

Formulation and Evaluation of Fast Disintegrating Tablet of Solid Dispersion of Rifaximin- A Research

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ABSTRACT

The aim of the present study was to formulate and evaluate fast disintegrating tablets of solid dispersions of Rifaximin. The solid dispersions of Rifaximin were prepared using PEG 6000 and PVP K30 in ratios of 1:1, 1:2, and 1:3 by the solvent evaporation method. These solid dispersions were then analyzed using Fourier Transform Infrared Spectroscopy (FTIR) there no drug an polymer interaction. The results showed that the solid dispersions had a better dissolution profile compared to the pure drug, with Formulation FD3 demonstrating the highest drug release of 96.6% in 40 minutes. Therefore, FD3 was selected as the optimized formulation for the preparation of fast disintegrating tablets of Rifaximin. For the tablet formulation, Croscarmellose Sodium and Crosspovidonewere used as disintegrants, and the tablets were prepared by the directcompression method. The post-compression parameters of all the prepared tablets were within acceptable limits. Formulation F3 was selected as the optimized formulation based on its excellent disintegration time and drug release of 95.8% in40 minutes.

KEYWORDS : Rifaximin, Solvent evaporation method, Solid dispersion, Solubility,

organisms. Rifaximin is primarily used for treating irritable bowel syndrome (IBS), reducing the recurrence of hepatic encephalopathy in adults, and treating Traveler'sdiarrhea caused by Escherichia coli. Rifaximin's mechanism of action involves binding to the beta subunits of microbial RNA polymerase, which inhibits transcription and RNA synthesis, thereby preventing bacterial growth. According to the Biopharmaceutical Classification System (BCS), rifaximin is classified as a Class IV drug, meaning it has both low solubility and bioavailability. To improve the solubility of rifaximin, solid dispersion techniques are often employed. Solid dispersions are an effective approach to enhancing the solubility of poorly soluble drugs.

Solid dispersion refers to the process where one or more active pharmaceutical ingredients (APIs) are dispersed in an inert carrier in the solid state. This method has been widely recognized for improving the solubility and bioavailability of drugs that are not easily soluble. As defined by Chiou and Riegelman, solid dispersions are created by dissolving the drug in a solvent, which is then combined with an inert solid carrier.

In the present study, Rifaximin solid dispersions were formulated using two different methods: co-grinding and solvent evaporation, in varying ratios. These techniques aimed to enhance the dissolution rate of Rifaximin. Hydrophilic polymers, such as Polyethylene Glycol 6000 (PEG 6000) and Polyvinyl Pyrrolidone K30 (PVP K30), were chosen as carrier substances due to their well-documented ability to increase the solubility of poorly soluble drugs. After preparing the solid

I. INTRODUCTION^{1,2,3}

Rifaximin is a semi-synthetic antibiotic derived from the rifamycin family, known for being water-insoluble and non-systemic. This means that it has minimal absorption in the gastrointestinal tract, yet still maintains strong antibacterial activity. The drug offers broad-spectrum coverage, working against both Gram-positive and Gram-negative bacteria, as well as aerobic and anaerobic

dispersions, the next step was to convert them into fast disintegrating tablets. Fast disintegrating tablets are designed to rapidly break down once they are placed in the mouth, allowing the drug to dissolve and be absorbed quickly in the gastrointestinal tract. To do this, the solid dispersion blend was combined with excipients that promote rapid disintegration, such as super disintegrants Crospovidone or croscarmellose sodium. These excipients help the tablets break apart quickly upon contact with moisture. Additional ingredients, such as Microcrystalline cellulose, were used to adjust the volume of the tablet and ensure its stability.

The powder mixture blend was then compressed into tablets using a tablet press. The compression force was optimized to create a porous structure, ensuring that the tablets would disintegrate rapidly and promote quick dissolution of the drug. After the tablets were formed, their disintegration time, dissolution profiles, and drug content were evaluated to assess their performance. The goal was to enhance Rifaximin's solubility and provide a fast onset of action due to the rapid disintegration and dissolution.

This study aimed to investigate the dissolution of Rifaximin from the solid dispersion formulations and further characterize them using techniques such as infrared spectroscopy, drug content analysis, and in vitro release studies. Ultimately, the research sought to optimize Rifaximin's formulation for improved therapeutic outcomes and better patient compliance, particularly through the use of fast disintegrating tablets. This study aims to optimize the formulation for better therapeutic outcomes and enhanced patient compliance.

II. MATERIALS & METHODS

Materials

The materials employed in this study were procured from several suppliers. The pure Rifaximin drug was kindly provided as a gift sample by Hetero Labs in Hyderabad, India. Polyethylene Glycol 6000 was obtained from LobaChemiePvt. Ltd. in Mumbai, India, while Polyvinyl Pyrrolidone K30 was supplied by Indian Research Products in Chennai, India. Croscarmellose Sodium was provided by Amster Microcell Pvt. Ltd. in India, and Crospovidone was sourced from CrospovidonePvt. Ltd. in India. Microcrystalline Cellulose was supplied by both Maple Biotech Pvt. Ltd. in Pune, India, and Signet Chemical Corporation Pvt. Ltd. in India. Magnesium Stearate was purchased from S.D. Fine Chem Ltd. in Mumbai, India, and Talc was supplied by Emcure Pharmaceutical Ltd. in India. All other chemicals used in the study were of analytical grade.

Method

PREPARATION OF SOLID DISPERSION

Preparation of Solid dispersions by Solvent evaporation method^{4,5}

The calculated amount of Rifaximin and the employed polymers (Polyethylene glycol 6000, Polyvinyl pyrrolidone K30) in the ratio (1:1, 1:2, 1:3) were prepared by solvent evaporation method. Weighed accurately drug and polymer mixed together in a porcelain dish. Different formulations were prepared using the polymers. The mixture was dissolved in the least amount of dimethyl sulfoxide (DMSO) as a common solvent. Then the solvent was evaporated in oven at temperature 50°C upto 24 hours till completed evaporation. The solid dispersion prepared were pulverized in a motor and sieved and the fraction of the powder that pass through 45µm was stored in desiccator and used for further investigation. Table 1

Table 1: Formulation of Drug and Polymer using by Solvent Evaporation Method

Formulation	Composition	Ratio
FD1	Rifaximin+ PEG 6000	1:1
FD2	Rifaximin+ PEG 6000	1:2
FD3	Rifaximin+ PEG 6000	1:3
FD4	Rifaximin+ PVP K 30	1:1
FD5	Rifaximin+ PVP K 30	1:2
FD6	Rifaximin+ PVP K 30	1:3

EVALUATION OF SOLID DISPERSION

The solid dispersion of Rifaximin were prepared and then evaluation parameter such as solubility study, percentage yield, drug content, dissolution study.

Physical Appearance⁶

The physical appearances is one of basic inspection of solid dispersion. All the batches of drug and polymer solid dispersions were evaluated for colour and appearance.

Solubility study

Solubility of pure drug and solid dispersions prepared by Solvent evaporation method has been studied. The amount of solid dispersion powder containing 5 mg equivalent Rifaximin weighed accurately in volumetric flask and dissolved sonication in 10 ml distilled water for 15 min. The solution was filtered using Whatman filter paper No. 40, and the filtered solution was then appropriately diluted with distilled water. The solid dispersion was analysed spectrophotometry at 440 nm. The measurement of solubility shown in Table 4

Drug Content

Weighed accurately 100 mg of formulation blend was taken into a 50ml volumetric flask and dissolve into a 40 ml of Phosphate buffer pH 6.8(Solvent). the solution was made up to volume with solvent. The solution was the suitable diluted with Phosphate buffer pH 6.8 and assayed for drug content using the UV spectrophotometric method at 440 nm.

In Vitro release studies⁷

In vitro dissolution studies were carried out on the Rifaximin solid dispersions, prepared using the solvent evaporation method, and were subjected to release testing. The in vitro drug release studies under the following conditions: the dissolution process was carried out using an Electro Lab USP Dissolution Test Apparatus. The paddle type apparatus was employed, and the temperature was maintained at $37 \pm 0.1^\circ\text{C}$. The rotation speed (RPM) was set to 50. The dissolution medium used phosphate buffer pH 6.8, with a total volume of 900 ml. Samples were withdrawn at regular intervals every 5 minutes, up to 45 hours. A sample volume of 5 ml was taken at each interval and replaced with an equal volume (5 ml) of distilled water to maintain the constant volume in the apparatus.

Infra-red spectrum⁸

Infra-red studies were conducted by the drug and polymer used in formulation of Rifaximin solid dispersion by potassium bromide disc method using Infrared spectrophotometer.

FORMULATION OF FAST DISINTEGRATING TABLET OF RIFAXIMIN SOLID DISPERSION

After evaluation of Rifaximin solid dispersion (Blend) prepared by Solvent evaporation method. The fast disintegrating tablets were prepared by using solid dispersion F3 formulation of fast disintegrating tablet in given Table 2

Table 2: Formulation of Fast Disintegrating Tablet of Rifaximin solid dispersion

Ingredients	F1	F2	F3	F4	F5	F6
solid dispersion complex (Equivalent to 50 mg)	100	100	100	100	100	100
Crosspovidone	25	30	35	-	-	-
Crosscarmellose sodium	-	-	-	25	30	35
Microcrystalline Cellulose	65	60	55	65	60	55

Magnesium Sterate	5	5	5	5	5	5
Talc	5	5	5	5	5	5
TOTAL	200	200	200	200	200	200

EVALAUTION OF BLEND OF FAST DISINTEGRATING TABLETOF RIFAXIMIN SOLID DISPERSION

The powder blend was evaluated for micrometric properties; the parameter like Angle of repose, Bulk density, Tapped density, Compressibility Index and Hausner ratio was evaluated and was shown in Table 8

Angle of repose

The angle of repose is the maximum angle at which a pile of powder can remain stable without the particles sliding off. It gives an indication of the flowability of a powder; a lower angle typically indicates better flow properties.

Angle of repose (θ) = Tan⁻¹ (h/r)

Bulk density

Bulk density refers to the mass of the powder per unit volume, which includes the spaces between the particles. It is used to evaluate the packing characteristics of powders.

Bulk Density = Weight of the powder/ Volume of the powder

Tapped density

Tapped density is the maximum volume a powder can occupy after being subjected to tapping or vibration, which eliminates air gaps between the particles. It is a measure of how compact the powder can become.

Tapped Density = Weight of the powder/ Tapped volume of the powder

Compressibility Index

The Compressibility Index is a measure of a powder's ability to reduce in volume under pressure. It gives an indication of the flowability and potential for compaction of a powder. A higher value indicates poor flowability, while a lower value indicates better flow.

Carr's Index (%) = Tapped Density- Bulk Density/ Tapped Density x 100

Hausner's ratio

Hausner's Ratio represents the relationship between tapped density and bulk density. It provides insight into the cohesiveness and flow properties of the powder. A higher Hausner's Ratio indicates poor flowability, and a lower value suggests good flow properties.

Hausner's ratio =Tapped Density/ Bulk Density

PREPARATION OF FAST DISINTEGRATING TABLET OF RIFAXIMN CONTAING SOLID DISPERSION BY DIRECT COMPRESSION METHOD

Accurately weighted 100 mg of powder blend was homogeneously mixed and was fed manually and compression with constant compression force and hardness on stations table compression machine with 8mm breakthrough, and flat faced punched on RIMEK MINIPRESS-IIMT. Total 6 formulation were prepared the results shown in Table 9

EVALUATION OF FAST DISINTEGRATING TABLET

Appearance

Appearance refers to the visual characteristics of a tablet or dosage form. It includes factors such as colour, shape, size, and surface texture. Appearance through visual inspection based on defined standards or specifications.

Thickness

Thickness refers to the vertical dimension of a tablet, Three tablets were selected randomly from each batch and thickness was measured by using verniercaliper.

Hardness

Hardness is the amount of force needed to fracture a tablet. The tablet crushing strength the force required to break a tablet in a diametric compression was measured by using Pfizer hardness tester. For the each formulation, the hardness of 6 tablets was determined using the

Pfizer hardness tester. The tablet is placed between two jaws of the tester. At this stage, the reading should be zero kg/cm². A constant force is then applied by turning the knob until the tablet fractures, and the value at this point is recorded in kg/cm².

Friability

Friability refers to the tendency of a tablet to crumble or break when subjected to mechanical stress. The friability test was determined by using Roche Friabilator. This device subjects the tablets to the combined effect of abrasions and shock in a plastic chamber revolving at 25 rpm and roping the tablets height of 6 inches in each revolution.

Pre weighed the sample of tablets was placed in friabilator and were subjected to 25 revolutions. Tablets were dedusted using a soft muslin cloth and reweighed, the friability (F) is given by the formula.

$$\text{Friability (\%)} = \frac{\text{Initial wt} - \text{Final wt}}{\text{Initial wt}} \times 100$$

Content uniformity

Content uniformity tests the consistency of the API (Rifaximin) in individual tablets. 20 tablets were finely powdered and weight equivalent to 25 mg of Rifaximin was dissolved in 100 ml of pH6.8 Phosphate buffer and assayed for drug content using UV-Visible spectrophotometer at 440 nm

Weight variation

Twenty tablets were randomly selected from the batch and individually weighted. The average weight and standard deviation of 20 tablets were calculated. The batch passes the test for weight variation test if not more than two of the individual tablets weight deviation from the average weight.

$$\text{Weight Variation (\%)} = \frac{W_{\text{tablet}} - W_{\text{avg}}}{W_{\text{avg}}} \times 100$$

Disintegration time

The disintegration time of tablet was determined by using Disintegration test apparatus. Tablets were placed in disintegration test assembly and disc was placed on the tablet in each glass tube of assembly. The assembly was dipped in a vessel containing 900 ml pH 6.8 Phosphate buffer at 37°C (± 1°C). The disintegration time was recorded as the time taken for the tablet residue to disappear above the mesh.

In vitro Dissolution

In vitro drug release studies were carried out using USP Type II Dissolution test apparatus set with a paddle speed of 50 rpm. Dissolution was performed in 900 ml of Phosphate buffer pH 6.8 maintained at 37°C (±0.5°C). The tablet of Rifaximin was taken in a vessel of dissolution apparatus, the paddle was rotated at 50 rpm. The 5ml sample was withdrawn at predetermine time interval and an equivalent amount of fresh dissolution fluid equilibrated at the same temperature was replaced and the sample was diluted suitably with dissolution medium. The solution was passed through Whatman filter paper. The filtrate was analysed by UV-Visible spectrophotometer. Three trials for each batch were performed and average percentage drug release was determined and shown in figure 2

III. RESULTS AND DISCUSSION

Physical Appearance

All formulation of Rifaximin solid dispersion were evaluated based on the colour and appearance. The physical appearance of each formulation is shown in Table 3

Table 3: Physical Appearance of Formulations Drug and Polymer

Formulations	Physical Appearance	
	colour	Appearance
FD1	Off- White	Powder
FD2	Off-White	Powder
FD3	Off-White	Powder

FD4	Off-White	Powder
FD5	Off-White	Powder
FD6	Off-White	Powder

Solubility study of Solid Dispersion

Solubility study of various formulation of Rifaximin soli dispersion prepared by Solvent

evaporation method was performed and shown in table 4

Table 4: Solubility study of Solid Dispersion

Formulations Code	Drug: Carrier	Solubility (mg/10ml)
Pure drug	Pure drug	1.34
FD1	Rifaximin + PEG 6000 (1:1)	11.81
FD2	Rifaximin + PEG 6000 (1:2)	14.81
FD3	Rifaximin + PEG 6000 (1:3)	19.87
FD4	Rifaximin + PVP K 30 (1:1)	9.46
FD5	Rifaximin + PVP K 30 (1:2)	12.21
FD6	Rifaximin + PVP K 30 (1:3)	17.39

Drug Content analysis of Solid Dispersion

The drug content of solid dispersion of Rifaximin of optimized FD3 Rifaximin+PEG 6000

(1:1) was found to be 0000%, indicating good content in solid dispersion. Table 5

Table 5: Drug Content analysis of Solid dispersion

Formulation	Drug Content %
FD1	90.50%
FD2	92.10%
FD3	98.78%
FD4	85.30%
FD5	88.25%
FD6	91.00%

In Vitro Drug release Study

The dissolution study were performed pure drug and Solid Dispersion Formulation were carried out to calculated the % drug release.

1.Dissolution study of pure drug

Dissolution of pure drug in pH 6.8 Phosphate buffer were carried out and absorbance

was taken in UV-Visible spectrophotometer which reported

The percentage drug release of pure drug after 40 min was found 18.20% each reading is taken was triplicate the mean values were calculated table 6

Table 6: Dissolution Study of Pure Drug

Time (Min.)	Cumulative % drug release
0	0.00%
5	2.50%
10	4.80%
15	7.10%
20	11.50%
30	14.00%
40	18.20%

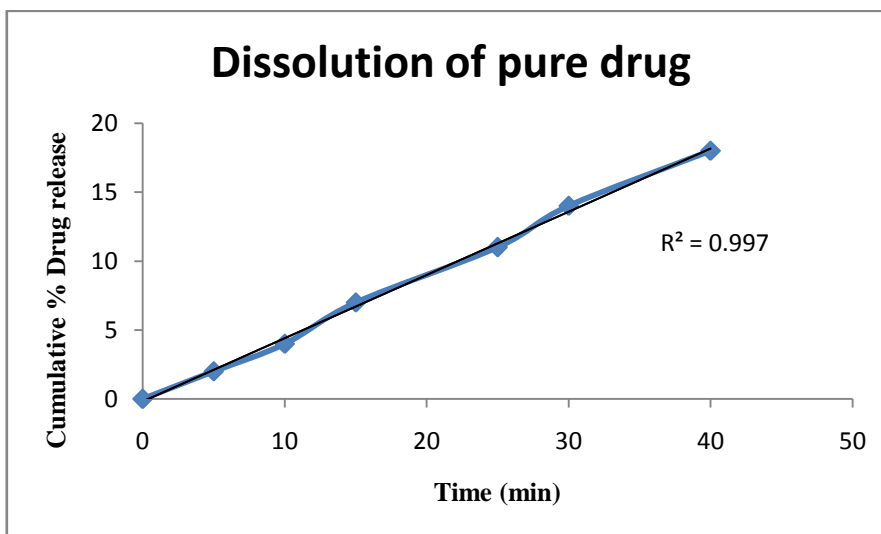


Figure 1: Dissolution profile of Rifaximin Pure drug

2.Dissolution profile of Solid Dispersion Prepared by Solvent Evaporation Method

The formulation of solid dispersion prepared by Solvent evaporation method (F1-F6) was subjected to dissolution study. The percentage

drug release of formulation is showed in table 5. And accordingly the graph was plotted to calculate the percentage drug release of formulation in pH 6.8 Phosphate buffer and it is shows in figure 2.

Table 7: Dissolution Profile of Rifaximin Solid Dispersions Prepared by Solvent Evaporation Method

Time(min)	Cumulative % Drug release					
	FD1	FD2	FD3	FD4	FD5	FD6
0	0	0	0	0	0	0
5	31.54±0.21	33.27±0.25	36.43±0.22	30.31±0.57	32.04±0.35	33.45±0.20
10	44.28±0.28	47.13±0.14	48.53±0.32	43.00±0.42	45.13±0.54	48.2±0.23
15	55.02±0.13	59.04±0.46	61.08±0.71	68.06±0.35	59.10±0.26	59.25±0.45
20	77.96±0.94	80.17±0.15	82.50±0.24	82.50±0.78	76.03±0.48	80.39±0.32
30	85.70±0.34	87.93±0.42	90.36±0.82	85.05±0.46	84.03±0.48	88.24±0.24
40	90.93±0.21	92.92±0.81	96.61±0.63	89.09±0.63	91.85±0.78	94.61±0.37

Among the six formulations, F3 exhibited the highest drug release, reaching 96.61%. Solid dispersion (FD3) of Rifaximin with PEG 6000 prepared by Solvent evaporation method showed significant improvement in solubility and dissolution rate. Increased wetting and solubilizing

effect of PEG 6000 as well as the molecular dispersion of drug in solid dispersion and alteration of surface properties of drug particle may be responsible for enhanced dissolution rate of Rifaximin from Solid dispersion compared to pure Rifaximin.

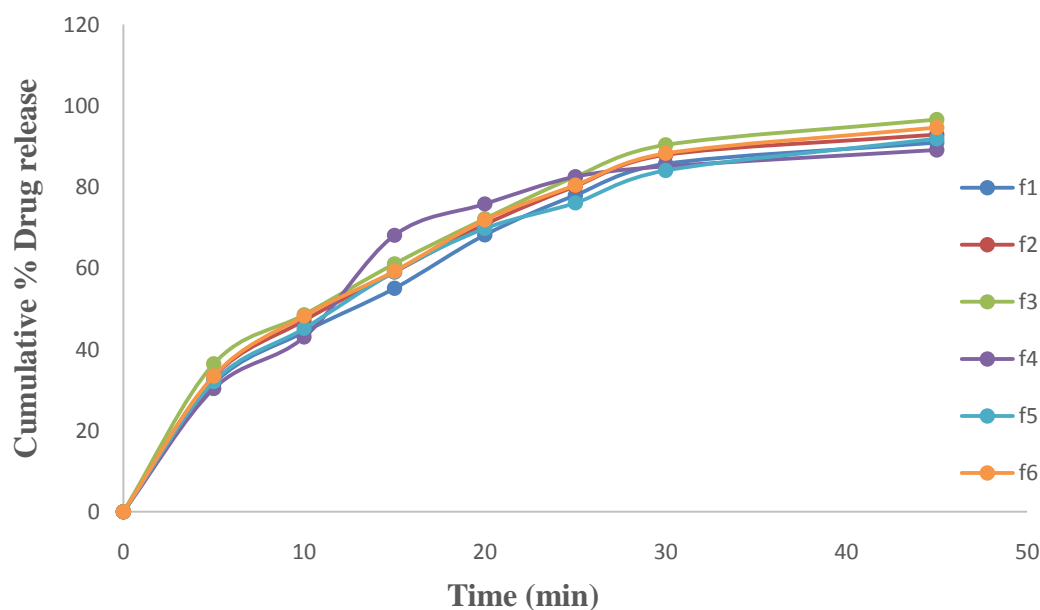


Figure 2: Dissolution profile of Solid Dispersion prepared by Solvent Evaporation Method

FT-IR Study of Solid Dispersion

The FTIR results for the Rifaximin and PEG 6000 mixture prepared using the solvent evaporation method in a 1:2 ratio show that there is no interaction between the drug and the polymer. In the FTIR spectrum of pure Rifaximin, we can see specific peaks at 1725 cm⁻¹ (indicative of C=O stretching), 1600 cm⁻¹ (indicating C=C stretching), and 1250 cm⁻¹ (related to C-O stretching). Similarly, the FTIR spectrum of pure PEG6000 shows peaks at 3450 cm⁻¹ (O-H stretching), 2880 cm⁻¹ (C-H stretching), and 1100 cm⁻¹ (C-O-C stretching). When we combine Rifaximin and PEG 6000 in a 1:3 ratio through the solvent evaporation method, the resulting FTIR spectrum includes the

same characteristic peaks as those observed in the spectra of the individual components. Importantly, the positions of these peaks remain unchanged, with no significant shifts or changes in intensity. This indicates that there is no chemical interaction between Rifaximin and PEG 6000. The absence of any chemical interaction means that the physical mixture of Rifaximin and PEG6000 retains the individual characteristics of each component without forming new chemical bonds. Therefore, the solvent evaporation method used to prepare the mixture ensures that there is no drug-polymer interaction, maintaining the stability and integrity of both the drug and the polymer in the formulation. Figure 3

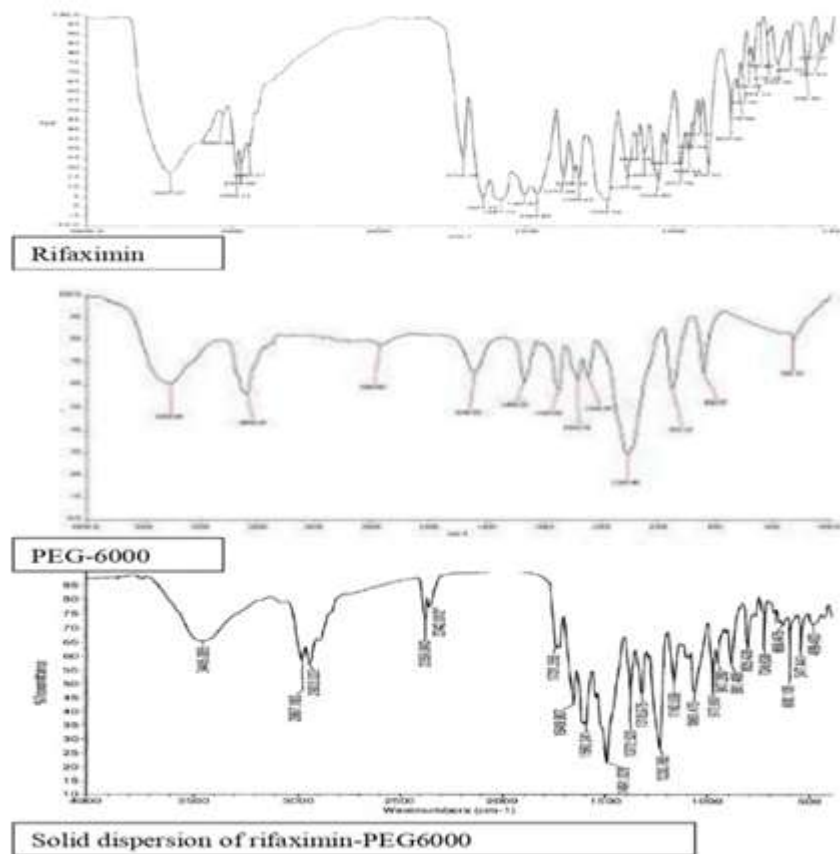


Figure 3: FTIR Studies of Solid Dispersion

EVALUATION OF FAST DISINTEGRATING TABLETS

All formulations were evaluated for various pre-compression parameter are Angle of

repose, Bulk density, Tapped density, Hauser's ratio, and Compressibility index, result as follows Table 8

Table 8: Evaluation of Tablets Blend for Fast Disintegrating Table

Formulations	Angle of response (θ)	Bulk Density (gm/ml)	Tapped Density (gm/ml)	Hausner's Ratio (HR)	Carr's Index (%)
F1	24.44 \pm 1.88	0.44 \pm 0.12	0.48 \pm 0.023	1.09 \pm 0.47	8.33 \pm 0.86
F2	22.52 \pm 0.95	0.48 \pm 0.16	0.55 \pm 0.059	1.14 \pm 0.32	12.72 \pm 0.50
F3	24.42 \pm 1.78	0.47 \pm 0.04	0.50 \pm 0.026	1.06 \pm 0.38	6 \pm 0.30
F4	23.40 \pm 1.27	0.42 \pm 0.10	0.47 \pm 0.012	1.11 \pm 0.20	10.63 \pm 0.88
F5	25.46 \pm 1.45	0.43 \pm 0.09	0.49 \pm 0.021	1.13 \pm 0.16	12.24 \pm 0.36
F6	22.43 \pm 1.18	0.45 \pm 0.12	0.50 \pm 0.021	1.11 \pm 0.22	10 \pm 0.16

Angle of repose

Table 6. Indicate the results obtained for angle of repose of all formulations. The values were found to be in the range from 23.44 θ to 25.46 θ all formulation showed the angle of repose within 30°. It indicates that all formulations showed good flow properties.

Bulk Density

Bulk density is reported in the Table 6. The bulk density of mixed varies between 0.48 to 0.42 gm/ml, it indicates good packaging capacity of tablets.

Tapped Density

The tapped density results are reporting in the Table 6. The tapped density of mixed blend in the range of 0.47 to 0.55 gm/ml, indicating good packing capacity of tablets.

Carr's Index

The percentage compressibility of powder mixture was determined. Table 6, indicates result obtained for percentage compressibility. The

percentage compressibility for all six formulation lies within the range of 8.33-12.72%. All the formulation shows good compatibility.

Hausner's Ratio

Hausner's ratio of the powder was determined from bulk density and tapped density. Hausner's ratio of all formulation in the range of 8.33-1.1. All formulation showed good flow property.

From the results of pre-compression studies of the blend from formulation F1-F6 it is concluded that all the formulations blend possesses good flow property and compressibility.

EVALUATION OF FAST DISINTEGRATING TABLETS

All formulations were subjected to post-compression evaluation in which various parameters are weight variation, thickness, hardness, friability, drug content, in vitro disintegration time, in vitro dissolution studies were evaluated. The result obtained are as follows. Table 9

Table 9: Evaluation of Fast Disintegrating Tablet

Formulations	Thickness (mm)	Hardness (Kg/ cm ²)	Friability (%)	Drug Content (%)	Weight Variation (mg)	Disintegration Time (min)
F1	2.50±0.10	3.26±0.45	0.69±0.15	92.64±0.11	199±0.93	5±1.3
F2	2.53±0.17	3.36±0.11	0.75±0.15	94.39±0.01	201±0.32	4±1.4
F3	2.55±0.25	3.22±0.15	0.79±0.18	96.92±0.15	199±0.51	3±1.2
F4	2.56±0.10	3.34±0.15	0.76±0.13	91.73±0.13	203±0.47	5±1.5
F5	2.52±0.17	3.40±0.25	0.80±0.07	95.76±0.06	201±0.85	4±1.3
F6	5.51±0.10	3.32±0.10	0.83±0.09	98.10±0.23	200±0.56	6±1.4

Thickness

The measured thickness of tablet of each batch ranged between 2.50-2.56mm. This ensure good handling and transportation of all tablets.

Weight Variations

All the formulation from (F1 to F6) tables passed weight variation test as the % weight variation was within the pharmacopeial limit of ±7.5 of the weight. The weight of all tablets were found to be uniform with low standard deviation values.

Hardness

The measured hardness of tablets of each batch ranged between 3.2 to Kg/cm². This ensures good handling and transport of all tablets.

Friability

The percentage friability was less than 1% in all formulations ensuring that the tablets were mechanically strong.

Drug Content in Fast Disintegrating Tablets

The percentages of drug content for Fast Disintegrating Tablets (FDT) for F1 to F6 were found to be between 91.73-10% of Rifaximin, it complies with official specifications.

Disintegration Time

The measured disintegration time of tablet of each batch ranged between 3 to 6 minutes. This ensures concentration of superdisintegrants increased, decreased in disintegration time. The formulation batch F3 containing crosspovidone shows less disintegration time i.e, 3 minutes. So formulation batch F3 was optimized batch.

In vitro Drug Release of Drug from Tablet

All the the six formulations were subjected from the in vitro dissolution studies using dissolution apparatus (USP). Phosphate buffer pH 6.8 was used as dissolution medium. The sample were withdrawn at different time intervals filtered, diluted and analysed at 440 nm. Cumulative % drug release was calculated on the basis of maximum amount of tablet present in respective table. The results obtained in the in vitro drug release for all formulation F1 to F6 are as follows.

Table 10: In vitro Cumulative Drug Release from Tablet

Time (Min)	Cumulative % Drug release					
	F1	F2	F3	F4	F5	F6
0	00	00	00	00	00	00
5	12.5±0.46	14.20±0.92	25.20±0.88	18.30±0.16	15.27±0.11	13.11±0.23
10	22±0.65	24.50±0.54	35.40±0.17	28.17±0.89	26.50±0.94	25.30±0.89
15	35.5±0.49	38.80±0.98	46.83±0.97	41.53±0.35	39.30±0.56	37.80±0.35
20	58.7±0.34	63.50±0.43	68±0.07	61.70±0.20	60.84±0.34	57.29±0.76
30	70.5±0.53	75.05±0.78	80.30±0.93	74.38±0.88	72.50±0.34	70.30±1.27
40	82.2±0.22	87.50±0.12	95.87±0.33	86.50±0.17	85.08±0.89	83.87±0.82

The rapid dissolution was observed in formulation F3 which was 95.87% at the end of 40 minutes. Formulations F1, F2 and F3 had shown releases 82.2%, 87.50% and 95.87% of drug

respectively at the end of 40 minutes were as formulation F4, F5 and F6 had shown release 86.50%, 85.08% and 83.87% of drug respectively at end of 40 minutes.

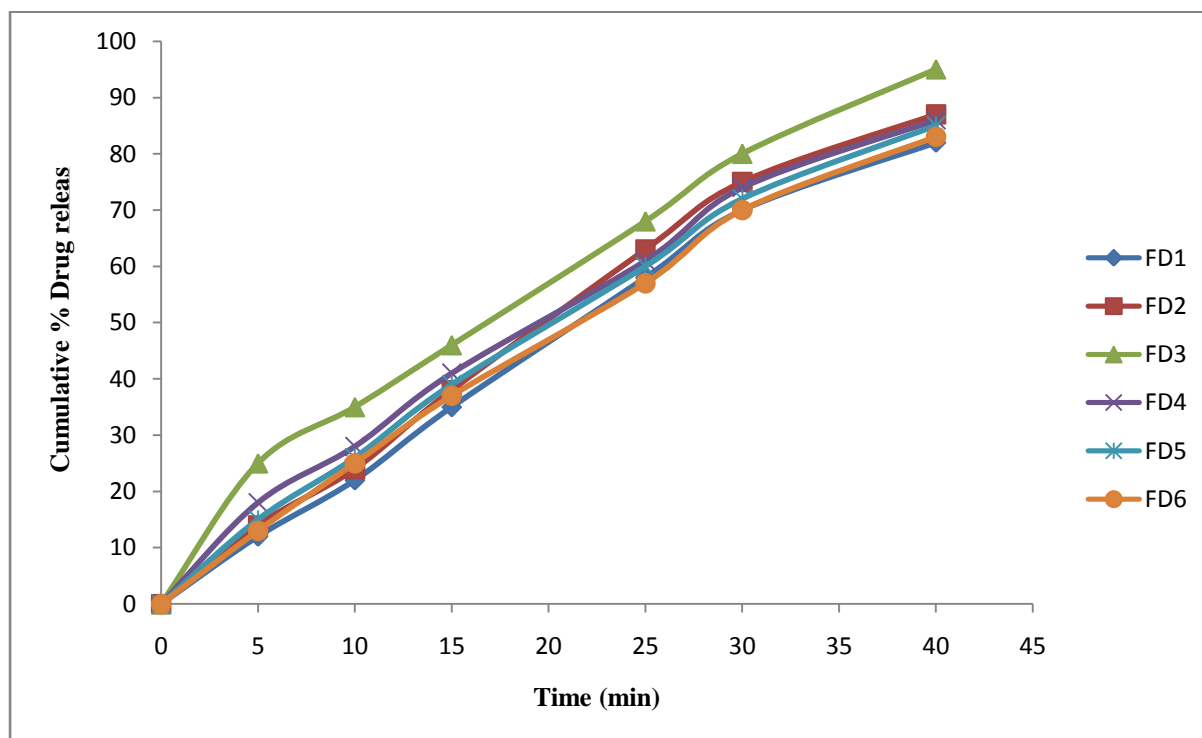


Figure 4: Cumulative % Drug Release of F1-F6 Formulations

IV. CONCLUSION

A preliminary solubility analysis was performed to select the appropriate polymer for the solid dispersion. Solid dispersions were prepared using Polyethylene Glycol 6000 (PEG 6000) and Polyvinyl Pyrrolidone K30 (PVP K30) through the solvent evaporation method. After preparation, the solubility and in vitro dissolution profiles of these solid dispersions were evaluated. Among the formulations, the solid dispersion of Rifaximin with PEG 6000 in the FD3 exhibited enhanced

solubility and a significantly improved dissolution rate compared to the others. Following this, the optimized solid dispersion blend was used to formulate fast disintegrating tablets. The prepared formulations were assessed, and Formulation F3 showed the highest performance. It provided the best dissolution rate, and the rifaximin fast disintegration tablets from this formulation demonstrated superior drug release and faster disintegration compared to all other formulations.



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