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PREPARATION AND EVALUATION OF SOLID DISPERTIONS OF EPROSARTAN

K.Kavitha[1], Aminul Mondal[2], Khairul Islam Sarkar[2], Bahadur Ali[2], Wasihim Akram Chowdhury[2], Saiful Islam[2], Bishal Devnath[2].

[1]Associate professor, Teja College of Pharmacy, kodad, suryapet, Telangana., [2]Teja College of Pharmacy, kodad, suryapet, Telangana.

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Abstarct:

"In the present study Eprosartan solid dispersions were formulated. The standard curve of Eprosartan was obtained and good correlation was obtained" with R^2 value 0f 0.999. The medium selected was pH 7.4 phosphate buffer. "Eprosartan was mixed with various proportions of excipients showed no colour change at the end of two months proving no drug excipient interactions" The precompression mix of Eprosartan solid dispersions were characterised with relevance angle of repose, bulk density, broached density, Carr's index and Hausner's magnitude relation. The precompression mix of all the batches indicating sensible to truthful flowability and squeezability. Solid dispersions were ready with varied concentrations of carriers, the ready solid dispersions were compressed into pills by exploitation rotary tablet punching machine, and eight millimeter punch, and with the hardness of 4.5kg /cm2.The developed tablets were evaluated for varied internal control parameters. The tablets were passed all the tests. Among all the formulations F1 formulation containing, Drug and Peg 4000 within the magnitude relation of 1:0.25 showed sensible result that's 94.95 you bored with fifty minutes. Because the concentration of compound will increase the drug unleash was faded. Whereas the formulations containing PEG 6000 showed less unleash. Therefore from the dissolution knowledge it absolutely was evident that F1 formulation is that the higher formulation.

Keywords: *Eprosartan, solid dispersions, PEG 4000, PEG 6000.*

Corresponding author:

K.Kavitha,

Associate professor,

Teja College of Pharmacy, kodad, suryapet, Telangana.

Email id: upendar.upi49@gmail.com

QR code

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INTRODUCTION:

The oral route of drug administration is the most common and preferred route of delivery due to convenience and ease of ingestion. From a patient's prospect, swallowing a dosage form is a comfortable means of taking medication. As a result, patient compliance is more effective with orally administered medications as compared with other routes of administration, for example, parenteral route. Although the oral route of administration is preferred, in case of many drugs it can be a problematic and inefficient mode of delivery for a number of reasons.

Limited drug absorption resulting in poor bioavailability is amongst the potential problems that can be overcome while delivering an active agent via the oral route. After administering a drug orally, it firstly dissolves in gastric media and then permeates the membranes of the GI tract to reach systemic circulation.

Therefore, a drug with poor aqueous solubility will typically exhibit dissolution rate limited absorption, and a drug with poor membrane permeability will typically exhibit permeation rate limited absorption. Hence, two areas of pharmaceutical research that focus on improving the oral bioavailability of active agents include:

(i) Enhancing solubility and dissolution rate of poorly water-soluble drugs and

(ii) Enhancing permeability of poorly permeable drugs. Solubility is a predetermined and rate limiting step for absorption.

Drug has to enter in to the systemic circulation to exert its therapeutic effect. In recent technologies, innovation of combinatorial chemistry and high throughput screening (HTS) can effectively discover the new drugs which exhibit good pharmacological activities. However, 35-40 % of these new drugs discovered by those technologies suffer from poor aqueous solubility.

It is clear that, depending on the classification of the drugs, different strategies can be applied to increase or accelerate the rate of absorption of a drug; either increasing the permeability of the absorbing membrane or increasing the amount of dissolved drug that is in contact with the absorbing membrane.

Especially supersaturated solid solutions of the drug are subjected to recrystallization phenomena. **Solid dispersion** refers to a group of solid products consisting of at least two different components, generally a hydrophilic matrix and a hydrophobic drug [3].

In general**, solid dispersion** is defined as the dispersion of one or more active ingredient in a carrier or matrix at solid state.

The term "**solid dispersion**" refers to the dispersion of one or more active ingredients in an inert carrier in a solid state, frequently prepared by the melting (fusion) method, solvent method or fusion solvent method. The drug can be dispersed molecularly, in amorphous particles (clusters) or in crystalline particles [4,5].

Advantages of Solid Dispersions:

1. Improving drug bioavailability by changing their water solubility has been possible by solid dispersion.
2. Solid dispersions are more efficient than these particle size reduction techniques, since the latter have a particle size reduction limit around 2-5 mm which frequently is not enough to improve considerably the drug solubility or drug release in the small intestine.
3. Increase in dissolution rate & extent of absorption and reduction in Pre systemic metabolism.
4. Transformation of liquid form of drug into solid form.
5. Parameters, such as carrier molecular weight and composition, drug crystallinity and particle porosity and wettability, when successfully controlled, can produce improvements in bioavailability [48].

Disadvantages of Solid Dispersions:

1. Most of the polymers used in solid dispersions can absorb moisture, which may result in phase separation, crystal growth or conversion from the amorphous to the crystalline state or from a metastable crystalline form to a more stable structure during storage. This may result in decreased solubility and dissolution rate.
2. Drawback of solid dispersions is their poor scale-up for the purposes of manufacturing.
3. Eprosartan is an angiotensin II receptor antagonist used for the treatment of high blood pressure. It acts on the renin-angiotensin system in two ways to decrease total peripheral resistance. First, it blocks the binding of angiotensin II to AT1 receptors in vascular smooth muscle, causing vascular dilatation. Second, it inhibits sympathetic norepinephrine production, further reducing blood pressure.

Angiotensin II, the principal pressor agent of the renin-angiotensin system, is formed from angiotensin I in a reaction catalyzed by angiotensin-converting enzyme [kininase II]. It is responsible for effects such as vasoconstriction, stimulation of synthesis and release of aldosterone, cardiac stimulation, and renal reabsorption of sodium. Eprosartan selectively blocks the binding of angiotensin II to the AT1 receptor, which in turn leads to multiple effects including vasodilation, a reduction in the secretion of vasopressin, and reduction in the production and secretion of aldosterone. The resulting effect is a decrease in blood pressure.

Aim and Objectives:

- ✓ To enhance the aqueous solubility of Eprosartan by suitable solid dispersion technique.
- ✓ To develop analytical profile of Eprosartan.
- ✓ To formulate solid dispersions by solvent evaporation method using methanol as solvent.
- ✓ To study the influence of various water soluble polymers on the dissolution enhancement of the solid dispersions.

Materials used in the work:

Eprosartan is bought from Dr. reddys labs, PEG 4000, PEG 6000, PVP K30, Magnesium stearate, Aerosil, Microcrystalline Cellulose, Potassium dihydrogen ortho phosphate, Sodium hydroxide are gift samples from Kp Labs Pvt Ltd. Hyderabad-035.

METHODOLOGY:

Preformulation Studies:

Pre formulation involves the appliance of biopharmaceutical principles to the chemistry parameters of drug substance area unit characterized with the goal of coming up with optimum drug delivery system.

Drug-Excipients compatibility studies:

Drug Excipients compatibility studies were applied by combination the drug with varied excipients in several proportions (in 1:1 quantitative relation were ready to own most probability interaction between them) was placed during a phial, and closed with rubber stopper and sealed properly.

Analytical methodology development for Eprosartan:

a) Determination of absorption maxima

A spectrum of the operating standards was obtained by scanning from 200-400nm against the chemical agent blank to mend absorption maxima. The λmax was found to be 235nm. Thus all additional investigations were applied at an equivalent wavelength.

b) Preparation of ordinary graph in pH 7.4 medium

100 mg of Eprosartan was dissolved in fuel five metric capacity unit, volumetric flask build up to one hundred metric capacity unit of Phosphate buffer of pH 7.4, from this primary stock ten metric capacity unit was transferred to a different volumetric flask created up to 100ml with Phosphate buffer of pH 7.4, from this secondary stock was taken on an individual basis and created up to ten metric capacity unit with Phosphate buffer of pH 7.4, to supply 10,20,30,40 and fifty µg/ml severally. The absorbance was measured at 235 nm by employing an UV radiation spectrophotometer.

Formulation Development:

Solid dispersions were ready by solvent evaporation methodology. Ethanol was used as solvent. Eprosartan dose was taken as 300mg. Water soluble polymers like PEG 4000 and PEG 6000 were elect as carriers. Drug and polymers were taken in several ratios explicit within the formulation chart (Table 2). The ready solid dispersions were had the sieve no twenty to induce uniform sized particles. The solid dispersions were mixed with needed quantities of dilutant, material and glidant. The mix was evaluated for precompression parameters.

Table 1: Formulation table showing various compositions

	F1	F2	F3	F4	F5	F6	F7	F8	F9
Drug	300	300	300	300	300	300	300	300	300
PEG 4000	100	200	300	400					400
PE 3000					100	200	300	400	400
MCC	QS	QS	QS	QS	QS	QS	QS	QS	QS
Aerosil	35	35	35	35	35	35	35	35	35
Magnesium stearate	35	35	35	35	35	35	35	35	35

Total weight of tablets = 1000 mg

The tablets were prepared by using 8 mm flat surfaced punch. The hardness of the tablets was maintained as 4.5 kg/cm^2.

Evaluation of tablets:

Pre compression parameters:

Measurement of Micromeritic Properties of Powders

1. Angle of repose

The angle of repose of API powder is determined by the funnel method. The accurately weight powder blend are taken in the funnel. The height of the funnel is adjusted in a way that, the tip of the funnel just touched the apex of the powder blend. The powder blend is allowed to flow through the funnel freely on to the surface. The diameter of the powder cone is measured and angle of repose is calculated using the following equation. [55]

$\tan \theta = h/r$ …… (1)

Where, h and r are the height and radius of the powder cone.

2. Bulk density

The powder sample under test is screened through sieve No.18 and the sample equivalent to 25 gm is weighed and filled in a 100 ml graduated cylinder and the power is leveled and the unsettled volume, V_0 is noted. The bulk density is calculated in g/cm^3 by the formula. [56]

Bulk density = M/V_0 …….. (2)

M = Powder mass

V_0 = apparent unstirred volume

3. Tapped density

The powder sample under test is screened through sieve No.18 and the weight of the sample equivalent to 25 gm filled in 100 ml graduated cylinder. The mechanical tapping of cylinder is carried out using tapped density tester at a nominal rate for 500 times initially and the tapped volume V_0 is noted. Tappings are proceeded further for an additional tapping 750 times and tapped volume, V_b is noted. The difference between two tapping volume is less the 2%, V_b is considered as a tapped volume V_f. The tapped density is calculated in g/cm^3 by the formula. [57]

Tapped density=M/V_f ..... (3)

M =weight of sample power taken

V_f =tapped volume

4. Compressibility Index

The Compressibility Index of the powder blend is determined by Carr's compressibility index to know the flow character of a powder. The formula for Carr's Index is as below:

Carr's Index (%) = [(TD-BD) /TD] x100 …….. (4)

5. Hausner's ratio

The Hausner's ratio is a number that is correlated to the flowability of a powder or granular material. The ratio of tapped density to bulk density of the powders is called the Hasner's ratio. It is calculated by the following equation. [58]

$H = \rho T / \rho B$ …….. (5)

Where ρT = tapped density, ρB = bulk density

Post compression parameters:

a) Thickness

The thickness of tablets was determined by using Digital micrometer. Ten individual tablets from each batch were used and the results averaged.

b) Weight variation

Twenty tablets were indiscriminately chosen from every batch and severally weighed. The common weight and variance 3 batches were calculated. It passes the check for weight variation check if less than 2 of the individual pill weights deviate from the common weight by over the allowed proportion deviation and none deviate by over double the proportion shown. It absolutely was calculated on Associate in nursing electronic scales.

c) Friability

The friability values of the tablets were determined using a Roche-type friabilator. Accurately weighed six tablets were placed in Roche friabilator and rotated at 25 rpm for 4 min.

Percentage friability was calculated using the following equation.

$$\text{Friability} = ([w_O - w]/w_O) \times 100$$

Where; w_O = weight of the tablet at time zero before revolution.

w = weight of the tablet after 100 revolutions.

d) Assay

The content of drug in five randomly selected tablets of each formulation. The five tablets were grinded in mortar to get powder; this powder was dissolved in 0.1 N HCl by sonication for 30 min and filtered through filter paper. The drug content was analyzed spectrophotometrically at 235 nm using UV spectrophotometer. Each measurement was carried out in triplicate and the average drug content was calculated.

e) Disintegration test

Six tablets were taken randomly from each batch and placed in USP disintegration apparatus baskets. Apparatus was run for 10 minutes and the basket was lift from the fluid, observe whether all of the tablets have disintegrated.

f) Dissolution test of Eprosartan tablets

Drug unleash from Eprosartan tablets by dissolution take a look at u.s. accumulation (USP) twenty four kind II (paddle). The parameters used for activity the dissolution were pH scale 7.4 medium because the dissolution medium of amount 900ml. the full study is being meted out at a temperature of 370 C and at a speed of 50rpm.

5ml aliquots of dissolution media were withdrawn whenever at appropriate time intervals (5, 10, 20 minutes.) and replaced with recent medium. Once retreating, samples were filtered and analyzed once acceptable dilution by UV photometer.

Solubility Studies:

Solubility study of Eprosartan and its formulations were carried out by shaking 10 mg of pure drug and its formulations (equivalent to 10 mg/ml) with 40ml of distilled water in 100ml volumetric flask for 72 hours on BOD shaker and then make up the volume up to 100ml. After 10 times dilution then filtering and analyzed spectrophotometrically at 235nm against suitable blank.

Solubility=absorbance at λmax/slope

RESULTS & DISCUSSION:

Determination of λ max:

The prepared stock solution was scanned between 200-400 nm to determine the absorption maxima. It was found to be 235 nm.

Calibration curve of Eprosartan:

The standard curve of Eprosartan was obtained and good correlation was obtained with R^2 value 0f 0.999.the medium selected was pH 7.4 phosphate buffer.

The standard graph values of Eprosartan are tabulated as below-

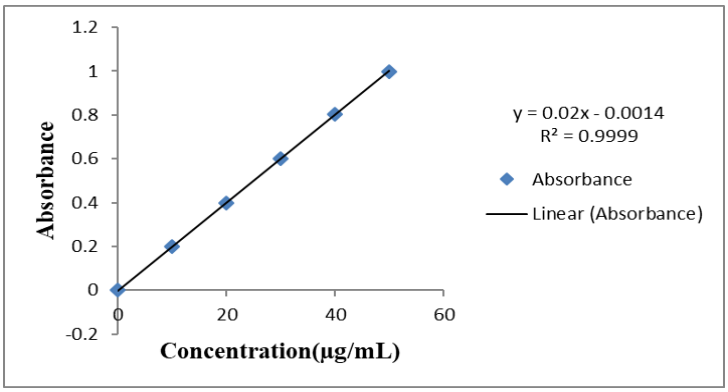

Fig no 1: standard curve of Eprosartan

Evaluation of Precompression Blend: The precompression blend as solid dispersions were characterized with respect to angle of repose, bulk density, tapped density, Carr's index and Hausner's ratio**.** Angle of repose was less than 28^0, Carr's index values were less than 11 for the pre compression blend of all the batches indicating good to fair flowability and compressibility. Hausner's ratio was less than 1.25 for all the batches indicating good flow properties.

Table 2. Physical properties of pre compression blend

Formulation Code	Angle of repose (Ɵ)	Bulk density (gm/cm^3)	Tapped density (gm/cm^3)	Carr's Index (%)	Hausner's ratio
F1	24.10°	0.52±0.01	0.51±0.01	9.42±0.12	1.02±0.02
F2	21.43°	0.54±0.03	0.62±0.02	9.41±0.13	1.10±0.01
F3	25.41°	0.53±0.02	0.67±0.03	10.03±0.19	1.13±0.06
F4	23.40°	0.51±0.01	0.66±0.06	11.14±0.02	1.15±0.04
F5	25.12°	0.58±0.03	0.67 ±0.06	13.66±0.06	1.16±0.03
F6	20.31°	0.60±0.03	0.65±0.04	10.12±0.34	1.10±0.06
F7	26.11°	0.56±0.01	0.63±0.01	9.93±0.11	1.12±0.03
F8	22.15°	0.53±0.03	0.58±0.03	13.12±0.02	1.11±0.01
F9	26.10°	0.54±0.01	0.61±0.03	14.21±0.13	1.13±0.03

All the values represent mean ± Standard deviation (SD), n=3

Evaluation of Tablets:

Physical Evaluation of Eprosartan solid dispersion tablets:

The results of the weight variation, hardness, thickness, friability, and drug content of the tablets area unit given in Table seven. All the tablets of various batches complied with the official demand of weight variation as their weight variation passes the boundaries. The hardness of the tablets ranged from 4.6 to 5 kg/cm2 and also the crumbliness values were but 0.561% indicating that the tablets were compact and exhausting. The thickness of the tablets ranged from 4.71-4.91cm. All the formulations happy the content of the drug as they contained 98-100% of Eprosartan and sensible uniformity in drug content was ascertained. Therefore all the physical attributes of the ready tablets were found to be much at intervals management limits.

Table 3 .Physical Evaluation of Eprosartan tablets

Formulation code	Weight variation (mg)	Thickness (mm)	Diameter (mm)	Hardness (Kg/cm^2)	Friability (%)	Content uniformity (%)
F1	1001±1	4.75±0.01	8.12±0.01	4.5±0.7	0.422	99±0.11
F2	1003±2	4.73±0.04	8.14±0.02	4.2±0.5	0.342	99±0.2
F3	1002±1	4.71±0.01	8.01±0.01	4.5±0.6	0.362	100±0.1
F4	1004±2	4.80±0.06	8.03±0.03	4.7±0.5	0.560	100±0.4
F5	1005±3	4.82±0.03	8.04±0.04	4.9±0.4	0.483	99±0.6
F6	1002±1	4.64±0.02	8.09±0.05	4.3±0.6	0.514	99±0.4
F7	1002±1	4.75±0.05	8.11±0.03	5.5± 0.1	0.414	98±0.8
F8	1006±2	4.72±0.04	8.09±0.06	4.6±0.2	0.430	99±0.1
F9	1001 ±3	4.73±0.02	8.03±0.02	4.5±0.4	0.511	100±0.1

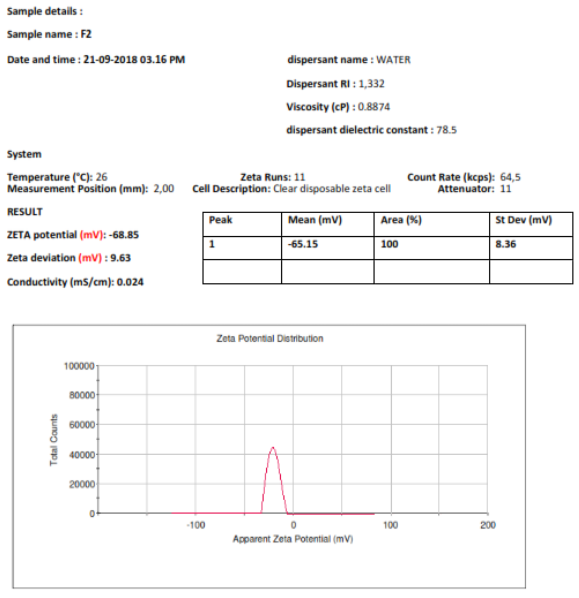

Fig 2: ZETA report of F2

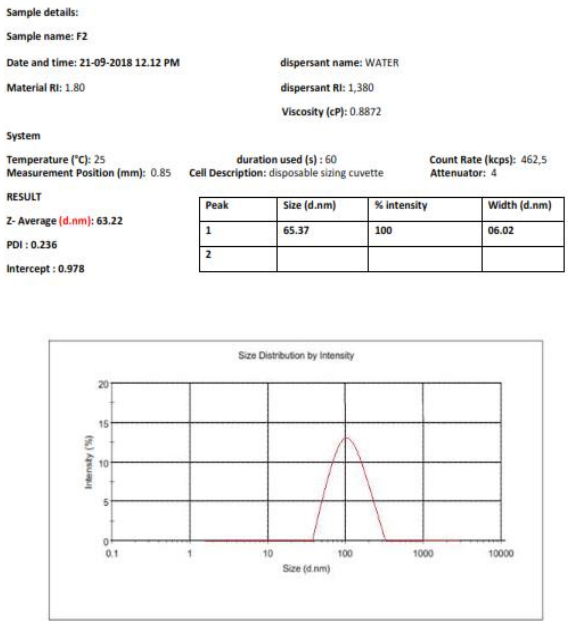

Fig 3: Particle size report of F2

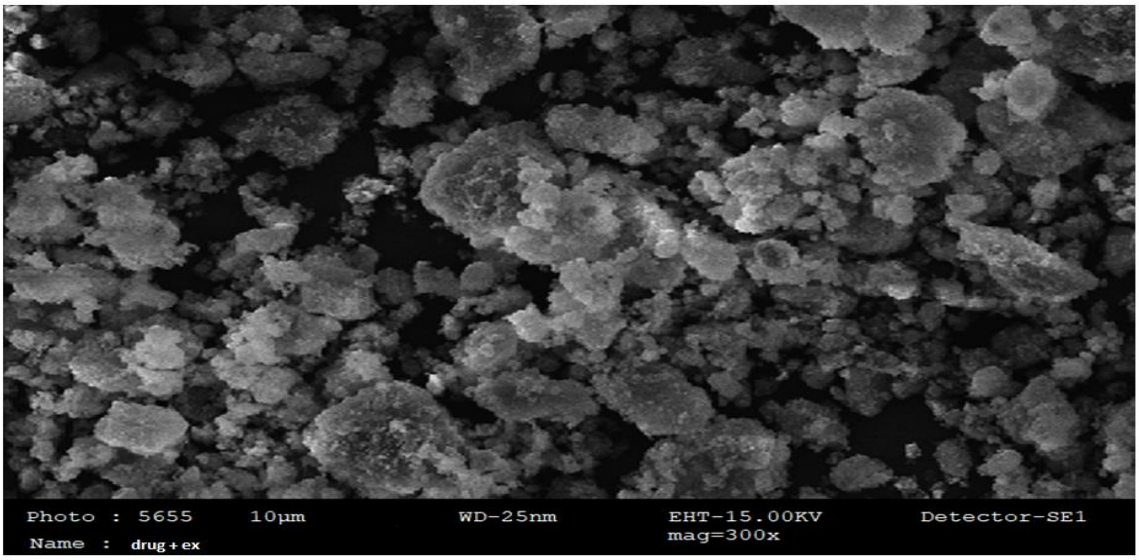

Fig 4: SEM image of F2

In vitro release studies:

The drug release rate from tablets was studied using the USP type II dissolution test apparatus. The dissolution medium was 900 ml of pH 7.4 phosphate buffer at 50 rpm at a temperature of 37 ± 0.5 °C. Samples of 5 ml were collected at different time intervals up to 1 hrs and analyzed after appropriate dilution by using UV Spectrophotometer at 235nm.

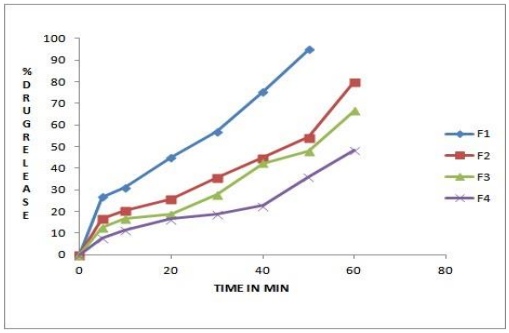

Fig 5: Invitro dissolution data for formulations F1 – F4 by using PEG 4000 Polymer

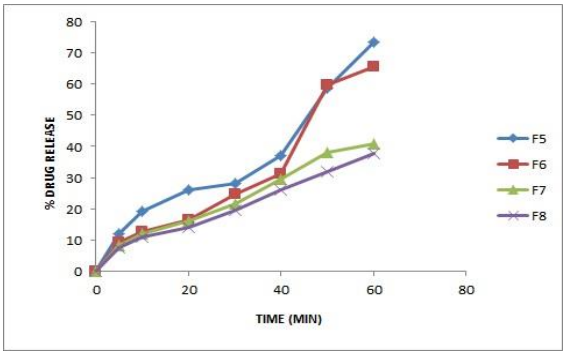

Fig 6: Invitro dissolution data for formulations F5– F8 by using PEG 4000 Polymer

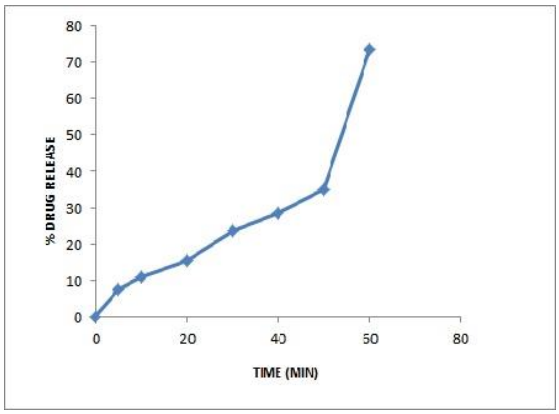

Fig 7: Invitro dissolution data for formulations F9 by using PEG 4000 & 6000 Polymer.

Among all the formulations F1 formulation containing, Drug and Peg 4000 within the magnitude relation of 1:0.25 showed sensible result that's 94.95 you tired of fifty minutes. Because the concentration of compound will increase the drug unleash was slashed. Whereas the formulations containing PEG 6000 showed less unleash. Thus from the dissolution information it absolutely was evident that F1 formulation is that the higher formulation. The formulation containing combination of PEG 4000& 6000 was conjointly not manufacturing desired share drug release. The formulation is following zero order release dynamics.

Solubility studies:

Table no 4: Solubility studies

S. No	Name	Distilled Water (µg/ml.)	7.4ph Phosphate Buffer (µg/ml.)
0	Eprosartan pure drug	02.56±0.56	01.91±0.35
1	**F1**	**31.26±0.25**	**33.56±0.63**
2	**F2**	**22.93±0.23**	**25.46±0.43**
3	F3	13.49±0.16	14.27±0.45
4	F4	11.37±0.15	12.74±0.27
5	F5	18.49±0.17	19.22±0.75
6	F6	19.76±0.37	18.25±0.15
7	F7	07.84±0.48	11.23±0.36
8	F8	11.39±0.65	10.34±0.43
9	F9	16.46±0.22	16.28±0.18

From the solubility studies it was confirmed that the formulation F1 and F2 showed increased solubility in the both given solvent and buffer solution.

CONCLUSION:

The standard curve of Eprosartan was obtained and smart correlation was obtained with R2 of 0.999. The medium chosen was pH scale 7.4 phosphate buffer. Eprosartan was mixed with numerous proportions of excipients showed no color amendment at the tip of 2 months, proving no drug-excipient interactions. The precompression mix of Eprosartan solid dispersions were characterised with reference to angle of repose, bulk density, tapped density, Carr's index and Hausner's magnitude relation. The precompression mix of all the batches indicating smart to honest flowability and softness. Solid dispersions were ready with numerous concentrations of carriers, the ready solid dispersions were compressed into pills by exploitation rotary tablet punching machine, and eight millimeter punch, with the hardness of 4.5kg /cm2. The developed tablets were evaluated for numerous internal control parameters. The tablets were passed all the tests. Among all the formulations F1 formulation containing, Drug and Peg 4000 within the magnitude relation of 1:0.25 showed smart result that's 94.95 you tired of fifty minutes. Because the concentration of compound will increase the drug unharness was shriveled. Whereas the formulations containing PEG 6000 showed less unharness. Thence from the dissolution information it absolutely was evident that F1 formulation is that the higher formulation. By conducting additional studies like in vivo studies, diagnosis and clinical studies we are able to commercialize the merchandise.

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Conflicts of interest:
The authors express no conflicts of interest regarding the publication, all the authors worked and provided support equally and credited equally.

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