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Original Article

Use of Liquid Solid Technique for Development and Evaluation Study of Nifedipine Tablets to Enhance Dissolution Characteristics

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ABSTRACT

Objectives: The current research finding suggests dissolution enhancement of nifedipine tablets using Liquid solid technique. **Materials and Methods:** The drug's solubility in various liquid carriers has been examined, out of which drug shows maximum solubility in PEG 400 which acts non-volatile liquid solvents. The prepared mixture dissolved with Avicel PH 102 which acts as carrier and Aerosil 200 acts as coating material using formula for Liquid Load Factor (L_f). The blend is then mixed with disintegrating agent Sodium Starch Glycolate (SSG) and other excipients to make the final formulation from which tablets are prepared by direct compression method. **Results:** Different physical parameters and *in vitro* drug release of tablets were evaluated. Comparison of the FTIR spectrum of Nifedipine drugs with the FTIR spectrum physical mixtures in terms of any incompatibility inferred compatibility of that the drug and other excipients with each other. The formulation batch in F1 with 85.81±1.0% dug release occurs within 15 min of time interval indicating better drug release compared with all other batches and it continue up to 120 min showing maximum drug release. The comparison of Drug release pattern of selected Formulation batch F1 with pure drugs and marketed tablets inferred better % cumulative drug release from F1 batch. Liquisolid technique used to enhanced drug release characteristics and consequently improved oral bioavailability. **Conclusion:** So, the tablets prepared by this method can be considered as an alternative for improving dissolution of water-insoluble drugs owing to its higher wetting properties and there by greater drug availability for dissolution.

Keywords: BCS class II, Nifedipine, Liquisolid Technique, Dissolution rate, PEG 400, Liquid Load Factor.

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INTRODUCTION

Oral route is the most preferred method of drug administration[1] but several factors can impact the bioavailability of drugs, including their solubility, permeability, dissolution rate and first-pass metabolism. The solubility of a drug is a critical factor for orally administered drugs and many new drug candidates and marketed drugs have exhibited low aqueous solubility, making it a significant challenge for the pharmaceutical industry to formulate suitable system of drug delivery. So, for improving the solubility of drugs which are poorly water-soluble, various techniques, such as microencapsulation, micronization, inclusion complexation, nanosuspension and self-nano emulsions are used. However, these approaches can be costly and the preparation methods may require sophisticated machinery.[2,3]

A promising approach to address this challenge is the use of Liquisolid systems, which can enhance the dissolution rate of poorly water-soluble drugs, particularly those belonging to the Biopharmaceutical Classification System (BCS) class II and IV with poor bioavailability.[4] The Liquisolid technique encompasses the transformation of liquid medications or those in a liquid form (such as solutions, suspensions, or emulsions) into dry, non-adhesive, easily flowable and readily compressible powder blends. This is achieved by either mixing or applying a liquid dispersion onto specific powder carriers and coating materials.[5,6] Liquisolid systems allows absorption of the liquid medication into the interior framework of carriers, such as magnesium alumina Meta silicates (Neusilin) or anhydrous dibasic calcium phosphate (Fujicalin) forming a layer of liquid on the surface of carrier particles, that is then adsorbed by the fine coating materials like Aerosil 200 resulting in formation of a free-flowing and dry compressible powder. Compared to other solubility enhancement techniques, Liquisolid systems are relatively simple to prepare and may offer a cost-effective solution to enhance the solubility of poorly water-soluble drugs.[7] They have shown promising results

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in enhancing drug solubility and bioavailability and can be a valuable tool in drug formulation and delivery.

Nifedipine is a highly non-polar, calcium-channel blockers has applications in managing HTN, angina pectoris and Raynaud's phenomenon. It shows limited aqueous solubility.[8-11] It exhibits poor dissolution characteristics and its oral absorption is dissolution rate limited. So Liquisolid technique is used to enhance drug release and hence improved the oral bioavailability of drugs.

The presented study deals with the formulation, *in vitro* drug release study and study of evaluation parameters of Nifedipine tablets prepared with Liquisolid systems containing varying concentration of liquid vehicles like PEG 400 to check maximum solubility of drug. Then the liquid mixture mixed with different concentration of carrier and coating materials to formulate Nifedipine tablets using direct compression method to improve the *in vitro* dissolution rate of nifedipine tablets.

MATERIALS AND METHODS

Materials

For our research, samples were purchased from different sources. Drug Nifedipine received from S.D fine chem. Limited, solvent PEG 400 from S.D fine chem. limited. Besides coating materials microcrystalline cellulose PH 102 and core materials Aerosil 200 along with disintegrant Sodium Starch Glycolate obtained from Matrix Laboratories, Bangalore. Magnesium stearate received from the S.D fine chemicals.

Methods

Determination of Solubility

The solubility of Nifedipine was studied in liquid vehicles which act as solvents for preparing the Liquisolid systems. To determine solubility, saturated solutions of drug in solvents like water and PEG 400 were prepared by shaking on the mechanical shaker for 48 hr at 25±0.5°C under constant vibration. After that the solutions were filtered, diluted and analyzing for drug content at 324 nm spectrophotometrically.

Design of Liquisolid system and Calculation of Liquid Load Factor (L_f)

To determine the amounts of powder excipients required for the production of Liquisolid systems, a mathematical approach by *Spireas* is followed. This approach relies on the flowable and compressible characteristics of the powder excipients (∅-value) and (φ-number) respectively. The φ-number of a powder is the maximum amount of non-volatile liquid the powder can retain inside its bulk while maintaining acceptable compatibility during compression. The liquid load factor determined by formula: L_f=∅+φ(1/R) Where, ∅ and φ are the ∅-values of the carrier and coating material, respectively. From literature, the Φ- values for Avicel PH 102 and Aerosil 200 in selected non-volatile solvent PEG 400 for our study were 0.005 and 2.42 respectively.[12] Liquid load factor is also the ratio of weight of liquid medication (W) to weight of carrier material (Q). Drug solutions are made in suitable non-volatile liquid vehicles at different concentrations by adding carriers and coating materials.

$$L_f = W/Q$$

W=Weight of liquid medication Q=Weight of carrier material.

The excipients ratio (*R*) is the weight ratio of the carrier material to the coating material. The present study include excipients ratio (*R*) selected is in the range from 5 to 20. The Spireas and Bolton mathematical approach used to calculate the required amount of carrier (*Q*) and coating material (*q*) which convert required amount of drug in liquid state (W) to an acceptable flow able behaviour of blended mass.[13,14]

Formulation of Liquisolid system and Nifedipine Tablets

The present research involves formulation of nine batches of Liquisolid tablets of Nifedipine by following direct compression method. The composition of the tablets is shown in Table 1. First in non-volatile solvent system PEG 400 drug nifedipine is dispersed with different drug to vehicle ratio. The solution was mixed thoroughly until a homogenous drug solution was obtained. Then calculated quantity of carrier i.e. Avicel PH 102 and Aerosil 200 acts as coating material of required quantity is incorporated to the above mixture to make it free flowing powder. The amount of carrier and coating materials was calculated from R value. Lastly SSG which acts as disintegrating agents is added to the final powder blend and it was compressed to tablets by using 9 mm Karnavati Tablet Press Punching machine.

Compatibility Study

The drug and the excipients compatibilty can be studied using Potassium Bromide pellet method and scanned from 4000 cm^{-1} to 400 cm^{-1} using Perkin Elmer BX II (Massachusetts, USA) Spectrophotometer by applying 10kg/cm^2 using a hydraulic press.

Pre-compression parameters

Bulk density

Bulk density was determined by pouring gently 25 gm tablet blends into 100 mL graduated cylinder and the volumes occupied by the samples was recorded.

Bulk density=weight of sample in gram/volume occupied by the sample

Tapped density

To determine tapped density author follow a laboratory method by taking 25 g of powder blend in a 100 mL graduated cylinder and tapped to get tapped volume reading.[15]

Tapped density=Wt. of sample in gm/Tapped volume

Compressibility Index and Hausner's ratio

These parameters were determined by using following formula.

Compressibility Index=(ρt-ρ0)/(ρt)x100

ρ_t=tapped density, ρ_0=bulk density.

Hausenr's Ratio=Tapped Density/Bulk Density

Angle of repose

Funnel method is used to determine the angle of repose of the powder blend. Powder samples was taken in a funnel and allowed to flow through funnel. The height of pile of powder and the diameter of the pile of powder was measured. Then angle of repose was calculated by using the equation.

Tan θ=h/r

Where,

h and r are the height of pile and radius of the pile.

Angle of slide

It is a specific parameter for evaluating the flow behaviour of Liquisolid mixtures and can be determined by following a laboratory method from literature survey.[16] Angle of slide was used to evaluate the flow properties of Powder mixtures. The tested powder sample (10 g) was placed on one end of a metal plate with a polished surface. This end was gradually raised until the Plate with the horizontal surface formed an angle at which the sample was about to slide. Angle of slide corresponding to 33° is regarded as optimal flow behaviour.[17,18]

Evaluation study Nifedipine Tablets

Weight Variation

20 tablets were selected randomly from each batch and weighed. The average weight and standard deviation was calculated. The batch passes the test if the percentage difference in the weight

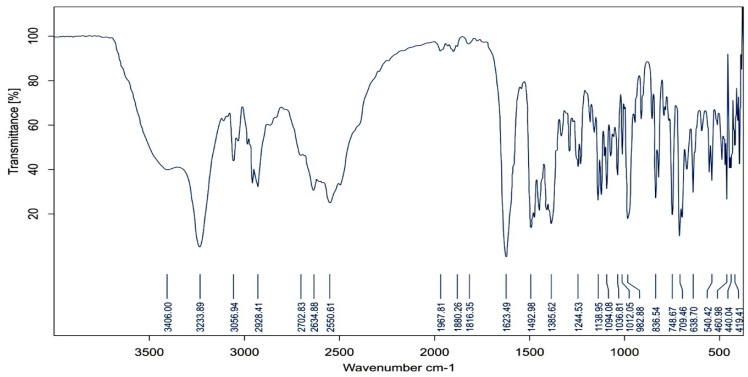

Figure 1: IR Spectrum of Nifedipine.

Table 1: Composition of Nifedipine Liquisolid Tablets.

Formulations	Drug conc .in PEG 400 (%w/w)	Avicel PH 102 (mg)	Aerosil 2 0 0 (mg)	Sodium starch Glycolate(mg)	Total Tablet weight (mg)	R (Q/q)	L_f
F1	2	300	20	40	380	15	0.2223
F2	2	250	25	40	380	10	0.331
F3	2	200	10	40	300	20	0.168
F4	4	225	55	40	330	5	0.657
F5	4	200	20	40	290	10	0.331
F6	4	250	20	40	360	5	0.657
F7	6	240	24	40	325	10	0.331
F8	6	200	15	40	330	5	0.657
F9	6	225	15	40	320	15	0.2223

Table 2: Interpretation of different functional groups of pure drug and Physical mixture prepared through Liquisolid Technique.

Presence of Functional group	IR band of pure drug in cm^{-1}	IR band of Physical mixture prepared through Liquisolid Technique in cm^{-1}
N-H aromatic	3233.89	3419.25
C-H aliphatic	2928.41	2903.56
C=O ester	1623.49	1636.48
C=C aromatic	1492.98	1456.03
C-C-O ester	1244.53	1109.54

variation should be within the prescribed limit of Official Compendia.

Hardness

It was measured by Pfizer harness tester in Kg/cm^2 for each tablet.

Friability

It was measured by friability apparatus (Roche Friabilator) which rotates at 25 rpm for 4 min and the Percent Friability (PF) was calculated using formula.

PF=(Weight original-Weight final)/Weight originalX100

Disintegration Time

Rapid tablet disintegration is necessary in tablets prepared with Liquisolid Technique for obtaining tablets quick collapse into smaller fragments to obtain the largest possible surface area accessible for dissolution media.[19] The disintegration time was noted for each batch tablets with complete disintegration.

In vitro Drug Release Studies

The *in vitro* drug release was determined using a USP-type 2 (paddle type) apparatus containing dissolution medium of 900 mL and 0.01M HCl maintaining 37±0.5°C temperature at 50 rpm. At specific time interval of (5, 10, 15, 30, 45, 60, 90 and 120 min) sample of 5 mL was withdrawn replacing equal volume of fresh media, filtered through Whatman filter paper and analysed at 324 nm wavelength using double beam UV-visible spectrophotometer (Genesis-2, USA).

RESULTS

Solubility

The drug mainly shows insoluble phenomena in water as we have found its water solubility value is 0.0089 mg/mL which is supported by similar findings reported in cited literature.[20]

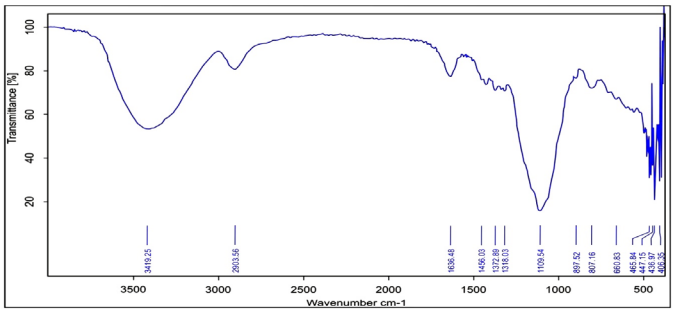

Figure 2: IR spectra of powder blend prepared through Liquisolid Technique.

Nifedipine shows maximum solubility in non-volatile solvents in PEG 400 which is about 149.65 mg/mL.[21]

Drug and Excipients Compatibility Study

Compatibility study can be done by Fourier Transform Infrared spectroscopy (FTIR) analysis to investigate the interactions that take place between Nifedipine drug sample with excipients used to formulate physical mixture for Nifedipine tablets. Figures 1 and 2 shows the FTIR spectrum of pure drug nifedipine and Physical mixture respectively. The IR interpretation of functional groups of Nifedipine drug and Physical mixture prepared through Liquisolid Technique is in Table 2. Comparison of the FTIR spectra of the powder mixtures of drug i.e. non-volatile solvents along with carrier and coating materials used in Nifedipine tablets by using Liquisolid technique and pure drugs at wavelength of (400 cm^{-1}-4000 cm^{-1}) was done. FTIR shows without any significant change in their position of peak or formation of any additional peak after successful mixing of pure Nifedipine with selected excipients.

Preformulation parameters of Different batches

Different preformulation parameters of physical mixture like Angle of repose, Bulk density, Carr's index and Hausner's ratio values are shown in Table 3. The angle of repose is less than 35° usually indicate good flow properties. The Carr's index value less than 15 and Hausner's ratio value below 1.25 for all batches indicates Liquisolid system helps in converting free flowing particles for easy manufacturing of Nifedipine tablets.

Angle of Slide

The angle of slide of slide is a parameter used for determining flow properties of Liquisolid mixtures and the results shows values lower than 33° were observed in all our formulation batches except for Batch F2 and F5 of 38° and 35° respectively which indicates inferior flow properties. The results are shown in Table 3.

Evaluation Parameters of Nifedipine Tablets of Different Batches

The results of evaluation parameters of tablets like Variation in Weight variation, tablet Hardness, Disintegration time, %

Table 3: Results of Preformulation Parameters of Different Tablet Batches.

Formulation	Angle of repose(θ)	Carr's Index (%)	Hausner's ratio	Angle of Slide(θ)
F1	27±0.21	09.68±0.3	1.17±0.11	33.00±0.98
F2	29±0.19	10.23±0.29	1.03±0.21	38.01±1.00
F3	29±0.39	13.49±0.33	1.19±0.25	34.54±1.53
F4	30±0.72	12.69±0.17	1.13±0.12	31.56±1.53
F5	29±0.76	11.34±0.21	1.18±0.16	35.67±0.98
F6	28±0.07	12.02±0.36	1.08±0.12	34.98±0.67
F7	30±0.20	09.74±0.32	1.12±0.20	29.79±1.54
F8	31±0.37	12.51±0.24	1.22±0.24	33.98±1.89
F9	30±0.75	12.07±0.31	1.19±0.11	32.79±1.76

n=5±S.D.

Table 4: Evaluation Parameters of Nifedipine tablets.

Formulations	Weight Variation (a)	Hardness (b)	Disintegration time (min)	Friability%(c)	% of Drug content (%w/w) d
F1	323±3.0	3.0±0.09	3	0.75±0.002	98.5
F2	297±2.5	4.5±0.05	5	0.69±0.043	96.2
F3	302±.91	3.0±1.01	4	0.43±0.019	92.9
F4	327±1.97	4.0±0.13	5	0.56±0.041	94.00
F5	293±2.14	4.5±0.14	3	0.87±0.012	95.9
F6	273±2.73	3.5±0.03	5	0.71±0.003	97.43
F7	315±0.43	3.0±0.01	4	0.59±0.046	92.24
F8	333±1.48	3.0±0.01	4	0.48±0.069	90.09
F9	302±0.90	3.5±0.03	5	0.52±0.081	94.89

a, d (*n*=3±S.D); b (*n*=5±S.D) and c (*n*=20±S.D).

Table 5: Results of Dissolution Study of formulations F1 to F9.

Time in min	F1	F2	F3	F4	F5	F6	F7	F8	F9
5	41.47±1.0	34.49±0.91	41.98±1.09	22.70±0.98	44.16±0.9	34.31±1.20	29.17±0.8	31.06±0.08	25.13±0.8
10	51.89±1.0	37.34±1.3	48.90±1.10	50.15±0.7	49.90±1.4	35.19±1.12	30.91±0.9	33.88±0.6	30.97±0.9
15	85.19±1.0	47.46±0.9	54.49±1.20	53.61±0.9	52.19±1.3	45.08±1.05	32.75±0.9	39.15±1.01	49.15±0.9
30	88.98±0.9	53.89±0.58	58.99±1.15	58.50±1.1	53.12±1.21	51.60±1.04	39.06±1.24	40.61±1.04	52.01±0.7
45	91.15±1.0	72.09±1.10	69.75±1.6	61.01±0.9	58.94±1.02	52.78±1.09	41.74±1.02	45.07±0.9	59.90±1.00
60	96.25±1.1	74.58±0.7	86.76±0.1	67.91±0.5	59.18±1.3	61.09±1.10	49.77±1.10	49.26±0.8	62.26±1.03
90	97.13±1.00	84.3±0.94	87.91±1.12	71.98±0.3	61.33±0.7	67.03±1.03	54.30±1.42	50.17±1.12	69.97±0.9
120	98.21±0.9	86.89±1.3	88.79±0.9	83.94±0.9	67.22±0.9	71.29±1.32	55.89±1.3	51.52±1.01	73.08±0.9

n=3±S.D; SD: Standard Deviation.

Table 6: Cumulative drug release of Batch F1 Comparison with Marketed Nifedipine Tablets and with the Pure Drugs.

Time in min	Selected Batch F1	Marketed Tablets	Nifedipine drug
0	0	0	0
5	41.47	17.98	10.87
10	51.89	35.75	11.15
15	85.19	55.16	16.21
30	88.98	61.64	18.18
45	91.15	80.66	25.49
60	96.25	84.69	31.20
90	97.13	98.14	34.95
120	98.21	101.89	57.01

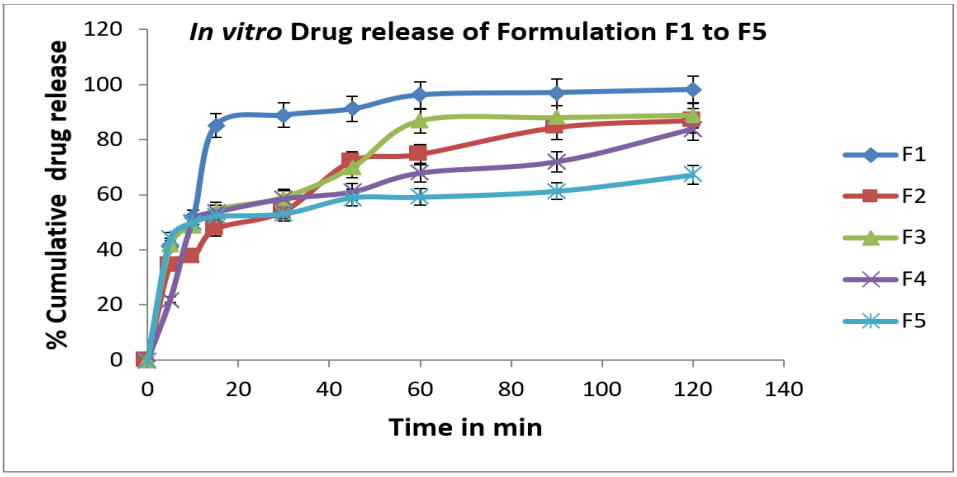

Figure 3: *In vitro* drug release pattern of Prepared Formulation Batch F1 to F5.

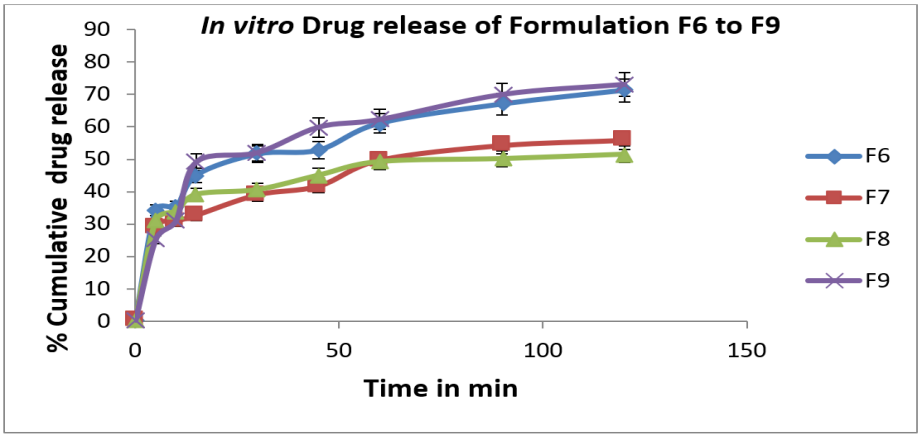

Figure 4: *In vitro* drug release pattern of Prepared Formulation Batch F6 to F9.

Friability and Percentage of drug content are shown in Table 4 and all results are within the acceptable limit as per official compendia available.

% Cumulative drug release of Prepared Batches

The *in vitro* drug release of all batches shown in Table 5 and the dissolution profiles of all nine formulation batches of nifedipine tablets prepared by Liquisolid technique shown in Figures 3 and 4.

The percentage of Drug release in batch F1 is about 85.19±1.0% within initial 15 min of time interval releasing 98±1.0% drug within 120 min indicating better drug release compared with all other batches. Formulation F2 showed 86.89% of drug release during same time. F3 shows 88.79% of drug is release, whereas Formulation F4 showed 83.94% and in batch F5 we have

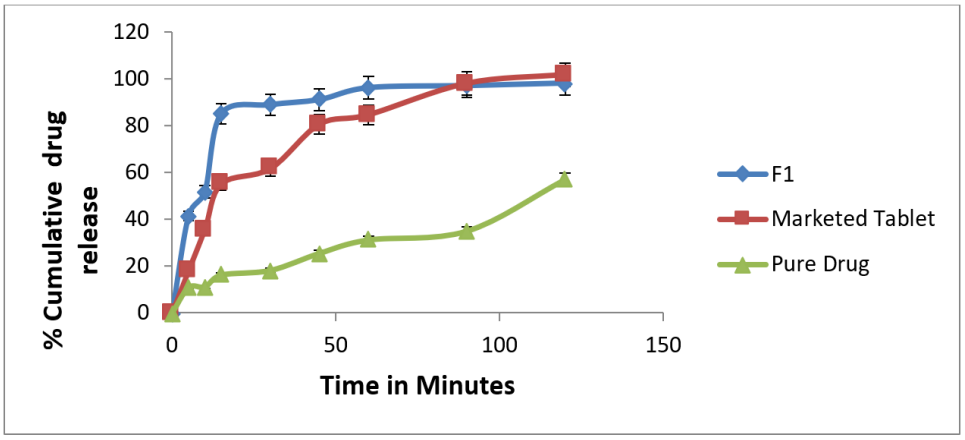

Figure 5: Comparison of Drug release profile of F1, Marketed Tablet and Pure Nifedipine Drug.

Table 7: Stability Study of Batch F1.

Sl. No.	Time in days	Percentage of Drug Release
1	Initial	98.21
2	30 days	99.67
3	60 days	97.77
4	90 days	98.17

observed 67.22% of drug release. Though in F3 and F5 shows same cumulative drug release as F1 in initial 5 min, but later on there is sharp decrease in drug release which may be due to use of low concentration of carrier Avicel PH 102 in both F3 and F5 which may decrease the drug release. Because various literature suggested the presence of carrier Avicel PH 102 which has high Specific Surface Area (SSA) about 1.18 m^2/g exhibits high liquid absorption capacity in dissolution media and hence increases drug release which is an important criteria for Liquisolid system.[22]

A drug release of 71.29% was exhibited by Formulation F6, whereas Formulation F7, F8 and F9 showed 55.89%, 51.52% and 73.08% of drug release respectively. The formulation batch F1 containing 2% of drug concentration in PEG 400 showed better drug release compared all other batches of Nifedipine Tablets because high concentration of non-volatile liquid acts as a surface-active agent and reduces interfacial tension between tablet surface and dissolution media increasing the release of drug.

DISCUSSION

In the present study, researcher has tried to improve the rate of *in vitro* dissolution of low solubility drug nifedipine prepared by Liquisolid technique.

Different preformulation parameters of physical mixture like Angle of repose, Bulk density, cars index and Hausners ratio values indicates Liquisolid system helps in converting free flowing particles for easy manufacturing of Nifedipine tablets.

FTIR shows without any significant change in their position of peak or formation of any additional peak after successful mixing of pure Nifedipine with selected excipients.

Evaluation Parameters of Nifedipine Tablets of Different Batches are within the acceptable limit as per official compendia. Disintegration of tablets increases the available surface area for dissolution due to breaking of tablets into smaller fragments. Table 4 shows the disintegration time of the Liquisolid tablets which validates that the inclusion of SSG (disintegrating agent), combined with PEG 400 (hydrophilic solvent) had enhanced the Liquisolid tablet's wetting properties and resulted in a shortened disintegration time. This finding in agreement with a previous study that confirmed the impact of these components on the disintegration behaviour.[23]

The higher drug release in Liquisolid tablets is accorded to higher surface area of drug, higher drug solubility and better wet ability of drug particles. The dispersed state leading to increase in wetting of drug particles which improves the dissolution in the Liquisolid tablets.[24-26]

The comparison of Drug release pattern of selected Formulation batch F1with pure-drugs and marketed tablets are presented in Table 6 and Figure 5. Better cumulative% drug release from in F1 batch tablets which are prepared with Liquisolid technique used to enhanced drug release characteristics and subsequently improved oral bioavailability for treatment of vascular diseases such as hypertension, angina pectoris and Raynaud's phenomenon. So Liquisolid tablets show dissolution greater than pure drug which belong to BCS class -II drugs. From the above outcomes, tablet batch F1 selected for stability study.

Stability study

Stability study carried out for tablet batch F1 as per ICH guidelines at 40°C and 75% Relative Humidity (RH) and data mentioned in Table 7 indicates stability of tablets.[27]

CONCLUSION

In the present study, researcher has tried to improve the rate of *in vitro* dissolution of low solubility drug nifedipine prepared by Liquisolid technique. Tablets were prepared by using suitable non-volatile solvents PEG 400 containing various drug concentration from 2% to 6% and carrier to coating ratio of 5 to 20 for different formulations. From cumulative % drug release study it was observed formulation batch of F1 of nifedipine tablets shows better release of low solubility drug Nifedipine when it is formulated in tablet form by Liquisolid technique.

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CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

ABBREVIATIONS

SSG: Sodium Starch Glycolate; **BCS:** Biopharmaceutical Classification System; **PEG:** Poly Ethylene Glycol.

SUMMARY

The presented study deals with the formulation, *in vitro* drug release study and study of evaluation parameters of Nifedipine tablets prepared with Liquisolid systems containing varying concentration of liquid vehicles like PEG 400 along with different concentration of carrier and coating materials to formulate Nifedipine tablets using direct compression method to improve the *in vitro* dissolution rate of nifedipine tablets. Tablets prepared by this method can be considered as an alternative for improving dissolution of water-insoluble drugs owing to its higher wetting properties and there by greater drug availability for dissolution.

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