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Research Article

ASSESSING THE BEST POLY VINYL PYRROLIDONE AS A CARRIER FOR ETORICOXIB SOLID DISPERSIONS: FABRICATION AND EVALUATION

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ABSTRACT

This present search is to find the best Poly Vinyl Pyrrolidone as a carrier for preparing solid dispersions by taking Etoricoxib as a model drug. Five varieties of Poly Vinyl Pyrrolidone i.e., PVP K-12, PVP K-17, PVP K-25, PVP K-30 and PVP K-90 were studied in this investigation. The drug polymer ratios in these formulations were ranged from 1:1, 1:2, 1:4 and 1:6. The solid dispersions were prepared by microwave fusion method and compressed by tablet punching machine. The prepared tablets were evaluated for physicochemical properties and dug release characteristics. The drug release was further analyzed kinetically with first order and Hixson Crowell's plots. All the batches of tablets were shown good release characteristics and among the Poly Vinyl Pyrrolidone polymers, PVP K-17 was found to be good as a carrier for increasing the solubility and Release rate from the solid dispersions of Etoricoxib.

Key words: Etoricoxib, Poly Vinyl Pyrrolidone, best carrier, microwave melting

INTRODUCTION

The pharmacist in industry makes many trials to increase the solubility of poorly water-soluble drug at economical way. Amongst the formulation findings, solid dispersions were gaining prominence day by day. This technique is used to increase the solubility poorly water-soluble drugs for oral drug delivery[1].

Etoricoxib is a non-steroidal drug (NSAID) used in the treatment of all the varieties of arthritis and pains. It is a poorly water soluble with 92% protein binding and poor bioavailability[2, 3].

The present investigation was to boost the solubility of Etoricoxib by formulating it into solid dispersions using PVP bases (PVP K-12, PVP K-17, PVP K-25, PVP K-30 and PVP K-90) and finding out the best polymer among them. The solid dispersions were prepared by microwave melting method.

MATERIALS AND METHODS

Etoricoxib was procured from Yarrow chemicals. PVP K-12, PVP K-17, PVP K-25, PVP K-30 and PVP K-90 were obtained from Amrutha organics, Hyderabad. Microcrystalline Cellulose, Magnesium stearate, Talc were procured from Colorcon, India.

Compatibility Studies

Stability Studies

Physical observations of drug and excipients (Etoricoxib Excipients) (1:1) compatibility study at stressed storage conditions[4] i.e., at a temperature of 40°C and a relative humidity of 75% were performed.

Hygroscopic Studies

The hygroscopic study of Etoricoxib was done under 33%, 53% and 75% RH for 30 days and the weight gain was studied. The experiments were conducted in triplicates[5].

Solubility Studies

Etoricoxib was tested for solubility in 0.1N HCl, water, pH 4.5 Acetate buffer, pH 6.8 Phosphate buffer and pH 7.4 Phosphate buffer[6].

Preparation of Solid Dispersions

The various formulae of Etoricoxib with PVP were shown in table 1.

Table 1: Drug (Etoricoxib): Carrier (PVP) ratios in various formulations

Drug: Carrier	ratio	Formulation name
ECB: PVP K-12	1:1	EPVP12-1
	1:2	EPVP12-2
	1:4	EPVP12-3
	1:6	EPVP12-4
ECB: PVP K-17	1:1	EPVP17-1
	1:2	EPVP17-2
	1:4	EPVP17-3
	1:6	EPVP17-4
ECB: PVP K-25	1:1	EPVP25-1
	1:2	EPVP25-2
	1:4	EPVP25-3
	1:6	EPVP25-4
ECB: PVP K-30	1:1	EPVP30-1
	1:2	EPVP30-2
	1:4	EPVP30-3
	1:6	EPVP30-4
ECB: PVP K-90	1:1	EPVP90-1
	1:2	EPVP90-2
	1:4	EPVP90-3
	1:6	EPVP90-4

Micromeritic Properties

The solid dispersions of the various formulations were evaluated for angle of repose, bulk density, tapped density, compressibility index and Hausner ratio[7, 8].

Preparation of Tablets Containing Solid Dispersion

Tablets containing solid dispersions equivalent to 60 mg of Etoricoxib were prepared by direct compression method after mixing with required amount of different ingredients as shown in in Table 2.

Table 2: Formulation of tablet containing solid dispersions (Etoricoxib)

Ingredients	Quantity per tablet
Solid dispersions equivalent to 60 mg of Etoricoxib	125
Lactose	50
Starch	15
Micro Crystalline Cellulose	50
Magnesium stearate	5
Talc	5
Weight of the tablets	250

EVALUATION OF SOLID DISPERSIONS OF ETORICOXIB

The following parameters were evaluated for the prepared solid dispersions of Etoricoxib[9-12].

General Appearance
In this study, tablets were tested for size, shape, colour, odour, taste, surface texture, consistency.

Thickness
Tablets were evaluated for their thickness using Vernier Calipers. These were performed for 3 times.

Hardness
The force of fracture was recorded using Pfizer tablet hardness tester. These tests were performed in triplicates.

Uniformity in Weight
Twenty tablets from each formulation were weighed individually using an electronic digital balance (Citizen, CY-104, Mumbai, India) and calculated the average weight and compared with the individual tablet weights. From this, percentage weight difference was calculated and then checked for IP specifications (Limit ± 7.5% of average weight).

Friability
It is the phenomenon whereby tablet surfaces are damaged or break when subjected to mechanical shock or attrition. This test was performed using Roche Friabilator. 10 tablets were initially weighed together ($W_{initial}$) and transferred into a friabilator. The friabilator was operated at 25 rpm for 4 minutes and the final weight of tablets (W_{final}) was determined. The % friability was then calculated by the following equation.

$$F = W_{initial} - W_{final}/W_{initial} \times 100$$

Disintegration
USP tablet disintegration test apparatus was used. 6 tablets were placed individually in each tube of disintegration test apparatus with disc in distilled water. The apparatus was maintained at 37° ± 2°C and operated. The time taken for the entire tablet to disintegrate completely was noted (IP limit NMT 15 min for uncoated tablets).

Percent Yield
The % recovery of formulated solid dispersion was resolute after complete removal of moisture. Thus % recovery calculation involves the weight of dried Solid dispersion to sum of the weight of drug and pharmaceuticals required for the formulation.

% Yield= Actual weight of the solid dispersions/Total weight of drug and excipients X 100

Uniformity of Drug Content
5 tablets of each type of formulation were weighed and crushed in mortar and powder equivalent to 60 mg of Etoricoxib was weighed and dissolved in 100 ml of 0.1N HCl (pH 1.2). This was the stock solution from which 0.2 ml sample was withdrawn and diluted to 10 ml with 0.1N HCl. The absorbance was measured at wavelength 233 nm using double beam UV-Visible spectrophotometer. Content uniformity was calculated from standard graph of Etoricoxib.

Calibration Curve of Etoricoxib
The method of estimation of Etoricoxib by UV spectrophotometer at 233 nm was standardized and the drug was found to obey Beer-Lambert's law in the concentration range of 2-12 µg/ml.

Dissolution Rate/In-vitro Drug Release
The dissolution parameters were as follows

- Apparatus used: USP XXIII dissolution test apparatus
- Dissolution medium: 0.1 N HCl
- Dissolution medium volume: 900 ml
- Temperature: 37±0.5°C
- Speed of basket paddle: 50 rpm
- Sampling intervals: 5 min
- Sample withdraws: 10 ml
- Absorbance measured at: 233 nm

Kinetic Modeling of Drug Release
The mechanism of the drug release was analyzed, and rate kinetics of the dosage form were obtained as[13]:

- Cumulative percentage drug released Vs. Time (Zero order plots)
- Log cumulative percentage drug remaining Vs Time (First order plots)
- Cube root of drug remaining Vs time (Hixson Crowell's plots)

Accelerated Stability Studies of Solid Dispersions of Etoricoxib
The evaluated solid dispersions of Etoricoxib were then subjected to stability studies for a period of 6 months under stressed storage conditions[14].

RESULTS AND DISCUSSION

The compatibility study revealed that Etoricoxib was found to be compatible with the excipients used and they are tabulated in table 3.

Physical Observations of Excipients Compatibility Study at stressed storage conditions

Table 3: Etoricoxib Excipients (1:1) compatibility study physical Observations

Binary mixture	Initial	Storage condition					
		Room temperature			40°C/75%RH		
		10 days	20 days	30 days	10 days	20 days	30 days
Etoricoxib	White-off white powder	NCC	NCC	NCC	NCC	NCC	NCC
E+PVP K-12	White waxy powder	NCC	NCC	NCC	NCC	NCC	NCC
E+ PVP K-17	White waxy powder	NCC	NCC	NCC	NCC	NCC	NCC
E+ PVP K-25	White waxy powder	NCC	NCC	NCC	NCC	NCC	NCC
E+ PVP K-30	White waxy powder	NCC	NCC	NCC	NCC	NCC	NCC
E+ PVP K-90	White waxy powder	NCC	NCC	NCC	NCC	NCC	NCC
E+ Lactose	Off white powder	NCC	NCC	NCC	NCC	NCC	NCC
E+ Starch	Off white powder	NCC	NCC	NCC	NCC	NCC	NCC
E+ MCC	Off white powder	NCC	NCC	NCC	NCC	NCC	NCC
E+ MS	Off white powder	NCC	NCC	NCC	NCC	NCC	NCC
E+ Talc	Off white powder	NCC	NCC	NCC	NCC	NCC	NCC
E- Etoricoxib; PVP- Poly Vinyl Pyrrolidone; MCC- Micro Crystalline Cellulose; MS- Magnesium Stearate							

The hygroscopic study of Etoricoxib at room temperature (25±2ºC) & humidity conditions was shown in table 4.

Table 4: Hygroscopicity Data (Etoricoxib)

Time Interval	% Weight Change		
	33% RH	53% RH	75% RH
Day 1	0.00	0.0	0.0
Day 2	0.00	0.01±0.001	0.02±0.001
Day 4	0.00	0.01±0.001	0.01±0.001
Equilibrium RH			
Day 0	0.101±0.002		
Day 4	0.113±0.001	0.115±0.003	0.117±0.002
Inference	Non-hygroscopic		
All values mentioned as mean ±SD; number of trials (n=3)			

The Hygroscopicity study of drug used (Etoricoxib) indicates that drug is non-hygroscopic in nature as the % weight increase in the samples at the study was less than 0.2%.

Etoricoxib shown good solubility in 0.1N HCl (0.3254±0.0011 µg/ml) and water (0.2125±0.0021 µg/ml). The solubility of Etoricoxib was found to be 0.2121±0.0023, 0.1255±0.0051 and 0.1847±0.0065 µg/ml in pH 4.5 Acetate buffer, pH 6.8 Phosphate buffer and pH 7.4 Phosphate buffer respectively. These details were shown in figure 1.

The solubility data indicates that drug has very poor solubility.

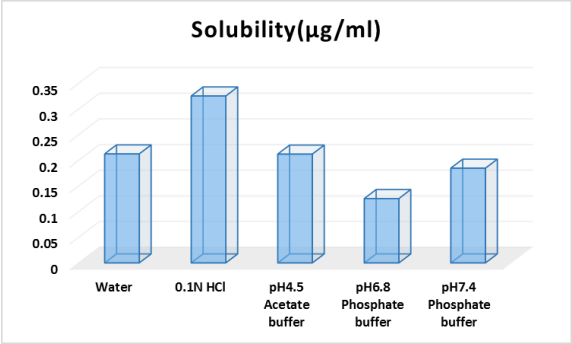

Figure 1: Solubility of Etoricoxib at various media

The prepared solid dispersions were evaluated for flow properties, they shown excellent to good flow properties and the values were shown in table 5.

Table 5: Flow character specifications

Formulation	Flow properties				
	Angle of repose (^{0})	LBD	TBD	CI	HR
EPVP12-1	28.37±0.09	0.135±0.01	0.144±0.01	6.250±0.03	1.066±0.03
EPVP12-2	30.20±0.02	0.369±0.02	0.399±0.03	7.518±0.02	1.081±0.01
EPVP12-3	31.52±0.06	0.659±0.03	0.677±0.03	2.658±0.01	1.027±0.02
EPVP12-4	29.43±0.01	0.658±0.01	0.691±0.04	4.775±0.02	1.050±0.03
EPVP17-1	26.38±0.04	0.941±0.03	0.985±0.07	4.467±0.02	1.046±0.01
EPVP17-2	27.96±0.05	0.286±0.01	0.303±0.03	5.610±0.04	1.059±0.01
EPVP17-3	28.34±0.06	0.385±0.02	0.432±0.02	10.876±0.02	1.122±0.03
EPVP17-4	32.26±0.05	0.365±0.02	0.401±0.03	8.977±0.02	1.098±0.01
EPVP25-1	33.50±0.06	0.285±0.01	0.298±0.01	4.362±0.03	1.045±0.03
EPVP25-2	29.15±0.03	0.654±0.03	0.668±0.04	2.095±0.01	1.021±0.02
EPVP25-3	29.30±0.04	0.256±0.01	0.287±0.01	10.801±0.07	1.121±0.03
EPVP25-4	28.05±0.06	0.748±0.02	0.795±0.02	5.911±0.045	1.062±0.03
EPVP30-1	26.37±0.09	0.458±0.01	0.521±0.03	12.092±0.02	1.137±0.01
EPVP30-2	31.24±0.06	0.136±0.01	0.142±0.01	4.225±0.03	1.044±0.01
EPVP30-3	30.56±0.08	0.195±0.01	0.213±0.01	8.450±0.02	1.092±0.04
EPVP30-4	29.49±0.06	0.358±0.02	0.385±0.03	7.012±0.02	1.075±0.03
EPVP90-1	29.37±0.08	0.365±0.01	0.407±0.02	10.319±0.05	1.115±0.03
EPVP90-2	28.95±0.06	0.458±0.02	0.489±0.03	6.339±0.02	1.067±0.01
EPVP90-3	29.36±0.07	0.526±0.04	0.536±0.03	1.865±0.01	1.019±0.01
EPVP90-4	32.65±0.05	0.956±0.07	0.978±0.03	2.249±0.02	1.023±0.03
LBD- Loose Bulk Density; TBD- tapped Bulk density; CI- Carr's Index; HR- Hausner's ratio; All values mentioned as mean ±SD; number of trials (n=3)					

Table 6: Physical Characteristics of Prepared solid dispersions

Formulation	Physical parameters						
	Thickness (mm)	Hardness (cm^2)	Uniformity of weight (mg)	Friability (%)	Disintegration time (min)	Yield (%)	Assay (%)
EPVP12-1	4.51±0.04	4.9±0.09	253.1±1.59	0.56±0.02	5.23±0.04	95.3±0.08	99.9±0.35
EPVP12-2	4.53±0.05	5.2±0.01	254.3±0.54	0.72±0.01	6.35±0.02	92.0±0.15	96.2±0.65
EPVP12-3	4.50±0.04	8.3±0.05	255.7±0.08	0.78±0.05	4.52±0.02	96.1±0.63	98.1±0.15
EPVP12-4	4.51±0.02	5.3±0.02	255.2±2.51	0.95±0.03	8.25±0.01	97.4±0.85	100.1±0.24
EPVP17-1	4.50±0.01	4.5±0.07	250.4±0.25	0.51±0.05	2.15±0.04	99.2±0.96	99.2±0.81
EPVP17-2	4.50±0.01	5.2±0.01	250.9±0.07	0.60±0.04	5.63±0.02	96.5±0.22	98.4±0.65
EPVP17-3	4.51±0.02	5.3±0.01	252.6±1.03	0.53±0.01	5.23±0.05	98.3±0.58	99.2±0.61
EPVP17-4	4.53±0.04	5.3±0.02	250.8±0.11	0.55±0.01	6.35±0.01	96.5±0.22	100.1±1.08
EPVP25-1	4.50±0.03	4.5±0.06	250.5±0.65	0.35±0.04	4.52±0.05	99.2±0.95	97.8±0.58
EPVP25-2	4.51±0.01	6.2±0.04	250.4±1.84	0.15±0.05	8.25±0.07	97.5±0.36	95.5±0.65
EPVP25-3	4.50±0.02	6.3±0.05	251.9±0.09	0.59±0.02	2.15±0.04	94.8±0.74	98.0±0.81
EPVP25-4	4.50±0.01	5.3±0.05	252.2±0.41	0.25±0.01	5.63±0.01	96.3±0.95	100.8±2.29
EPVP30-1	4.51±0.02	4.5±0.02	251.8±3.32	0.51±0.04	5.23±0.05	95.2±0.16	97.3±0.54
EPVP30-2	4.53±0.07	9.2±0.08	252.3±0.66	0.82±0.05	6.35±0.01	92.1±0.05	96.6±0.58
EPVP30-3	4.50±0.04	6.3±0.05	251.2±1.95	0.53±0.01	4.52±0.04	91.8±0.09	97.0±0.84
EPVP30-4	4.51±0.02	7.3±0.04	250.2±0.85	0.65±0.05	8.25±0.02	97.0±0.80	96.0±3.21
EPVP90-1	4.53±0.04	4.5±0.01	250.4±0.26	0.52±0.01	2.15±0.04	92.5±0.81	99.0±2.29
EPVP90-2	4.50±0.01	7.2±0.02	251.6±1.57	0.84±0.07	5.63±0.03	91.8±0.67	100.5±0.51
EPVP90-3	4.51±0.04	6.3±0.01	250.6±0.68	0.75±0.02	5.23±0.05	97.9±0.99	97.2±0.95
EPVP90-4	4.53±0.04	5.3±0.05	252.1±0.39	0.74±0.04	6.35±0.01	96.3±1.24	96.8±2.58
All values mentioned as mean ±SD; number of trials (n=3)							

Evaluation of Solid Dispersions of Etoricoxib Results

The prepared tablets were found to have uniform in size, shape, off white in colour, odourless with smooth surface.
The prepared tablets were found to have uniform thickness (4.5 mm) and weight. The loss on friability was less than 1% and the hardness was more than 4 Kg/cm^2 indicating that the prepared tablets having good mechanical strength. The uncoated tablets disintegrated within 15 min, the yield was found to good (>90%) and the drug content was also found to be uniform. These values were tabulated in table 6.

Solubility Studies of Etoricoxib Solid Dispersions Results

The solubility of prepared tablets was found good in 0.1N HCl and distilled water. These values were shown in figure 2 to 6
All the Etoricoxib solid dispersions batches with PVP K-12 showed good solubility in 0.1 N HCl (up to 0.49±0.01 µg/ml) and in distilled water (up to 0.58±0.02 µg/ml). Drug solubility in these batches were shown in figure 2.

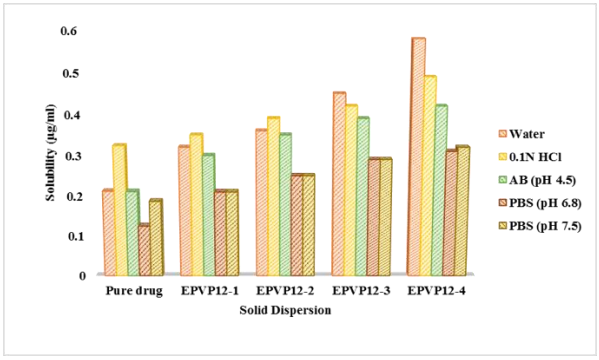

Figure 2: Solubility of Etoricoxib and solid dispersions with PVP K-12 in various media

All the Etoricoxib solid dispersions batches with PVP K-17 showed good solubility in 0.1 N HCl (up to 0.51±0.01 µg/ml) and in distilled water (up to 0.51±0.01 µg/ml). Drug solubility in these batches were shown in figure 3.

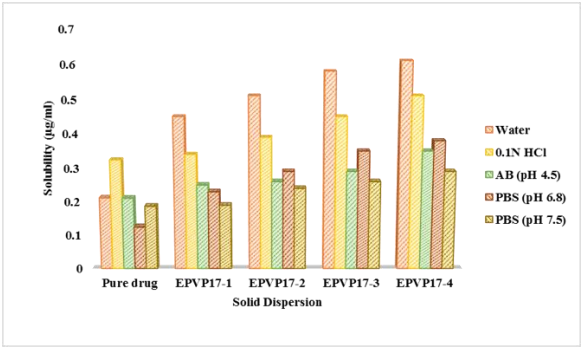

Figure 3: Solubility of Etoricoxib and solid dispersions with PVP K-17 in various media

All the Etoricoxib solid dispersions batches with PVP K-25 showed good solubility in 0.1 N HCl (up to 0.66±0.01 µg/ml) and in distilled water (up to 0.68±0.01 µg/ml). Drug solubility in these batches were shown in figure 4.

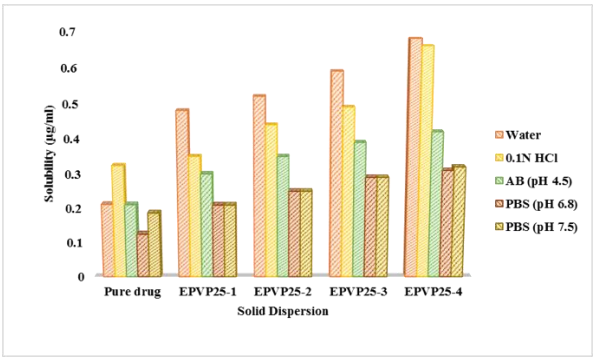

Figure 4: Solubility of Etoricoxib and solid dispersions with PVP K-25 in various media

All the Etoricoxib solid dispersions batches with PVP K-30 showed good solubility in 0.1 N HCl (up to 0.59±0.03 µg/ml) and in distilled water (up to 0.52±0.02 µg/ml). Drug solubility in these batches were shown in figure 5.

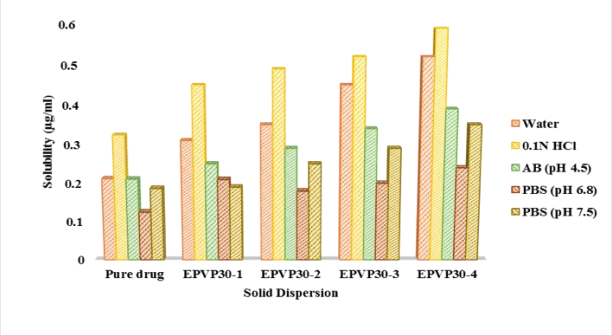

Figure 5: Solubility of Etoricoxib and solid dispersions with PVP K-30 in various media

All the solid dispersions batches of PVP K-90 showed good solubility in 0.1 N HCl (up to 0.56±0.03 µg/ml) and in distilled water (up to 0.45±0.02 µg/ml). Drug solubility in these batches were shown in figure 6.

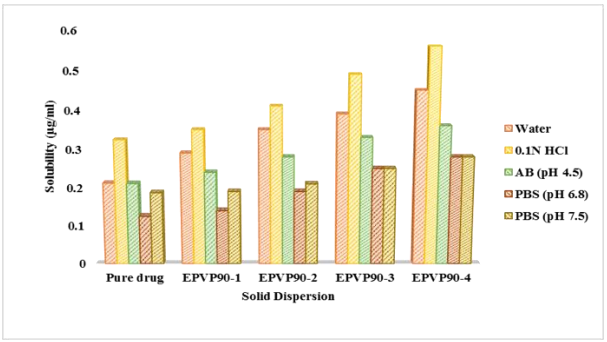

Figure 6: Solubility of Etoricoxib and solid dispersions with PVP K-90 in various media

Calibration Curve of Etoricoxib

The calibration curve of Etoricoxib was shown in table 7 and shown figure 7.

Table 7: Concentration vs. absorbance values for the estimation of Etoricoxib

Concentration (µg/ml)	Absorbance
2	0.125±0.0013
4	0.318±0.0011
6	0.473±0.0052
8	0.668±0.0013
10	0.851±0.0062
All values mentioned as mean ±SD; number of trials (n=3)	

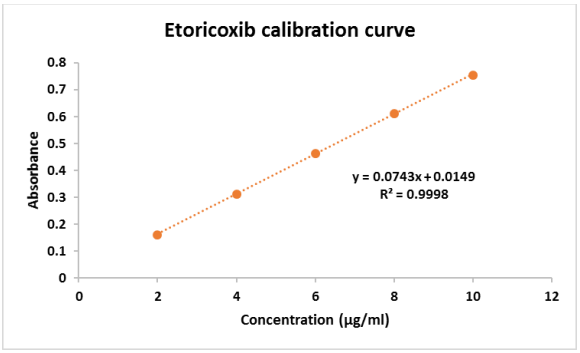

Figure 7: Calibration curve for the estimation of Etoricoxib

Dissolution Data of Etoricoxib from PVP Solid Dispersions

The dissolution of prepared tablets was found good in EPVP17 shown in figure 8 to 12.

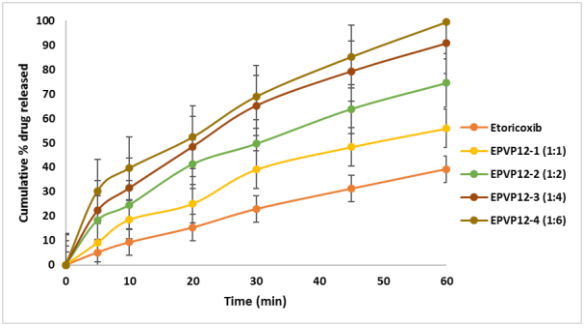

Figure 8: In vitro drug dissolution plots of Etoricoxib and PVP K-12 solid dispersions

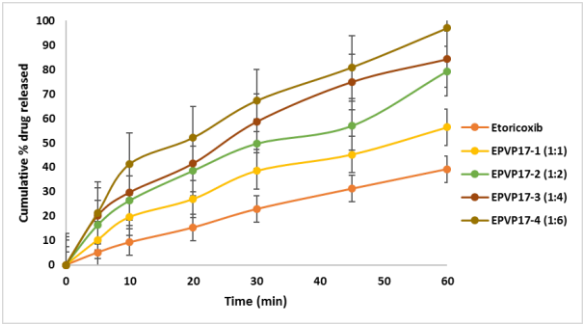

Figure 9: In vitro drug dissolution plots of Etoricoxib and PVP K-17 solid dispersions

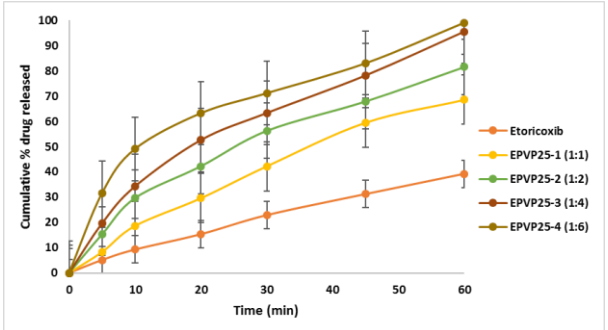

Figure 10: In vitro drug dissolution plots of Etoricoxib and PVP K-25 solid dispersions

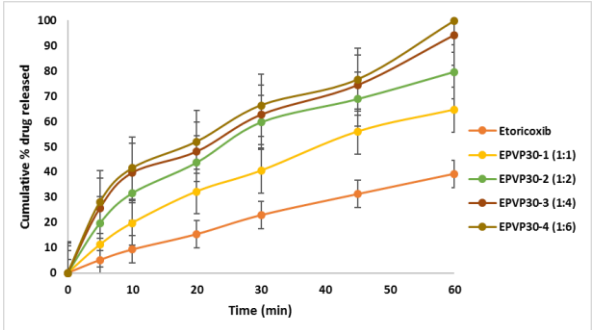

Figure 11: In vitro drug dissolution plots of Etoricoxib and PVP K-30 solid dispersions

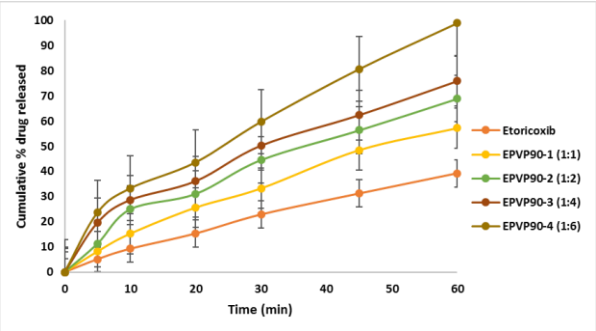

Figure 12: In vitro drug dissolution plots of Etoricoxib and PVP K-90 solid dispersions

Kinetic Modeling of Drug Release

The formulations which shown good drug release pattern (EPVP12-4, EPVP17-4, EPVP25-4, EPVP30-4 and EPVP90-4) were further studied mathematically by release rate kinetics. The correlation (R^2) values (table 8) from the different kinetics equation, the drug release from the prepared solid dispersions was found to follow different models but the best fit model was selected i.e., First order and Hixson Crowell's plots. The plots were shown in figure 13 and 14.

Table 8: Correlation coefficients (R) for different release kinetics of Etoricoxib solid mixtures

Formulation	Correlation (R^2)		
	Zero order	First order	Hixson Crowell's
EPVP12-4	0.9893	0.9776	0.9927
EPVP17-4	0.9611	0.9902	0.9853
EPVP25-4	0.9504	0.9891	0.9753
EPVP30-4	0.9814	0.9929	0.9872
EPVP90-4	0.9976	0.9588	0.9789

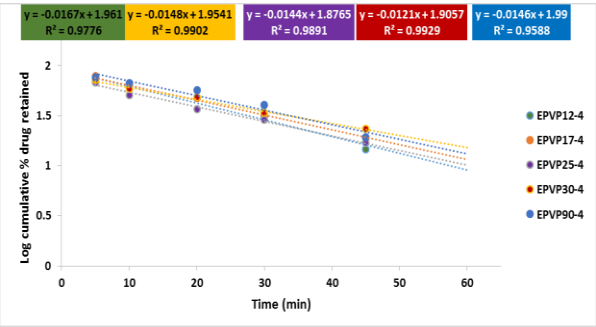

Figure 13: First order plots for EPVP-4 tablets

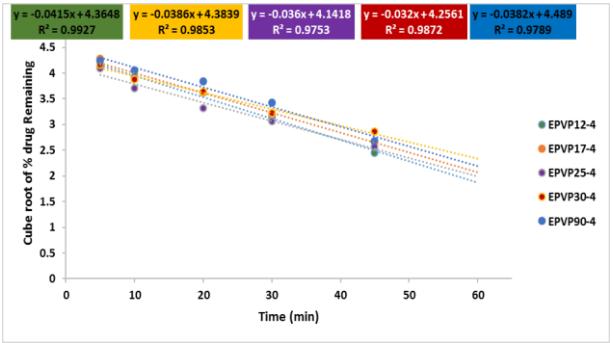

Figure 14: Hixson Crowell's plots for EPVP-4 tablets

Accelerated Stability Studies of Solid Dispersions of Etoricoxib

Accelerated stability studies was performed for optimized formulations EPVP17-4 by exposing it to 40°C/75% RH for Six months and analyzed the sample at the interval of 0, 30,60,90 and 180 days. The sample was analyzed for drug content, hardness and cumulative percentage drug release. The prepared tablets retain their physical characteristics even after stressed storage conditions.

CONCLUSION

This investigation in finding best Poly Vinyl Pyrrolidone for preparing solid dispersions by taking Etoricoxib as model drug. The formulation EPVP-4 in the ratios 1: 6 was found to have good solubility and drug dissolution characteristics. And among the PVP K-12, PVP K-17, PVP K-25, PVP K-30 and PVP K-90, Poly Vinyl Pyrrolidone 17 was found to be best PVP among the tested.

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