

International Journal of Pharmaceutical Sciences and Drug Research

2018; 10(4): 260-267



Research Article

ISSN: 0975-248X
CODEN (USA): IJPSP



Preparation and *in vitro* Evaluation of Solid Dispersions Containing Nifedipine

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ABSTRACT

The objective of this study was to develop solid dispersions of Nifedipine which has low aqueous solubility and bioavailability. Preliminary solubility studies were carried out using various hydrophilic polymers. The formulations were then optimized and evaluated by *in-vitro* dissolution studies, X-ray diffraction, FTIR and SEM. Formulation with 1:4:2 ratios of Nifedipine, Labrosol and SLS was found to be the best as it possessed better drug release properties compared to pure drug and other physical mixtures. The optimized formulation SD12 was found to have better drug release of $98.74 \pm 5.19\%$ in 90 minutes. From FTIR studies no interaction was takes place between drug and polymers. XRD peaks indicate the successful transformation of drug from crystalline to amorphous form. The final results indicate that the solid dispersion of Nifedipine remained stable over 90 days.

Keywords: Nifedipine, Solid dispersions, Hypertension, Labrosol, Solubility.

DOI: 10.25004/IJPSDR.2018.100408

Int. J. Pharm. Sci. Drug Res. 2018; 10(4): 260-267

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Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Received: 12 May, 2018; **Revised:** 31 May, 2018; **Accepted:** 04 June, 2018; **Published:** 20 July, 2018

INTRODUCTION

Bioavailability of drugs having poor water solubility is limited because of their solubility and dissolution rate. Numerous studies have been carried out to increase the dissolution rate of such drugs. [1] One such research outcome was solid dispersions that showed promising results in improving solubility, wettability, drug dissolution rate and therefore its bioavailability. [2] In

solid dispersion formulation, the particle size of drug is reduced to fine or molecular form. The crystalline drug is converted into amorphous form which increases wettability of the formulation. [3] Several poorly soluble drugs like Ketoprofen [4], Nimodipine [5] and Tenoxicam [6] have been successfully formulated to solid dispersions.

Nifedipine is a calcium channel blocker mainly used for treatment of hypertension. It reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. [7] There are fewer products available commercially for solid dispersions inspite of numerous advantages. [8] In solid dispersions, the drug is dispersed in a fine crystalline or amorphous form in the matrix which when exposed to aqueous media disperses the drug as fine colloid particles. [9]

Various methods have been designed for the formulation of solid dispersions. They are fusion/melting, solvent evaporation, lyophilization (freeze drying), melt agglomeration process, extrusion method; spray dry method, use of surfactants, electro static spinning and super critical fluid technology. Solvent evaporation method is most convenient for formulation of solid dispersions without much hassle. It employs an organic solvent to dissolve and disperse the drug and carrier molecule. Use of large volume of solvent formulation may sometimes pose difficulty in removing it and also may lead to toxicity. [10-11] Thus small amounts of easily volatile solvents may be used.

MATERIALS AND METHODS

Materials

Nifedipine pure drug was generous gift from Aurobindo Pharma Ltd, Hyderabad, India. Kleptose HPB, Poloxamer 407 and PEG 8000 were obtained from BASF, Mumbai. Kolliwax GMS II, Labrosol, Kolliphor RH 40, Avicel PH 102 and Colloidal Silicone dioxide (Aerosil 200) were obtained from Signet Chemical Corp. Pvt. Ltd., Mumbai. Soluplus was gifted by BASF, Germany. Urea and PVP K-30 were gifted by Dow Chemicals, USA. All other chemicals used were of analytical grade.

Preliminary solubility studies of Nifedipine

Solubility measurements of Nifedipine were performed according to a published method given by Higuchi and Connors in 1965. [12] An excess amount of Nifedipine was added to 25 ml of aqueous solution of water soluble carriers like Urea, PEG 8000, Labrosol, Soluplus, Kolliphor RH 40, Kolliwax GMS II, Poloxamer 407, Kleptose HPB, Colloidal Silicone dioxide (Aerosil 200), and PVPK-30 in screw capped bottles. Samples were shaken for the 24 hours at room temperature. Subsequently, the suspensions were filtered through a Whatman filter paper no 1. Filtered solution was diluted with methanol and analyzed for the Nifedipine at UV 338 nm. [13]

Preparation of Nifedipine solid dispersion by the solvent evaporation method

The calculated amount of Nifedipine and the employed polymers of Labrosol, Soluplus, Kolliphor RH 40, Kolliwax GMS II and SLS in different drug, polymer and surfactant ratios of 1:1:0.5, 1:2:1, 1:3:1.5 and 1:4:2 (Shown in table 1) are weighed and mixed together in a porcelain dish. Sixteen different formulae were prepared by the solvent evaporation method. The mixture was dissolved in small amount of methanol.

Then the solvent was evaporated in oven at temperature 50°C until complete evaporation. The solid dispersions prepared were pulverized in a mortar and sieved. The fraction of the powder that passed through 45µm was stored in a desiccator and utilized for further study.

Evaluation of Nifedipine solid dispersions

Solid dispersions obtained by solvent evaporation method were tested for their percentage practical yield, drug content, FTIR, SEM, XRD, *in-vitro* release and stability studies.

Percentage Practical Yield

Percentage practical yield was calculated to know about percent yield or efficiency of any method and help in selection of appropriate method of production. SDs were collected and weighed to determine practical yield from the following equation. [14]

$$\% \text{ Practical Yield} = \frac{\text{Practical Mass (Solid dispersion)}}{\text{Theoretical Mass (Drug + Polymer + Surfactant)}} \times 100$$

Drug content

Solid dispersions equivalent to 16 mg of Nifedipine was weighed accurately and dissolved in 100 ml of methanol. The solution was filtered, diluted suitable and drug content was analyzed at λ_{max} 236 nm against blank by UV spectrometer. The actual drug content was calculated using the following equation as follows. [15]

$$\% \text{ Drug content} = \frac{\text{Actual amount of drug in solid dispersion}}{\text{Theoretical amount of drug in solid dispersion}} \times 100$$

In vitro Dissolution study of solid dispersion

The USP dissolution test type II apparatus (Electrolab TDT- 06 N, India) was used. Amount of samples equivalent to 16 mg of drug were dispersed into the dissolution vessel containing 900 mL of 0.1 N HCl with pH 1.2 at 37°C and stirred at 50 rpm. Samples were withdrawn periodically, filtered and replaced with a fresh dissolution medium. After filtration through 0.45µm microfilter, concentration of Nifedipine was determined spectrophotometrically at λ_{max} 236 nm. [16]

Characterization

FTIR studies

The instrument used for FTIR study was Shimadzu FTIR-8700 spectrophotometer. In this study, potassium bromide disc method was employed. Pure drug, physical mixtures, and solid dispersion studied by IR. The powdered sample was intimately mixed with dry powdered potassium bromide. The mixture was then compressed into transparent disc under high pressure using special dies. The disc was placed in IR spectrophotometer using sample holder and spectrum was recorded. [17]

Powder X-ray diffraction (XRD)

X-ray powder diffraction patterns were recorded on an X-ray powder diffraction system (Shimadzu, Japan) using copper target, a voltage of 40 Kv and a current of 30 mA. [18] The scanning was done over 2 θ range of 5° to 60°. [19]

Table 1: Composition of Nifedipine solid dispersions

Ingredients & formulation ratios	Nifedipine (mg)	Kolliwax GMS (mg)	Kolliphor RH 40 (mg)	Labrasol (mg)	Soluplus	SLS (mg)	Methanol (mL)
SD11:1:0.5	30	30	-	-	-	15	Qs
SD2 1:2:1	30	60	-	-	-	30	Qs
SD3 1:3:1.5	30	90	-	-	-	45	Qs
SD4 1:4:2	30	120	-	-	-	60	Qs
SD5 1:1:0.5	30	-	30	-	-	15	Qs
SD6 1:2:1	30	-	60	-	-	30	Qs
SD7 1:3:1.5	30	-	90	-	-	45	Qs
SD8 1:4:2	30	-	120	-	-	60	Qs
SD9 1:1:0.5	30	-	-	30	-	15	Qs
SD10 1:2:1	30	-	-	60	-	30	Qs
SD11 1:3:1.5	30	-	-	90	-	45	Qs
SD12 1:4:2	30	-	-	120	-	60	Qs
SD13 1:1:0.5	30	-	-	-	30	15	Qs
SD14 1:2:1	30	-	-	-	60	30	Qs
SD15 1:3:1.5	30	-	-	-	90	45	Qs
SD16 1:4:2	30	-	-	-	120	60	Qs

SEM (Scanning Electron microscope) studies

The surface morphology of the layered sample was examined by SEM (Hitachi, Japan). A small amount of powder was manually dispersed onto a carbon tab (double adhesive carbon coated tape) adhered to aluminum stubs. These sample stubs were coated with a thin layer (30Å) of gold by employing POLARON-E 3000 sputter coater. The samples were examined by SEM and photographed under various magnifications with direct data capture of the images onto a computer. [20]

Stability studies

The optimized solid dispersions were placed inside sealed 40cc HDPE container with child resistant cap under controlled temperature environment inside stability chamber (Thermo Lab, India) with relative humidity of $75\% \pm 5\%$ RH and temperature of $40 \pm 2^\circ\text{C}$ for stability studies. Samples were removed after 1, 2 and 3 months and evaluated for percent drug content and *in vitro* dissolution studies. [21]

RESULTS AND DISCUSSION**Preliminary solubility studies of Nifedipine**

Initially preliminary solubility analysis was carried out to select the appropriate water-soluble carriers for the preparation of solid dispersion in which Nifedipine pure drug solubility was found to be 0.0177 mg/ml. From this study, drug and Labrasol in the ratio of 1:1 exhibits highest drug solubility of 0.442 ± 0.04 mg/ml, almost 25-fold increase compared to that of pure drug. Among all the water-soluble carriers used, Urea, PEG 8000, PVP K 30, Kleptose HPB, Poloxamer 407, Aerosil 200 and Urea showed low solubility and therefore are not included in the preparation of Nifedipine solid dispersions.

Evaluation parameters**Solubility studies of Nifedipine solid dispersions**

Nifedipine solid dispersions were prepared by solvent evaporation method with their respective carriers. After preparation of solid dispersion solubility analysis was carried out. The formulation (F12) with Soluplus in the ratio of 1:3 and with SLS shown highest solubility

i.e. 0.672 ± 0.03 mg/ml, almost 11-fold compared to that of the pure drug (Pure drug solubility is 0.0177 ± 0.04 mg/ml). The results are tabulated in table 3 and graphical representation is shown in Figure 1 & 2.

Percent Practical yield and drug content

The formulation SD12 was found to have highest percent practical yield and percent drug content of 98.82% and 99.04% respectively when compared with other formulations. The results are given in Table 4.

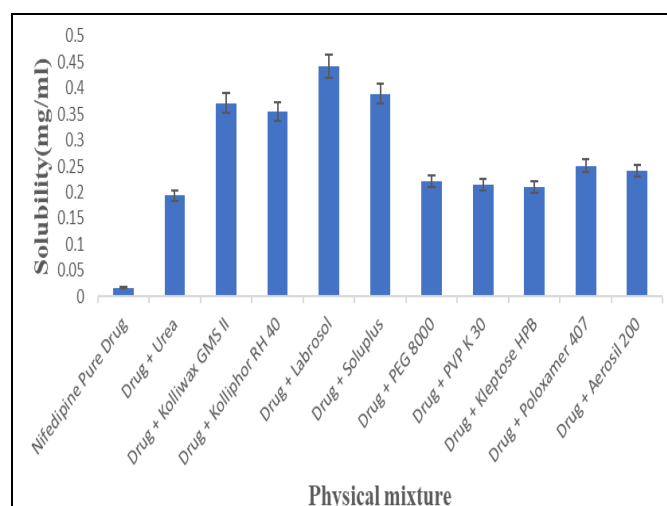
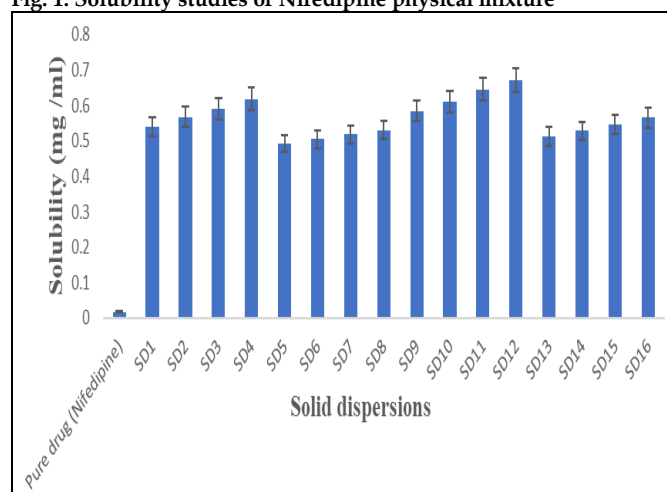
**Fig. 1: Solubility studies of Nifedipine physical mixture****Fig. 2: Solubility studies of Nifedipine solid dispersion**

Table 2: Preliminary solubility studies of Nifedipine in different polymers

Physical Mixture (1:1)	Solubility (mg/ml)*
Nifedipine Pure Drug	0.0177 ± 0.04
Drug + Urea	0.194 ± 0.003
Drug + Kolliwax GMS II	0.371 ± 0.13
Drug + Kolliphor RH 40	0.354 ± 0.01
Drug + Labrosol	0.442 ± 0.04
Drug + Soluplus	0.389 ± 0.05
Drug + PEG 8000	0.221 ± 0.07
Drug + PVP K 30	0.214 ± 0.11
Drug + Kleptose HPB	0.217 ± 0.02
Drug + Poloxamer 407	0.251 ± 0.12
Drug + Aerosil 200	0.241 ± 0.12

*n= SD ± 3

Table 3: Solubility studies of Nifedipine solid dispersions prepared by solvent evaporation method

S. No	Formulation code	Solubility (mg/ml)*
1	Pure drug (Nifedipine)	0.0177 ± 0.04
2	SD1	0.539 ± 0.07
3	SD2	0.568 ± 0.10
4	SD3	0.590 ± 0.22
5	SD4	0.619 ± 0.08
6	SD5	0.492 ± 0.02
7	SD6	0.505 ± 0.03
8	SD7	0.518 ± 0.02
9	SD8	0.531 ± 0.04
10	SD9	0.585 ± 0.03
11	SD10	0.612 ± 0.04
12	SD11	0.646 ± 0.01
13	SD12	0.672 ± 0.03
14	SD13	0.513 ± 0.04
15	SD14	0.528 ± 0.03
16	SD15	0.547 ± 0.04
17	SD16	0.566 ± 0.07

*n= SD ± 3

Table 4: Percent Practical yield and drug content for Nifedipine solid dispersions

S. No	Formulation	% Practical Yield	% Drug content
1	SD1	94.21 ± 0.02	91.47 ± 0.01
2	SD2	94.46 ± 0.01	94.77 ± 0.15
3	SD3	95.68 ± 0.03	95.33 ± 0.11
4	SD4	95.88 ± 0.11	96.33 ± 0.17
5	SD5	95.55 ± 0.12	92.47 ± 0.07
6	SD6	96.68 ± 0.08	93.92 ± 0.09
7	SD7	95.98 ± 0.04	94.50 ± 0.10
8	SD8	96.22 ± 0.02	94.52 ± 0.13
9	SD9	95.87 ± 0.09	96.53 ± 0.15
10	SD10	96.26 ± 0.14	96.86 ± 0.17
11	SD11	96.99 ± 0.05	96.97 ± 0.03
12	SD12	98.82 ± 0.14	99.04 ± 0.13
13	SD13	93.87 ± 0.31	92.43 ± 0.05
14	SD14	94.27 ± 0.15	93.37 ± 0.09
15	SD15	95.26 ± 0.09	94.52 ± 0.07
16	SD16	96.28 ± 0.10	95.08 ± 0.03

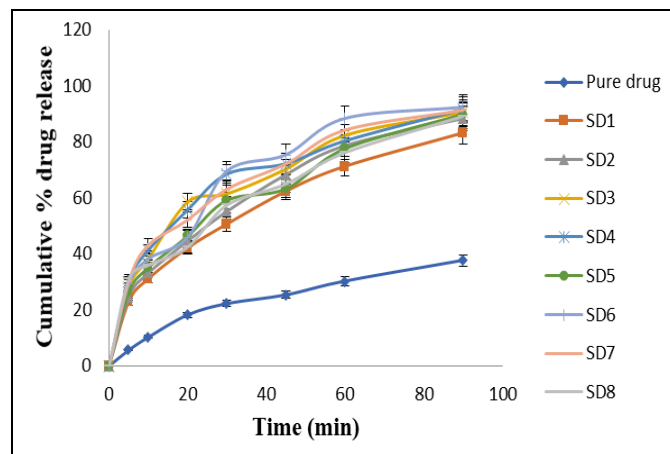
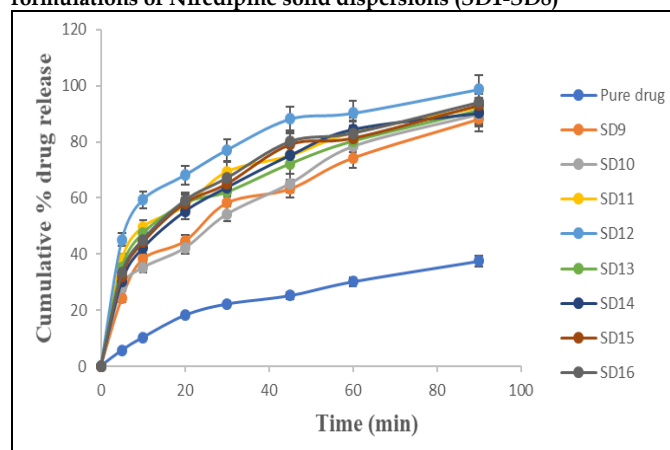
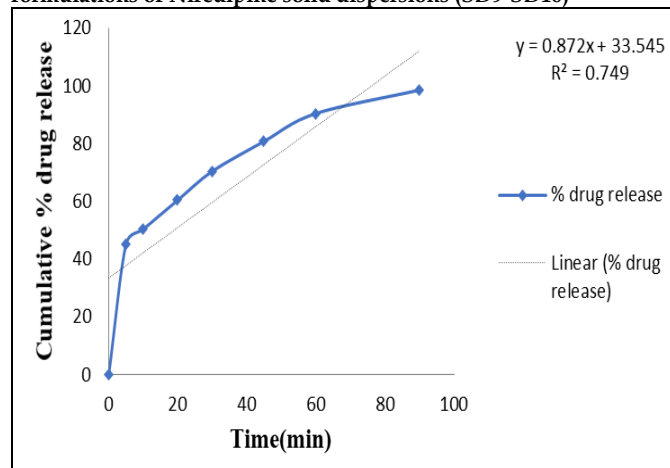
In vitro dissolution studies

The drug release data obtained for formulations SD1-SD16 are tabulated in Tables 5 and 6 which represent the cumulative percent drug released as a function of time for all formulations. *In vitro* studies reveal that there is marked increase in the dissolution rate of Nifedipine from all the solid dispersions when compared to pure Nifedipine itself. From the *in vitro* drug release profile, it can be seen that formulation SD12 containing Nifedipine, Labrosol and SLS in 1:4:2 ratio shows higher dissolution rate of 98.74 ± 5.19

compared with other formulations. The graphical representation of solid dispersions of SD1- SD16 with pure drug is shown in Figures 3 and 4.

Study of release order kinetics

The obtained *in-vitro* drug release data was fitted into zero order, first order, Higuchi and Korsmeyer-peppas equations to know the pattern and mechanism of drug release. The release profiles best fitted into first order and Korsmayer-peppas plots with good linearity of 0.9891 and 0.9609 respectively. This indicates fickian diffusion or burst release as one of the predominant mechanism of drug release (figures 5, 6, 7 and 8).

**Fig. 3: *In vitro* dissolution profile of pure drug and different formulations of Nifedipine solid dispersions (SD1-SD8)****Fig. 4: *In vitro* dissolution profile of pure drug and different formulations of Nifedipine solid dispersions (SD9-SD16)****Fig. 5: Zero Order release plot for SD12**

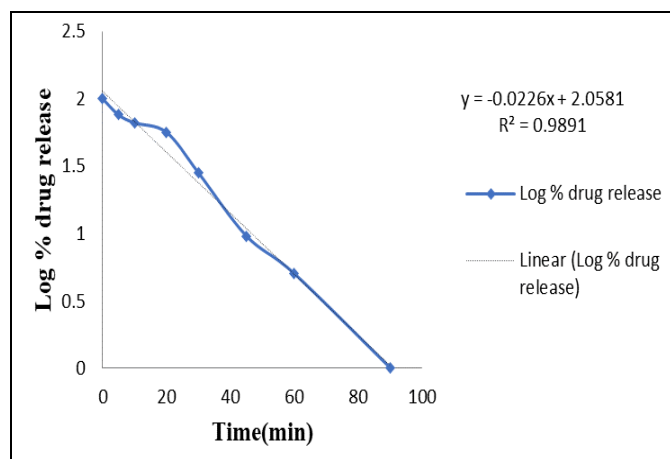


Fig. 6: First Order release plot for SD12

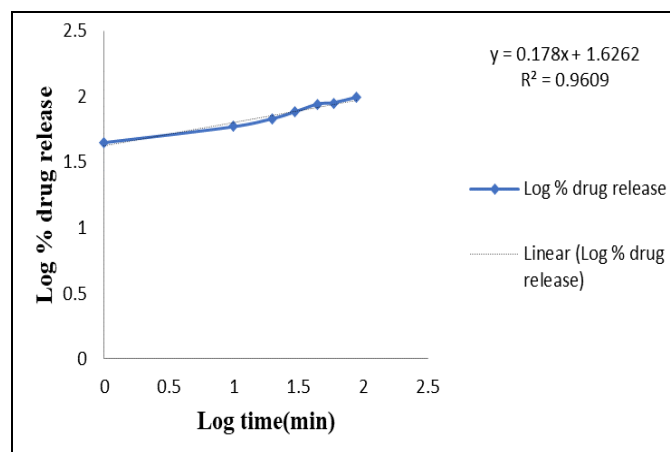


Fig. 8: Korsmayer - Peppas release plot for SD12

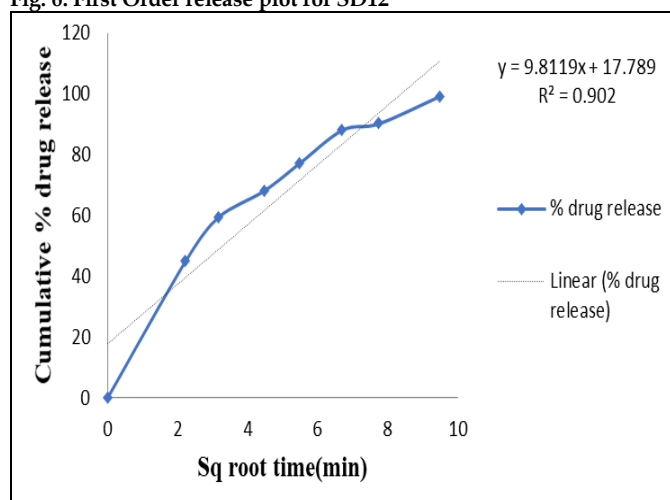


Fig. 7: Higuchi release plot for SD12

Characterization FTIR studies

FTIR spectroscopy of Nifedipine was performed to identify the supplied pure drug and find out any possible interactions between drug and the polymers. FTIR study of Nifedipine showed the peak at 3250.26, 1677.21, 1224.14, 1119.06, 1018.86 and 711.14 cm^{-1} due to the functional group like C-H, C=C, O-H, C-C, C-O and N-H respectively. The physical mixture of drug and polymer also retained the same peak indicating no interaction between the selected drug and the polymers. The FTIR spectra of nifedipine and polymer mixture are shown in figures 9, 10 and 11. Here, the N-H stretching in secondary amine groups of Nifedipine confirm the formation of hydrogen bonding between Nifedipine and water molecules.

Table 5: *In vitro* dissolution profile of pure drug and different formulations of Nifedipine solid dispersions (SD1-SD8)

Time (min)	Pure drug	SD1	SD2	SD3	SD4	SD5	SD6	SD7	SD8
0	0	0	0	0	0	0	0	0	0
5	5.67 ± 0.78	22.89 ± 1.35	24.62 ± 1.37	28.11 ± 1.90	30.13 ± 2.22	26.30 ± 1.37	29.16 ± 1.90	30.15 ± 2.19	31.15 ± 2.21
10	10.25 ± 0.80	31.18 ± 2.21	33.17 ± 2.37	38.20 ± 2.49	41.29 ± 2.54	35.12 ± 2.36	38.18 ± 2.49	43.16 ± 2.55	36.04 ± 2.34
20	18.17 ± 0.98	42.15 ± 2.56	44.58 ± 2.58	58.46 ± 2.80	55.67 ± 2.75	46.34 ± 2.59	45.89 ± 2.60	52.17 ± 2.63	42.54 ± 2.56
30	22.19 ± 1.33	50.68 ± 2.60	55.14 ± 2.75	61.38 ± 3.11	68.47 ± 3.26	59.14 ± 2.81	69.47 ± 3.28	63.18 ± 3.21	57.51 ± 2.81
45	25.20 ± 1.45	62.36 ± 3.23	68.27 ± 3.25	70.22 ± 3.84	72.18 ± 3.87	63.22 ± 3.25	75.26 ± 3.86	72.18 ± 3.84	65.40 ± 3.28
60	30.17 ± 1.92	71.24 ± 3.85	78.54 ± 3.96	82.19 ± 4.86	80.24 ± 4.80	77.51 ± 3.96	88.18 ± 4.98	84.26 ± 4.90	76.24 ± 3.97
90	37.55 ± 2.43	83.16 ± 4.90	88.26 ± 4.98	90.44 ± 5.02	91.50 ± 5.05	89.19 ± 4.99	89.78 ± 4.99	91.36 ± 5.02	92.18 ± 5.08

Table 6: *In vitro* dissolution profile of different formulations of Nifedipine solid dispersions (SD9-SD14)

Time (min)	Pure drug	SD9	SD10	SD11	SD12	SD13	SD14	SD15	SD16
0	0	0	0	0	0	0	0	0	0
5	5.67±0.78	24.18±1.37	28.16±1.49	38.16±2.49	45.11±2.60	35.19±2.36	30.19±2.19	32.15±2.36	32.15±2.36
10	10.25±0.80	38.19±2.49	35.18±2.36	49.71±2.62	59.42±2.81	47.33±2.59	42.16±2.56	44.19±2.58	44.19±2.58
20	18.17±0.98	44.6±2.58	42.19±2.55	57.18±2.85	68.15±3.30	58.19±2.8	55.25±2.75	58.16±2.80	58.16±2.80
30	22.19±1.33	58.22±2.80	54.26±2.75	69.44±3.28	77.12±3.98	62.11±3.15	63.81±3.21	65.11±3.30	65.11±3.30
45	25.20±1.45	63.22±3.21	65.19±3.20	75.17±3.86	88.14±4.89	72.18±3.84	75.22±3.86	79.10±3.96	79.10±3.96
60	30.17±1.92	74.26±3.85	78.45±3.96	83.45±4.89	90.26±5.02	80.25±4.80	84.49±4.90	81.42±4.80	81.42±4.80
90	37.55±2.43	88.15±4.98	89.96±4.99	92.46±5.11	98.74±5.19	91.26±5.03	90.32±5.02	93.14±5.10	93.14±5.10

X-Ray Diffraction patterns

The Nifedipine solid dispersions were studied for XRD to know whether the solid dispersions are crystalline or amorphous. The presence of numerous distinct peaks in the XRD spectrum of pure Nifedipine indicates that Nifedipine was present as a crystalline material (Figure 12). On the other hand, the spectrum of optimized

formulation SD12 was characterized by the complete absence of any diffraction peak, which is characteristic of an amorphous compound (Figure 13). The enhancement in the dissolution rate of the drug from the drug-Labrosol-SLS solid dispersion is because of marked reduction in the crystallinity of the drug.

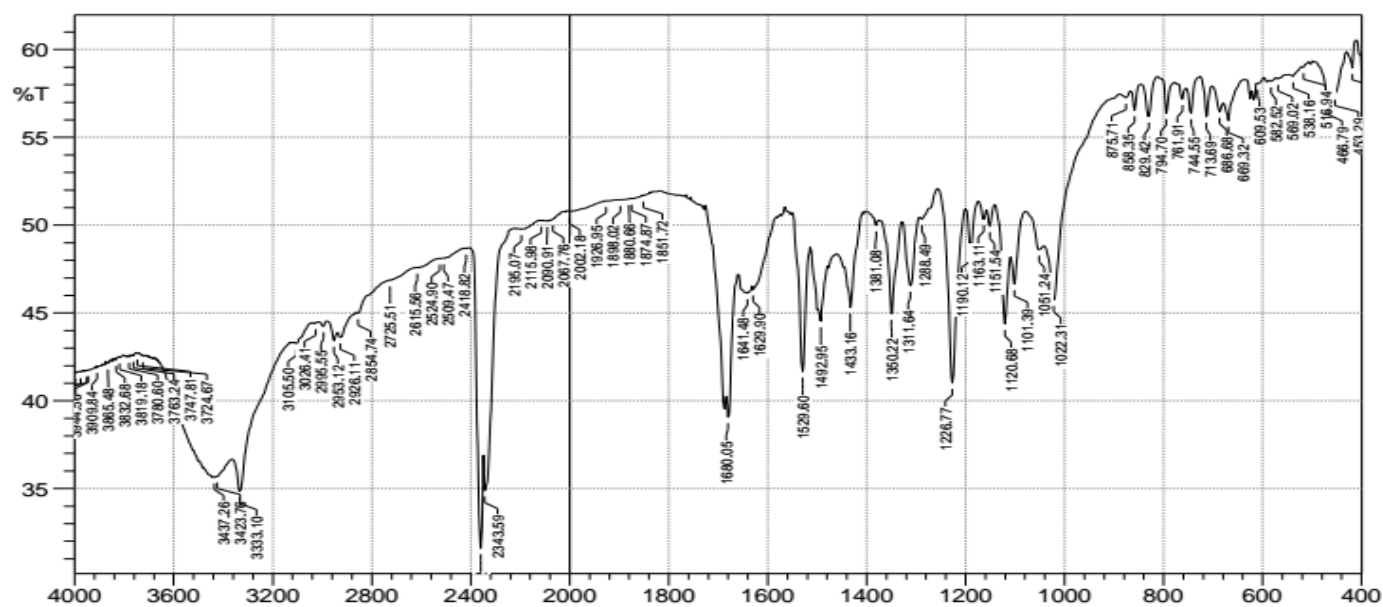


Fig. 9: FTIR spectrum of Nifedipine pure drug

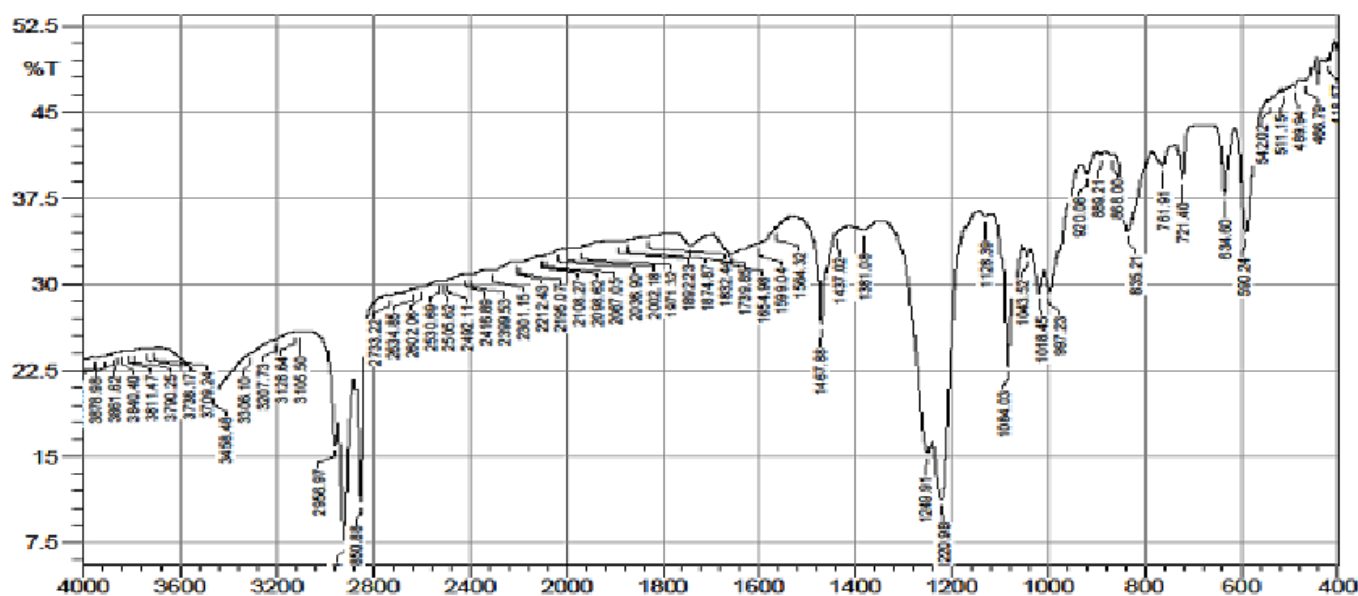


Fig. 10: FTIR spectrum of Nifedipine physical mixture

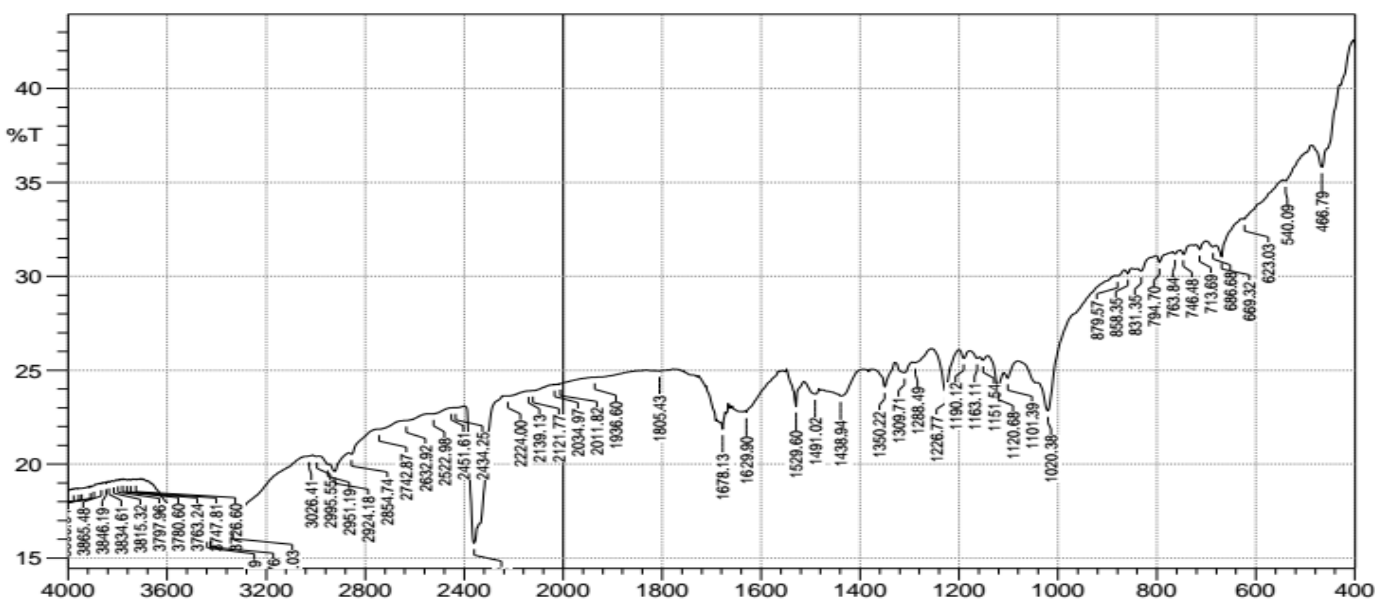


Fig. 11: FTIR spectrum of optimized formulation of Nifedipine SD12

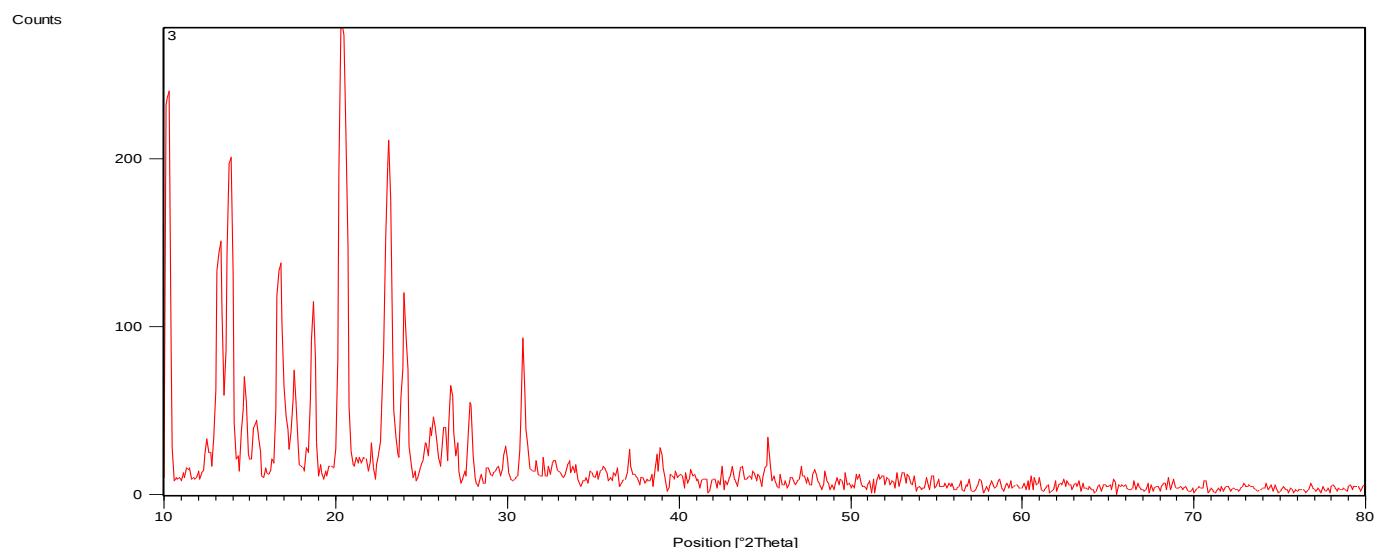


Fig. 12: X-Ray diffractograms of Nifedipine pure drug

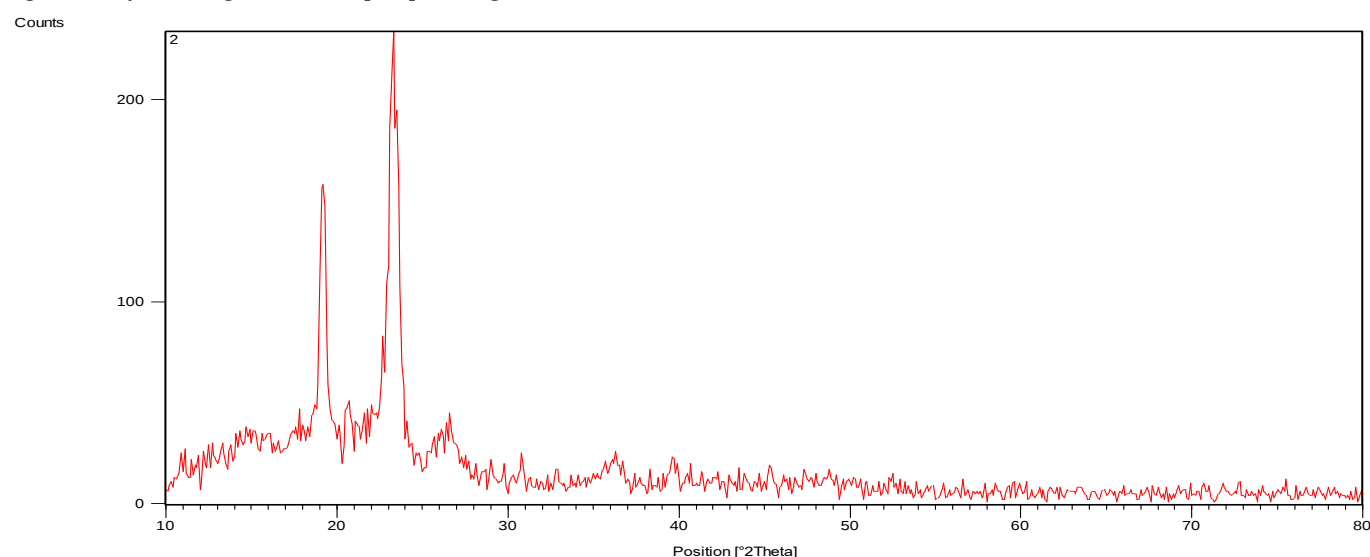


Fig. 13: X-Ray diffractograms of Nifedipine optimized formulation SD12

SEM Studies

SEM photographs for pure drug and optimized formulation SD12 are shown in figures 14 and 15. The drug crystals seemed to be smooth-surfaced, irregular in shape and size. For solid dispersions, it was difficult to distinguish the presence of drug crystals. The drug surface in solid dispersion seems to be more porous in nature. Solid dispersions appeared as a homogeneous mass with wrinkled surface. Drug crystals appeared to be incorporated into the particles of the polymers. The solid dispersion looked like matrix particles. This could be due to dispersion of the drug in the molten mass of the polymer.

Stability studies

Stability studies of SD12 formulation was performed for drug content and In vitro drug release studies for 3 months at accelerated stability conditions as per ICH guidelines. The optimized formulation was stable during 3 months period. From these results it was concluded that the formulation was stable and retained most of its properties with minor differences. The results are summarized in table 7.

Table 7: Evaluation parameters of SD12 stored at 40 $\pm$ 2 $^{\circ}$ C /75 $\pm$ 5%RH

Retest time for optimized formulation	% Drug content	In-vitro drug release (%)
0 days	99.04	99.70
30 days	98.19	98.95
60 days	97.65	98.15
90 days	97.05	97.62

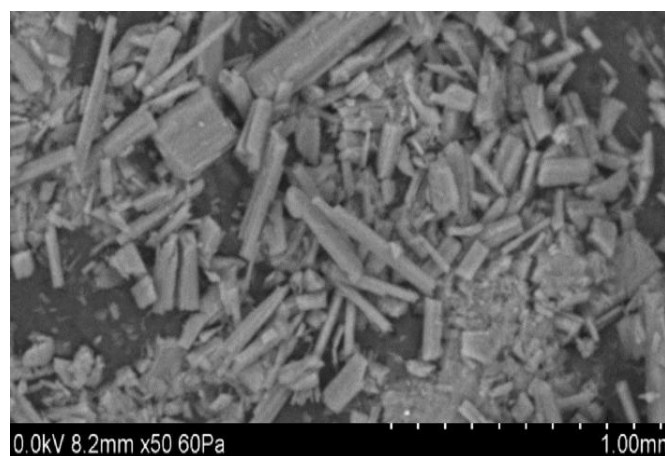


Fig. 14: Pure drug of Nifedipine



Fig. 15: Nifedipine optimized formulation SD12

Solid dispersions of Nifedipine were prepared by solvent evaporation method using hydrophilic polymer Labrosol and SLS as a surfactant. The type and amount of carrier was found to be important in increasing the solubility of Nifedipine. The *in-vitro* dissolution and kinetic modelling studies indicate that solid dispersions are one of the best methods to enhance the oral solubility and bioavailability of Nifedipine.

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HOW TO CITE THIS ARTICLE: Muralichand G, Bhikshapathi DVRN. Preparation and *in vitro* Evaluation of Solid Dispersions Containing Nifedipine. *Int. J. Pharm. Sci. Drug Res.* 2018; 10(4): 260-267. DOI: 10.25004/IJPSDR.2018.100408