocessor Dissolution Test Apparatus) The in-vitro dissolution test was performed using 900 ml of phosphate buffer pH 6.8 at (37±0.5°C) 50 rpm. Aliquot of test sample was withdrawn at 10, 20, 30, 40, 50,60. Min intervals, and the same volume of pre-warmed fresh dissolution medium was replaced. The samples were filtered, and the amount of talinolol released was determined by Shimadzu-UV 1800, Japan spectrophotometer at 267 nm.[24]

4. Results and Discussion

4.1. Solubility study of talinolol

The talinolol solubility was evaluated in demineralised water, ethanol, acetone, and methanol. The results of talinolol solubility were tabulated in Table 5 and pH dependent solubility showed in.

The solubility graph of talinolol in different solvents.

4.2. Precompression parameter

Bulk density varies between 0.41 ± 0.026 to 0.53 ± 0.065 g/mL for all batches of formulations prepared. Angle of repose and Carr's index are within limits ensuring good flow properties of precompression powder blends indicating its acceptability for direct compression of tablets.

Table 2: Formula for the preparation of fast release tablets of talinolol

S. No	Ingredients (mg)	T1	T2	T3	T4	T5
1	Talinolol (20mg) P407 (100mg)1:5 Solid dispersion	120	120	120	120	120
2	Crospovidone	4	6	8	-	-
3	Croscarmelloe sodium	-	-	-	8	12
4	Magnesium stearate	2	2	2	2	2
5	Aerosil	2	2	2	2	2
6	Microcrystallie cellulose	72	70	68	68	64
	Total(mg)	200	200	200	200	200

Table 3: Solubility study of LTG in different mediums

S. No	Solvent	Solubility (mg/ml)
1.	Water	0.001
2.	Ethanol	11.5
3.	Acetone,	12.6
4.	Methanol	10
5.	Dimethyl formamide	32
6.	DMSO	15

Table 4: Precompression parameters of powder blends.

S.no	Formulation code	Bulk Density (g/ml)	TappedDensity (g/ml)	Angle of Repose ± SD, n=3	Carr's Index (%)±SD, n=3	Hausner's Ratio± SD, n=3
1.	T1	0.41±0.025	0.61±0.01	21.13±1.74	15.17±1.70	1.23±0.07
2.	T2	0.45±0.044	0.71±0.02	20.16±2.56	14.23±1.23	1.224±0.06
3.	T3	0.54±0.014	0.70±0.14	22.29±1.35	15.32±1.32	1.22±0.04
4.	T4	0.47±0.024	0.66±0.21	26.18±1.82	15.21±1.57	1.17±0.03
5.	T5	0.53±0.065	0.67±0.10	24.31±1.51	16.22±1.61	1.16±0.05

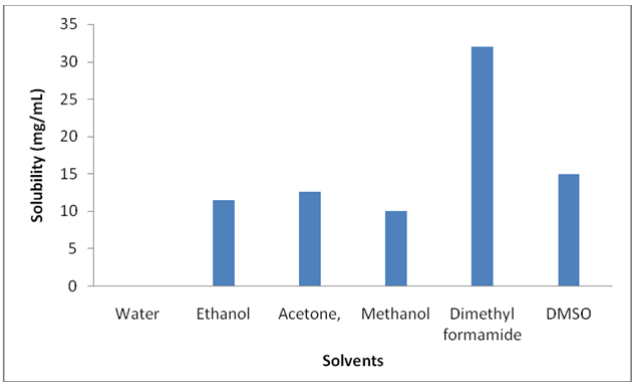

Fig. 1: Solubility of Talinolol

Precompression parameter of solid dispersion was evaluated and shown in Table 4.

4.3. Drug content

The solid dispersions of talinolol were investigated for their drug content using UV method at 237 nm and the % drug content obtained was 96.5±3% w/w. From the drug content analysis it was found to be that all the solid dispersions were uniform in drug content.

4.4. FT-IR Spectroscopy of Talinolol, Poloxamer 407 and prepared formulations

The FTIR spectrum of talinolol, P407 and prepared formulation were performed and the spectra, it was discovered that no significant interaction can be found between talinolol and the polymers used in the preparation of solid dispersions. The FTIR spectroscopy studies of pure talinolol showed characteristic peaks at its respective range, and were tabulated below in Table 6.

4.5. DSC

DSC can be determined the crystalline state or the amorphous state of drug, physical mixture and solid dispersion. As shown in figure (a), the melting point of talinolol was 160 °C indicating the presence crystalline nature. In the thermogram of a 10% talinolol solid

Table 5: Content uniformity of solid dispersions of talinolol

S. No	Code	Solid dispersion(Drug: Carrier)	% Drug Content (n=3)
1	T1	P 407 1:1	95.8±0.34
2	T2	P 407 1:2	98.2±0.56
3	T3	P 407 1:3	91.5±0.82
4	T4	P 407 1:4	94.7±0.61
5	T5	P 407 1:5	98.5±0.26

Table 6: FT-IR Spectroscopy of Talinolol, Poloxamer 407 and Prepared Formulations

S. No	IR Absorption Peak	Functional Group
1	3323cm-1	N-H group of DPH moiety
2	Peaks at 2885 and 3243cm-1	aromatic and aliphatic C-H bond
3	1654 and 1705cm-1	carbonyl group
4	1492 cm-1	aromatic C=C bond
5	1215 and 1113 cm-1	C-O stretching

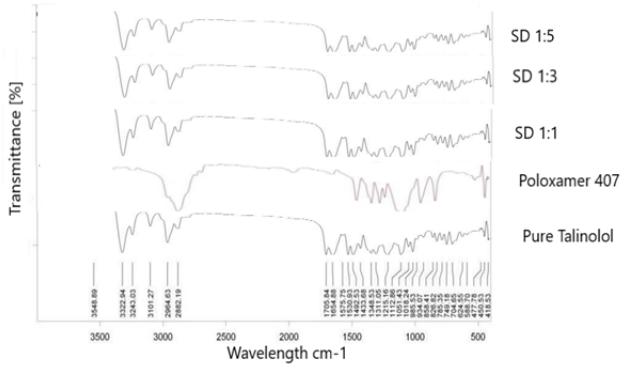

Fig. 2: FTIR spectra of tanilolol, poloxamer 407, and their solid dispersions

dispersion in isomalt, no sharp peaks were observed, which could be due to the formation of an amorphous state of ingredients in the solid dispersion as shown in figure (b). The melting point of talinolol was shifted from 160 °C to 130.45 °C in this thermogram. This reduction in the talinolol melting point might be attributed to the presence of an amorphous state of drug in its solid dispersion.

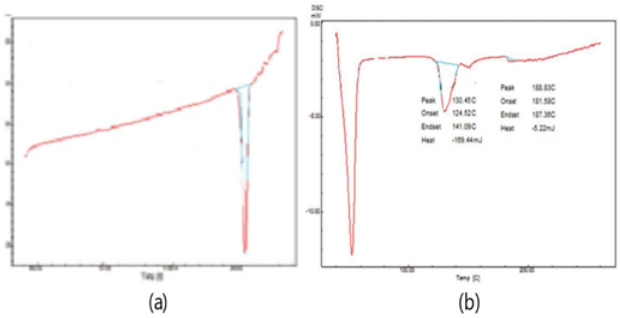

Fig. 3: Differential scanning calorimetry curve of (a) Pure Tanilolol, (b) Tanilolol P407 SD 1:5 Solid Dispersion

4.6. Result of post compression parameter with tabulated formulation

Results of evaluation parameter of PT formulation of lamotrigine were recorded in Table 7.

4.7. In-vitro drug release study

The drug release rate of pure drug showed only 1.57% at 10 th min. Also with the case of the drug release rate of talinolol dissolved in 60 min was found to be 16.53% which shows its lipophilicity and its high crystallinity. There was found to be a marked enhancement in the drug release rate of prepared SDs with P407. The drug release rate is compared with that of pure talinolol. The solid dispersions of talinolol with P407 in the ratio of 1:5 gave highest dissolution rate of 87.53% at 60min. This result shows the necessity for higher concentrations of the polymer to convert it into amorphous form and to achieve better dissolution parameters.

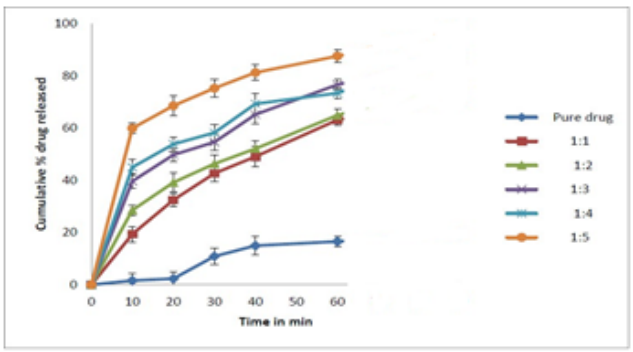

Fig. 4: Dissolution profile of Talinolol from poloxamer 407 SD at different drug: carrier ratios

Table 7: Post compression parameters

Formulation Code	Hardness (Kg/cm2) ± SD	Friability(%) ± SD	Disintegration Time (min)** ± SD	Weight Variation (mg) ± SD	Drug Content(mg) ± SD
T1	5.4±0.02	0.62±0.04	80	2.81±0.03	97.23
T2	6.8±0.04	0.63±0.03	64	3.15±0.02	96.67
T3	4.4±0.01	0.60±0.09	33	2.63±0.08	98.14
T4	6.1±0.02	0.61±0.12	72	3.44±0.32	91.54
T5	6.4±0.06	0.64±0.07	58	2.85±0.13	98.35

** Disintegration Time (min) for tablets in pH 7.4.

Table 8: Dissolution studies of solid dispersions of Talinolol: carrier ratios

Time (Min)	% Talinolol dissolved from poloxamer 407 solid dispersion					
	Pure talinolol	1:1	1:2	1:3	1:4	1:5
10	1.57	19.37	28.50	39.62	44.95	65.95
20	2.31	32.44	39.18	49.71	53.84	68.57
30	10.85	42.61	46.29	54.59	58.19	75.28
40	14.97	49.05	52.11	65.21	69.29	81.25
60	16.53	63.12	64.90	76.63	73.35	87.53

5. Summary and Conclusion

Studies were performed in the formulation and evaluation of solid dispersions of talinolol a view of developing fast dissolving tablets of talinolol. The solid dispersions were prepared by employing solid dispersion technology using poloxamer 407 and poloxamer 188 as hydrophilic carriers. Various drug carrier ratios such as 1:1, 1:2, 1:3, 1:4 and 1:5 were utilized for preparing SDs. From the infrared spectral analysis, it was understood that there was no significant interaction between drugs and the carriers incorporated in solid dispersions. The drug content of solid dispersions was uniform in all batches.

Results of dissolution studies showed the rapid and fast dissolution of talinolol from all their solid dispersions when compared with the pure drug. Poloxamer 407 which was used as a carrier in the ratio of 1:5 in solid dispersions gave the highest drug release.

The solid dispersions of talinolol and solid dispersions of with poloxamer 407 in the ratio of 1:5 were formulated into fast dissolving tablets using various proportions of sodium starch glycolate, croscarmellose sodium and crospovidone as superdisintegrants. The in vitro drug release profile of fast dissolving tablets was found to be increased with increase in superdisintegrant level.

The formulation of fast dissolving tablets by using the solid dispersion of talinolol is a promising method. This can be useful because it has the advantage that the rate of dissolution of the drug can be rapidly increased. Therefore, it can be concluded that the combination of solid dispersion technology as well as using superdisintergrants in tablet formulation is an encouraging and effective technique to prepare efficient FDT of poorly water soluble drug talinolol.

6. Source of Funding

None.

7. Conflict of Interest

None.

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