IJPSR (2014), Vol. 5, Issue 2 **(Research Article)**

INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH

Received on 28 September, 2013; received in revised form, 18 November, 2013; accepted, 14 January, 2014; published 01 February, 2014

FORMULATION AND EVALUATION OF NIFEDIPINE LIQUISOLID TABLET

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Keywords:

Nifedipine, Liquisolid tablets, Dissolution rate, Content uniformity

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ABSTRACT: The liquisolid technique is a novel concept, where a liquid may be transformed into a free flowing, readily compressible and apparently dried powder by simple physical blending with selected carrier and coating material. The in vitro dissolution property of poorly water soluble Nifedipine was improved by exploring the potential of liquisolid technique. Different liquisolid tablets were prepared by suspending Nifedipine in PEG 400 with Avicel PH 102 as carrier, Aerosil 200 as coating material and Sodium starch glycolate as disintegrating agent. The liquid load factors for liquid vehicle was calculated to obtain the optimum amounts of carrier and coating materials necessary to produce acceptable flowing and compactable powder admixtures viable to produce tablets. The formulated liquisolid tablets were evaluated for post compression parameters such as weight variation, hardness, friability and drug content uniformity. The interaction between drug and excipients in prepared Liquisolid tablets were studied by differential scanning calorimetry (DSC) and FT-IR. The result showed that liquisolid formulation of Nifedipine exhibited higher percentage of drug release than directly compressed tablets which show significant benefit of liquisolid tablet in increasing wetting properties and surface area of drug available for dissolution. From this study it concludes that the liquisolid technique is a promising alternative for improvement of dissolution property of poorly water soluble drugs.

INTRODUCTION: Among all newly discovered chemical entities about 40% drugs are lipophilic and fail to reach market due to their poor aqueous solubility. Active ingredient in a solid dosage form must undergo dissolution before it is available for absorption from the gastrointestinal tract. The poor dissolution characteristics of water insoluble drugs are a major challenge for pharmaceutical scientists.

QUICK RESPONSE CODE

DOI: 10.13040/IJPSR.0975-8232.5(2).588-95

Article can be accessed online on: www.ijpsr.com

DOI link: http://dx.doi.org/10.13040/IJPSR.0975-8232.5(2).588-95

The absorption rate of poorly water-soluble drug, formulated as an orally administered solid dosage form, is controlled by its dissolution rate in the fluid present at the absorption site, i.e the dissolution rate is often the rate determining step in drug absorption [1, 2]. There are several methods for enhancing dissolution rate of poorly water-soluble drugs including Micronization, Solid dispersion, Use of complexing agent, Microemulsions, Cocrystalisation, Cosolvency and Hydrotrophy [3].

Several studies have shown that the liquisolid technique is a new and promising method that can change the dissolution rate of drugs. It has been used to enhance the dissolution rate of poorly water-soluble drugs.

A liquisolid system refers to formulations formed by conversion of liquid drugs, drug suspensions or drug solution in nonvolatile solvents into dry, non-adherent, free-flowing and compactible powder mixtures by blending the suspension or solution with selected carrier and coating materials[4]. The liquid portion, which can be a liquid drug, a drug suspension or a drug solution in suitable non-volatile liquid vehicles, is included into the porous carrier material. As the carrier is saturated with liquid, a liquid layer is formed on the particle surface which is instantly adsorbed by the fine coating particles and gets converted into a drylooking, non-adherent, free flowing and readily compactable powder [5, 6]. The liquisolid technique has been successfully employed to improve the in vitro release of poorly water soluble drugs such as carbamazepine, famotidine, piroxicam, indomethacin, naproxen, furosemide and prednisolone [7].

Nifedipine (Dihydropyridine derivative) is a calcium channel blocker mainly useful in the treatment of hypertension and angina pectoris. It is yellow crystalline powder practically insoluble in water coming under BCS class-2 having elimination half-life of about 2-5 hours. Although it is completely absorbed from the gastrointestinal tract, the systemic availability is approximately 45-46% because of high first-pass metabolism. The rate-limiting step in the absorption of Nifedipine is its dissolution rate in gastrointestinal fluids. If its aqueous solubility is increased it will give higher dissolution rate and improved bioavailability therefore, Nifedipine establishes a good candidate for the formulation of liquisolid tablet.

In the present study, an attempt is made to enhance dissolution rates of Nifedipine using liquisolid tablet technique and dissolution profiles of the liquisolid tablets were compared with directly compressed tablets [8].

MATERIALS AND METHODS:

Materials: Nifedipine was received as a gift sample from Alkem Laboratories Ltd, Mumbai, India. Avicel PH 102, Aerosil 200 and Sodium starch glycolate were received as gift samples from Loba Chemical, Mumbai, India. All other chemicals and reagents used were of AR grade.

Methods:

Drug excipient interaction study [9, 10]: Drug excipient compatibility study was performed by mixing drug with polymer in equal proportion and the mixture was kept under accelerated stability condition (i.e. 40ºC and 75±5% RH) for a period of 21 days in a glass vial. It was hermetically sealed with rubber stopper using molten carnauba wax. Same mixture under control condition (i.e. 5% H_2O) was kept and the interval of 7 days they are analyzed by IR and DSC. On the basis of result obtained the polymers are selected. The IR spectra of previously dried samples were recorded by potassium bromide dispersion technique. 2-3 mg of sample was mixed with previously dried IR grade potassium bromide and kept in sample cell, the cell was then fitted on sample holder and spectrums were recorded with FTIR.

Formulation of Liquisolid Tablets:

Selection of suitable solvent [4]: To select the best non-volatile solvent for dissolving or suspending of Nifedipine in liquid medium, solubility studies of Nifedipine were carried out in different nonvolatile solvents, i.e. PEG 400, glycerin, PG and polysorbate 80. Saturated solutions were prepared by adding excess drug to the vehicles and shaking on shaker. and then cooled to 25 °C. After this, the solutions were filtered, diluted and analyzed by UV-spectrophotometer.

Preparation and mixing of the powders [8, 11]: The amounts of excipients depended on their Φ -values, as well as liquid load factors. Aerosil 200 was used as coating material, while Avicel PH 102 was used as carrier. Three liquid load factors were used, Lf = 0.331, 0.222 and 0.168 based on flowable liquid retention potential for Aerosil 200 (Φ-value) using the following equation:

$$\mathbf{Lf = \Phi + \Phi\ (1/R)}$$

Where, Φ, Φ are the values flowable liquid retension potential of carrier and the coating material respectively which are constants. With any of the three liquid load factors the dose of Nifedipine was 10 mg in each tablet. Nifedipine was suspended in polyethylene glycol 400 (PEG 400), and the suspension was made into slurry by mixing it with Avicel PH 102 (carrier).

The excess fluids were adsorbed by Aerosil 200 (coating material), that was added later. Sodium starch glycolate was finally added to the powders to make 5 % of the tablet weight. Nifedipine was suspended in PEG 400 at concentrations of 10 %, 20 %, 30% and 40% w/w. The composition of different liquisolid formulations is shown in **table 1.**

Compression of the Powders: Liquisolid tablets were prepared by direct compression method using eight station rotary punch tablet compression machine.

TABLE 1: FORMULATION OF LIQUISOLID TABLETS

Formulation (LST)	Drug Conc. (%w/w)	R	Lf	Carrier (Q)	Coating (q)	Tablet Weight (mg)
LS1	10	10	0.331	271.90	27.19	419.04
LS2	10	15	0.222	405.40	27.02	559.05
LS3	10	20	0.168	535.71	26.78	695.61
LS4	20	10	0.331	120.84	12.08	192.06
LS5	20	15	0.222	180.18	12.01	254.29
LS6	20	20	0.168	238.09	11.90	314.98
LS7	30	10	0.331	69.48	6.94	114.89
LS8	30	15	0.222	103.60	6.90	150.67
LS9	30	20	0.168	136.90	6.84	185.57
LS10	40	10	0.331	45.31	4.53	78.58
LS11	40	15	0.222	67.56	4.50	101.91
LS12	40	20	0.168	89.28	4.46	124.67

All formulations contains 5% SSG and 10 mg of Nifedipine

Precompression Studies:

Angle of repose [12, 13]: The angle of repose was determined by the funnel method. The accurately weighed powder was taken in a funnel. The height of the funnel was adjusted in such a way that the tip of the funnel just touched the apex of the heap of the powder. The powder was allowed to flow through the funnel freely onto the surface. The angle of repose was calculated by substituting the values of the base radius 'r' and pile height 'h' in the following equation:

$$\tan \theta = h/r$$

Where, h = Pile Height and r = Radius of Pile.

Bulk density (BD) [12, 13]: Bulk density was determined by pouring the blend into a graduated cylinder. The bulk volume and Mass of the powder was determined. The bulk density was calculated by using below mentioned formula:

Bulk density = Mass of powder blend/ Bulk Volume of powder blend

Tapped density (TD) [12, 13]: The measuring cylinder containing a known mass of blend was tapped for a fixed time. The minimum volume occupied in the cylinder and the Mass of the blend was measured. The tapped density was calculated using the following formula:

Tapped density = Mass of powder blend/Tapped Volume of powder blend

Compressibility Index [12, 14]: Percent compressibility can be determined from the formula:

C (%) = [(TD-BD)/ TD] x100

Evaluation of Liquisolid Tablets:

Thickness [12, 15]: The thickness of the tablets was determined using a Micrometer Screw Gauge. Tablets from each type of formulation were used and average values were calculated. It is expressed in mm.

Hardness [12, 15]: For each formulation, the hardness of tablets was determined using the Monsanto hardness tester. The tablet was held along its oblong axis in between the two jaws of the tester. At this point, reading should be zero kg/cm^2. Then constant force was applied by rotating the knob until the tablet fractured. The value at this point was noted.

Friability [15, 16]: Roche Friabilator was used for testing the friability using the following procedure. This test subjects a number of tablets to the

combined effect of shock abrasion by utilizing a plastic chamber which revolves at a speed of 25 rpm, dropping the tablets to a distance of 6 inches in each revolution. A sample of preweighed tablets was placed in Roche friabilator which was then operated for 100 revolutions i.e. 4 minutes. The tablets were then dusted and reweighed. A loss of less than 1 % in weight in generally considered acceptable. Percent friability (% F) was calculated as follows:

% F = (Initial wt. - Final wt. / Initial wt.) x 100

Weight variation test [16]: To find out weight variation, Tablets of each type of formulation were weighed individually using an electronic balance, average weight was calculated and individual tablet weight was then compared with average value to find the deviation in weight.

Uniformity of content [16]: Twenty tablets were accurately weighed and finely powdered. A quantity equivalent to 10 mg of Nifedipine was transferred to a 200 ml volumetric flask. To it, 50 ml of methanol was added and shaken to dissolve drug. Resulting solution is diluted to volume with methanol and filtered. 20 ml of filtrate diluted to 100ml with methanol and mixed. Absorbance of the resulting solution at maximum at about 237.5 nm was measured UV spectroscopically.

***In-vitro* dissolution studies [16]:** The release rate of Nifedipine from liquisolid tablets was determined using USP dissolution testing apparatus (Paddle: type II) (Electrolab TDT-08L). The dissolution test was performed using 900 ml of 0.1N HCl, at 37 ± 0.5°C and speed of 50 rpm. Aliquot (10 ml) of the solution was collected from the dissolution apparatus at an interval of 10 min. and were replaced with fresh dissolution medium. The aliquots were filtered through whatmann filter paper no. 41. Absorbance of these solutions was recorded at 237.5 nm using UV spectrophotometer (Lab India, 3000+). Drug content in dissolution sample was determined by software PCP Disso v2.08.

Stability Study of Optimized Batch [9]: The stability study was carried out using the best batch. The prepared tablets were placed in borosilicate screw capped glass containers. The samples were kept at condition of 45°C+ 2 ^{o}C and 70% RH and were analyzed at 15, 30 and 45 days for their physical changes and in drug content.

RESULT AND DISCUSSION:

Drug excipient interaction study:

FT-IR Study: Drug, excipients, drug – excipients mixture and optimized formulation were subjected to FTIR studies to investigate the drug – excipient interactions and does not show well-defined interaction between Nifedipine and excipients. This indicates that the drug is compatible with the formulation components.

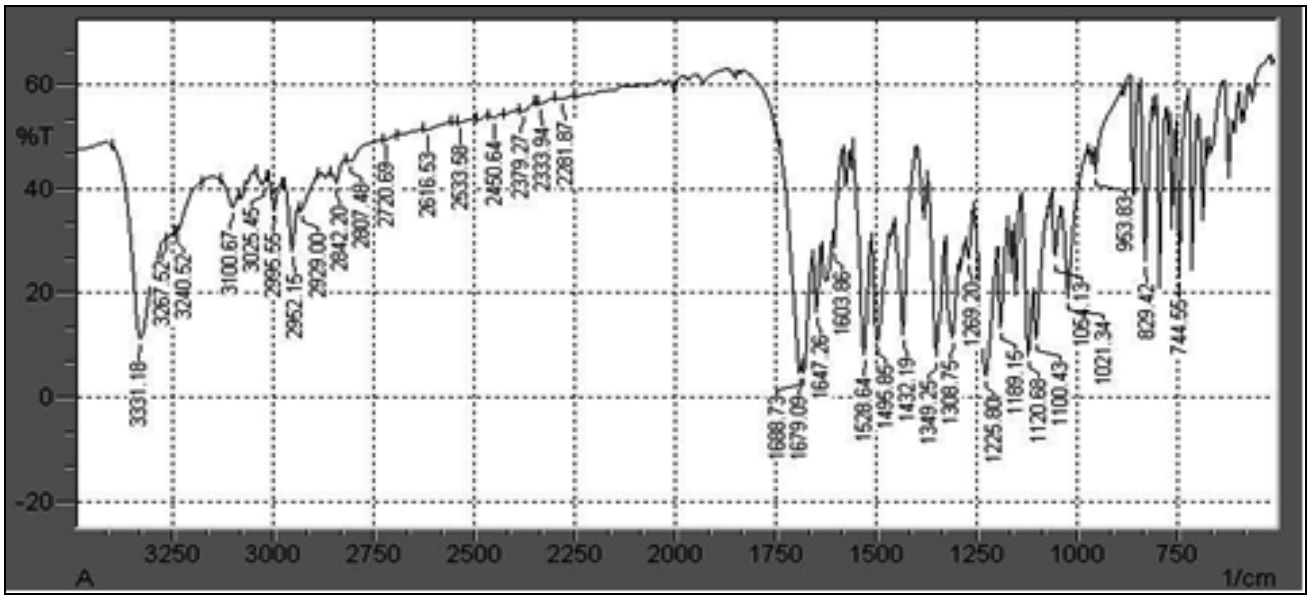

FIG. 1: FTIR SPECTRUM OF NIFEDIPINE

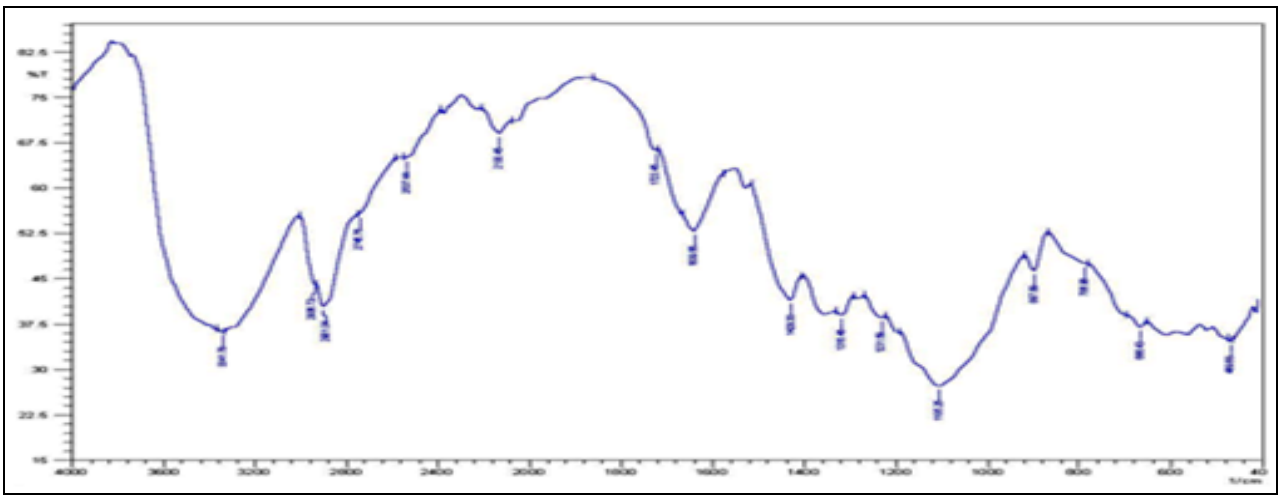

FIG. 2: FTIR SPECTRUM OF OPTIMIZED FORMULATION (LS3)

DSC Study: Comparison of DSC themograms of drug as well as in the presence of polymer gives an idea about the glass transition temperature of drug in liquisolid formulation and confirmed that there is no interaction between drug and excipients. It also showed a reduction in intensity of the peak and there is no new peaks found and endothermic to exothermic change not occur. Hence, it was confirmed there was no interaction between drug and excipients.

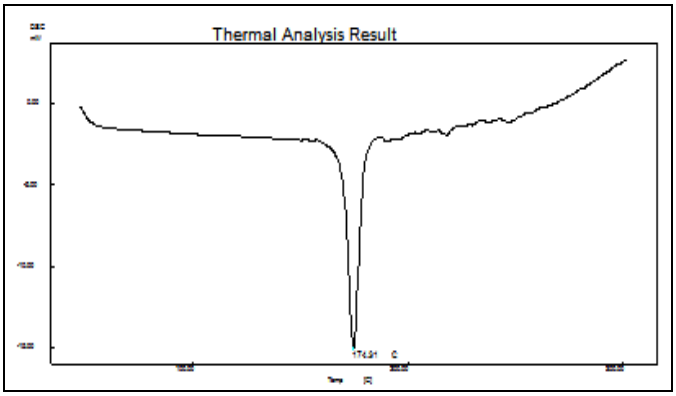

FIG. 3: DSC THERMOGRAM OF NIFEDIPINE

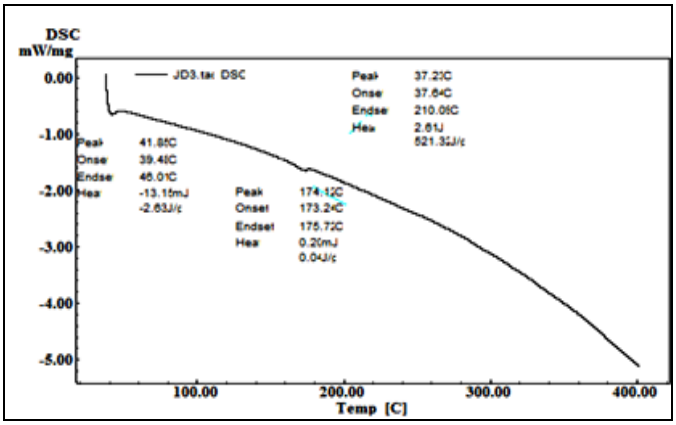

FIG. 4: DSC THERMOGRAM OF OPTIMIZED FORMULATION (LS3)

Selection of suitable solvent: The solubility of Nifedipine in different Non-volatile solvent is given in below **table 2**.

TABLE 2: SOLUBILITY OF NIFEDIPINE IN VARIOUS SOLVENTS

Solvent	Solubility (mg/ml) (mean± S.D.) n = 3
PEG 400	3.30±0.035
Propylene glycol	2.88±0.01
Glycerin	0.16±0.005
Polysorbate 80	0.18±0.026

The maximum solubility of Nifedipine was found to be 3.30 ± 0.035 mg/ml in PEG 400. Therefore PEG 400 has been used as non-volatile solvent for preparation of liquisolid tablet.

Precompression Parameter: The powder mixtures for all batches were evaluated for bulk density, tapped density, compressibility index and angle of repose. All these results indicated that, the powder mixture possess good to fairly acceptable flow properties (**table 3**).

Evaluation of liquisolid tablet: The prepared formulations were evaluated for the physical characteristics like thickness, hardness, friability, weight variation and uniformity of content; the results obtained are shown in **Table 4**. All the physical parameters of the liquisolid tablet were within pharmacopoeial limits. The deviation from the average weight was found to be within the prescribed official limits. Hardness of tablets was found to be in the range of 1.8 to 3.2 Kg/cm^2. The friability of all tablets was found to be in range of 0.51-0.73 which is less than 1% that showed good mechanical strength.

TABLE 3: BLEND PROPERTIES OF FORMULATION OF LIQUISOLID TABLET

Formulations	Bulk Density (g/ml)* (± SD)	Tapped Density (g/ml)* (± SD)	Compressibility Index (%)* (± SD)	Angle of Repose* (± SD)
LS1	0.383±0.01	0.46±0.005	16.72±0.01	28.25±0.04
LS2	0.376±0.005	0.45±0.02	16.44±0.005	26.16±0.05
LS3	0.39±0.01	0.45±0.01	13.34±0.01	25.64±0.04
LS4	0.366±0.005	0.45±0.005	18.65±0.005	29.84±0.04
LS5	0.386±0.005	0.45±0.02	14.24±0.02	27.03±0.04
LS6	0.37±0.01	0.43±0.005	13.92±0.02	26.55±0.05
LS7	0.345±0.02	0.42±0.01	17.85±0.01	27.84±0.04
LS8	0.389±0.01	0.47±0.005	17.23±0.005	28.32±0.04
LS9	0.398±0.005	0.50±0.02	20.4±0.005	29.98±0.05
LS10	0.382±0.02	0.46 ±0.01	16.95±0.02	27.12±0.04
LS11	0.364±0.005	0.45±0.005	19.11±0.02	27.78±0.05
LS12	0.367±0.01	0.44±0.01	16.59±0.01	28.12±0.05

TABLE 4: PHYSICAL EVALUATION OF NIFEDIPINE LIQUISOLID TABLET

Formulations	Thickness ± SD*	Hardness (kg/cm^2) ± SD*	Friability (%) ± SD	Weight Variation (mg) ± SD*	Uniformity of content ± SD*
LS1	4.26±0.02	2.4±0.2	0.55±0.0032	417.45±0.033	98.23±0.024
LS2	5.32±0.01	2.7±0.26	0.65±0.0035	559.01±0.16	98.94±0,038
LS3	5.44±0.02	3.2±0.28	0.65±0.0032	695.50±0.11	99.62±0.03
LS4	3.34±0.02	2.1±0.11	0.63±0.0015	192.04±0.03	98.14±0.027
LS5	3.38±0.01	2.3±0.05	0.73±0.003	254.30±0.15	98.54±0.035
LS6	3.33±0.03	2.3±0.11	0.72±0.0015	314.90±0.037	98.92±0.024
LS7	2.25±0.01	1.9±0.20	0.50±0.0032	114.12±0.033	98.02±0.027
LS8	2.28± 0.02	2.1±0.22	0.54±0.0032	150.16±0.11	98.11±0.024
LS9	3.46±0.03	2.2±0.05	0.60±0.003	185.05±0.037	98.15±0.03
LS10	1.46±0.01	1.8±0.11	0.55±0.0032	78.45±0.033	98.10±0.024
LS11	2.18±0.03	2.2±0.11	0.51±0.0015	101.12±0.037	98.17±0.03
LS12	2.27±0.02	2.1±0.05	0.54±0.0015	124.13±0.11	98.22±0.027

***In-vitro* dissolution studies:** The release profiles of Nifedipine from the different formulation are shown in **Table 5, 6 and Fig. 5**. From dissolution data it is concluded that all formulation batches shows more than 50% drug release in 40 min and in all that formulations, batch LS3 shows maximum drug release so formulation LS3 containing 10% drug conc. with excipient ratio R=20 is selected as optimized batch. Dissolution profile of Formulation LS3 was compared with dissolution profile of conventional tablet (**Table 7 and Fig. 6**). The formulation LS3 shows more than 50% drug release in 20 min. whereas conventional tablet requires 50 min to show the same release. Hence liquisolid tablets of Nifedipine shows better drug release than conventional tablet

TABLE 5: % DRUG RELEASE OF FORMULATION LS1 TO LS6

Time (min)	LS1	LS2	LS3	LS4	LS5	LS6
0	0	0	0	0	0	0
10	29.82±0.015	30.11±0.01	32.88±0.01	28.5±0.01	28.89±0.05	29.71±0.01
20	41.11±0.01	43.34±0.05	51.3±0.01	40.11±0.01	40.31±0.01	41.03±0.05
30	50.87±0.01	50.12±0.02	66.45±0.02	50.04±0.04	50.43±0.02	50.61±0.01
40	62.12±0.01	63.31±0.01	70.46±0.02	60.83±0.01	61.01±0.01	61.81±0.01
50	64.1±0.005	68.11±0.01	77.31±0.01	62.98±0.01	63.42±0.02	63.86±0.05
60	70.48±0.01	75.11±0.01	82.04±0.01	67.64±0.01	68.98±0.01	69.91±0.01
70	74.34±0.05	80.33±0.02	88.61±0.01	71.81±0.01	72.86±0.05	73.36±0.01
80	80.32±0.01	85.11±0.01	90.45±0.05	78.81±0.05	79.03±0.02	79.92±0.01
90	86.96±0.02	89.04±0.03	91.89±0.05	83.13±0.01	84.86±0.03	85.11±0.01
100	87.43±0.02	89.94±0.02	93.85±0.01	86.03±0.01	86.85±0.04	87.11±0.02
110	89.21±0.005	90.31±0.01	95.61±0.02	87.97±0.01	88.43±0.01	88.9±0.005
120	90.93±0.01	92.86±0.01	97.6±0.02	89.11±0.02	90.00±0.02	90.14±0.01
130	94.35±0.01	96.32±0.02	99.14±0.01	92.16±0.01	93.32±0.01	94.11±0.01

TABLE 6: % DRUG RELEASE OF FORMULATION LS7 TO LS12

Time (min)	LS7	LS8	LS9	LS10	LS11	LS12
0	0	0	0	0	0	0
10	27.89±0.01	28.2±0.01	28.34±0.03	26.98±0.02	27.12±0.01	27.80±0.01
20	38.32±0.05	39.98±0.02	40.09±0.02	36.78±0.05	37.45±0.01	37.91±0.02
30	48.18±0.05	49.89±0.02	50.12±0.01	47.89±0.04	48.12±0.04	49.15±0.01
40	57.98±0.01	58.46±0.04	58.98±0.02	56.78±0.02	57.89±0.03	58.34±0.05
50	61.86±0.02	62.01±0.03	62.89±0.04	60.82±0.01	61.56±0.05	62.17±0.04
60	65.67±0.04	66.12±0.01	66.90±0.03	64.45±0.05	65.45±0.04	65.78±0.01
70	69.86±0.02	70.80±0.02	71.87±0.01	68.43±0.03	69.56±0.05	70.45±0.05
80	76.87±0.04	77.14±0.05	77.89±0.05	75.35±0.02	76.45±0.01	77.12±0.02
90	81.45±0.04	82.13±0.01	83.09±0.03	80.45±0.03	81.12±0.05	81.76±0.03
100	84.12±0.01	85.17±0.03	85.98±0.02	83.14±0.01	83.91±0.03	84.65±0.01
110	85.45±0.02	86.98±0.03	87.87±0.01	84.32±0.02	84.95±0.04	85.54±0.04
120	87.14±0.04	88.13±0.04	88.89±0.03	86.12±0.04	86.86±0.03	87.12±0.02
130	90.36±0.01	91.12±0.03	92.32±0.04	89.14±0.01	90.13±0.01	90.89±0.01

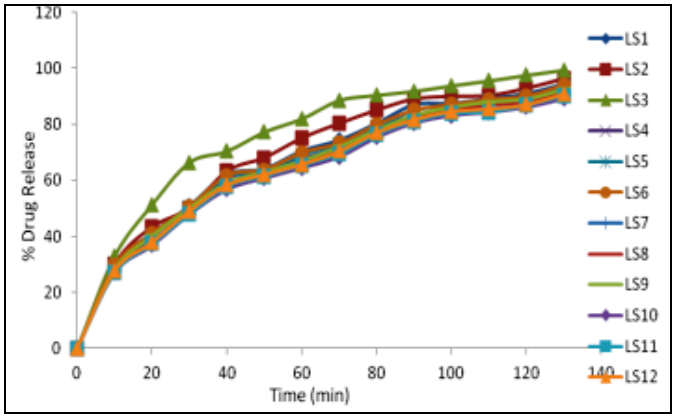

FIG. 5: % DRUG RELEASE OF FORMULATION LS1 TO LS12

Percentage drug release of Nifedipine from its liquisolid tablet and conventional tablet:

TABLE 7: COMPARISON OF % DRUG RELEASE OF FORMULATION LS3 AND CONVENTIONAL TABLET

Time (min)	LS3	Conventional tablet
0	0	0
10	32.88±0.01	20.32±0.01
20	51.3±0.01	28.13±0.005
30	66.45±0.02	32.16±0.01
40	70.46±0.02	45.35±0.01
50	77.31±0.01	51.03±0.01
60	82.04±0.01	58.13±0.01
70	88.61±0.01	64.33±0.02
80	90.45±0.05	69.81±0.01
90	91.89±0.05	75.11±0.01
100	93.85±0.01	77.83±0.04
110	95.61±0.02	82.33±0.02
120	97.6±0.02	84.40±0.01
130	99.14±0.01	86.30±0.01

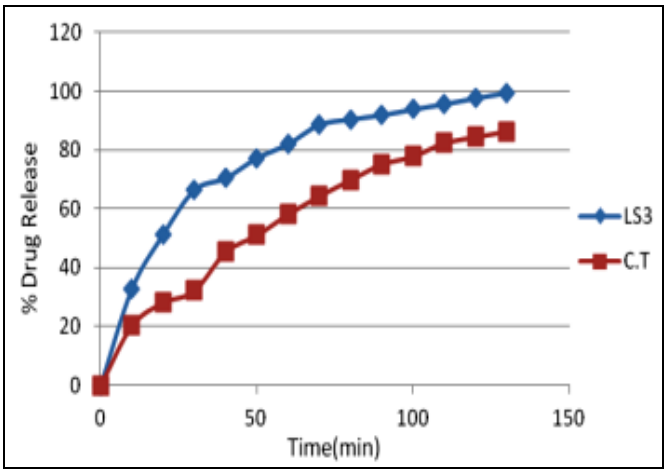

FIG. 6: COMPARISON OF % DRUG RELEASE OF FORMULATION LS3 AND CONVENTIONAL TABLET

Stability Study: Stability studies was carried for optimized batch LS3 by exposing it to 40°C/75%RH for 15, 30 and 45 days. The sample was analyzed for physical parameters color, hardness, uniformity of content, and percentage drug release. The optimized batch showed no significant effect on physical parameters. Thus, formulation batch LS3 was found to be stable (**table 8**).

TABLE 8: STABILITY STUDIES

Parameters	Initial Days	15 Days	30 Days	45 Days
Color	No change	No change	No change	No change
Hardness ± SD	3.2±0.28	3.2±0.11	3.2±0.26	3.0±0.11
Drug Content (%) ± SD	99.62±0.03	98.92±0.035	98.32±0.028	97.96±0.024
% Release ± SD	99.14±0.01	98.67±0.05	97.23±0.02	97.14±0.05

CONCLUSION: The present study was aimed at developing liquisolid tablet of Nifedipine using Avicel PH 102 as carrier, Aerosil 200 as coating and Sodium starch glycolate as disintegrating agent. Result generated in this study showed that Nifedipine release from liquisolid tablet is faster than conventional tablet and concluded that liquisolid technique could be a promising strategy in improving dissolution of water insoluble drug Nifedipine. Enhanced dissolution rate obtained in the present study in turn indicates increase in oral bioavailability due to increased wetting and surface area available for dissolution. This novel approach to the formulation may be helpful to improve oral bioavailability.

ACKNOWLEDGEMENT: The authors are thankful to TVES'S college of Pharmacy, Faizpur for providing necessary facility to carry out this research. Authors are thankful to Alkem Laborities Ltd, Mumbai, India and Loba Chemical, India for providing Drug and excipients.

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How to cite this article:
Chaudhari JY, Tekade BW, Thakre VM and Patil VR: Formulation and evaluation of Nifedipine Liquisolid Tablet. *Int J Pharm Sci Res* 2014; 5(2): 588-95.doi: 10.13040/IJPSR.0975-8232.5(2).588-95