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Formulation And Characterization of Nicardipine Hydrochloride Solid Dispersion by Using Solvent Evaporation Approach

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Abstract:
Nicardipine Hydrochloride is a calcium Channel blocker possessing antihypertensive & antianginal capabilities that's also frequently employed in the handling of both hypertension & angina (chest pain). Due to its poor aqueous solubility, it falls towards BCS class II and has low oral bioavailability (26%). The original study objective was to enhance Nicardipine Hydrochloride's water solubility using the Solvent Evaporation Approach. One of the most serious issues with this medication is its poor solubility in biological fluids, resulting in poor oral bioavailability. To boost its water solubility, solid dispersions (SDs) of nicardipine hydrochloride were produced employing PEG6000, Mannitol Chitosan extremely viscous, and Poloxamer 188. Nicardipine Hydrochloride SDs was produced in drug-to-polymer ratios of 1:1:2, 1:1:1, and 1:1:0 (w/w). The in-vitro release characteristics of entirely SDs (F1 to F9) were compared and estimated to pure Nicardipine Hydrochloride. Solid dispersion with (1:1:1) drug: PEG 6000: Poloxamer 188 ratio showed quicker dissolution. The increase in drug dissolving rate might be recognized to an increase in wettability, the hydrophilic character of the carrier, or a fall in drug crystallinity. Solubility, drug content, dissolution rate, infrared (IR) spectroscopy, & scanning electron microscopy (SEM) tests were conducted on the solid dispersion. Infrared spectroscopy revealed no evidence of substantial drug-carrier interaction (IR). The best formulation in this investigation was a solid dispersion of formulation (F8) Nicardipine Hydrochloride, PEG 6000, and Poloxamer 188 produced in a (1:1:1) ratio that indicated best formulation solubility & a dissolution rate of 99.04% in solid dispersion.
Keywords: *Solid Dispersion, Scanning electron microscopy, Poly ethylene glycol, Hydroxyl propyl cellulose, infrared spectroscopy.*

1. INTRODUCTION

Nicardipine hydrochloride is extensively soluble in chloroform, methanol, glacial acetic acid, sparingly soluble in anhydrous ethanol, mildly soluble in n-butanol, water, 0.01 M potassium dihydrogen phosphate, acetone, and dioxane, but almost totally and utterly insoluble in benzene, ether, and hexane [1,2].

Nicardipine hydrochloride diminishes extracellular calcium influx across cardiovascular smooth Muscle cell membranes by deforming the channel, interacting with calcium release from the sarcoplasmic reticulum, and modifying the ion control gating mechanism. The reduction in intracellular calcium suppresses the contractile activities of cardiac, and smooth muscle cells, resulting in coronary and systemic arterial dilatation, enhanced supply of oxygen to the myocardial tissue, lower total peripheral vascular resistance, and diminished systemic blood pressure and after load. Nicardipine hydrochloride has a more selective effect on vascular endothelium than cardiac muscle. Nicardipine hydrochloride relaxes the coronary vascular smooth muscle in animal models at frequencies with no inotropic impression [3,4].

Nicardipine hydrochloride is rapidly and fully immersed in the gastrointestinal system. However, it is prone to saturable first-pass hepatic digestion. A steady-state bioavailability of roughly 35% takes stayed documented after a 30 mg dosage. Nicardipine hydrochloride pharmacokinetics is non-linear through saturable central pass hepatic metabolism, and increasing the dosage may result in a disproportionate rise in plasma levels. Nicardipine hydrochloride is more than 95% obligated to plasma proteins, is broadly processed in the liver, and is evacuated in the urine and feces, primarily as indolent metabolites. Because the terminal plasma half-life is approximately 8.6 hours, uniform-phase plasma concentrations are obtained after 2 to 3 cycles of three-daily treatment [4].

Solid dispersion is the only of these strategies that have been applied frequently and efficaciously to recover the solubility, dissolution amounts, and therefore bioavailability of weakly soluble medications. The word "solid dispersion" describes a class of hard goods made up of by slightest dual distinct elements, often a hydrophilic atmosphere and a hydrophobic medication which are molecularly dispersed in shapeless elements (clusters) or crystal-like elements [5]. The dispersion procedure considers the collaboration among the carrier & medication. One of the fundamental ideas of solid dispersion creation is the creation of the amorphous phase, which is thought to be additional solvable than the crystal-like foam as no dynamism is needed to disruption the crystal lattice observed in the crystalline period [6]. Method of Fabrication of Solid Dispersion are Solvent Evaporation Method [7], Kneading Approach [8], Melting or fusion technique [9], Melt extrusion method [10], Co-Evaporation Method [11], Spray Drying Method [12], Gel Entrapment System [11], Supercritical fluid skill [13,14], Lyophilization method [15,16]. The Most typical way of creating a solid dispersion is to liquefy the medication or transporter in a corporate organic solvent, monitored by evaporation of the solvent [18,19,7]. Since the medicine Charity for solid dispersion is often hydrophobic as well as the transporter is hydrophilic, identifying a mutual solvent to melt equally constituents might be challenging. To dissolve both components completely, large amounts of solvent and heating may be required. Chiou and Riegel man [18] liquefied 0.5 g of griseofulvin and 4.5 g of PEG 6000 in 500 ml of ethanol. Although the solvents required to create solid dispersions were not indicated in most other published trials, they were probably equally substantial. Usui et al.[8] liquefied an Essential medication in a potent hydro combination of 1 N HCl and methanol, through Medication to co-solvent relations fluctuating from 1:48 to 1:20, since the medication remained Additional solvable in the sharp co-solvent arrangement than in methanol unaccompanied as a Protonated species. Other researchers dissolved the medication individually in the biological Solvent, or the elucidations were further added to the molten transporters. Vera et al.[9] melted 1g of oxodipine in 150mL ethanol, formerly combining the elucidation through Melted PEG 6000. Fernandez et al. [10] prepared piroxicam-PEG 4000 solid dispersion by dissolving the medication in chloroform or mixing the elucidation with PEG 4000 dissolved at 70°C. Several alternative procedures were recycled to remove biological solvents after solid dispersions. Simonelli et al. [11] disappeared an ethanolic solvent on a vapour immersion, or the leftover solvent stayed subsequently detached under decreased compression. According to Chiou and Riegel, man [18] desiccated an ethanolic elucidation of griseofulvin and PEG6000 in an emollient immersion at 115°C till no ethanol foams emerged. The fluid mixture stayed then permitted to solidify through chilling in a tributary of icy air. Further researchers utilized vacuum-drying, spray-drying, [12-15] covering on honey droplets consuming a fluidized low covering coordination [16], lyophilization [17] and other ways to remove natural solvents after solid dispersions. However, none of the publications lectured how considerably outstanding solvents existed in solid dispersions once alternative solvents, transporters, or desiccating processes were utilized.

2. MATERIALS AND METHOD

2.1 Materials:

Nicardipine Hydrochloride was obtained as a gift sample from Yarrow Chem Products, Mumbai, India. Mannitol, Poloxamer 188, PEG 6000, Chitosan, Lactose, Starch, Acetone, Methanol, Hydrochloric acid, Petroleum ether, Ethanol, HPMA, PVA, HPC, PVP, PEG 4000, Urea, PVP-VA, Dextran was obtained from CDH laboratory, New Delhi, India.

2.2 Preparation of solid dispersion from Nicardipine hydrochloride

2.2.1 Physical mixture (PM)

The medication Nicardipine hydrochloride or the chosen carriers/transporter is in a different ratio. They stayed approved via sieve no. 40 before being diverse uniformly in a glass pestle mortar for 45 minutes per batch design.

2.2.2 Solvent Evaporation Method [20]

Tables 1-3 illustrate solid dispersions with various polymers. In each Petric plate, 50mg nicardipine hydrochloride or 4ml acetone were added. The medication stayed entirely melted in the solvent. The solution was sonicated for 1 minute with several polymers before being dried in a hot air oven. Once the elucidations had wholly disappeared, they stayed kept in a desiccator. The originations stayed removed from the petri dish, pulverized using a mortar pestle, and conceded over 36-micron sieves. In conclusion, lactose was added to the mixture. The preparations stayed then relocated to Petric dishes or kept in a desiccator.

Table 1: Nicardipine Hydrochloride solid dispersion by altering the proportions of Mannitol with PEG 6000.

Component	F1(mg)	F2(mg)	F3(mg)
Nicardipine Hydrochloride	50	50	50
PEG 6000	100	100	100
Mannitol	200	100	0
Lactose	Qs	Qs	Qs
Total	400	400	400

Table 2: Nicardipine Hydrochloride solid dispersion formulation by altering the proportions of high chitosan viscosity with PEG 6000.

Components	F4(mg)	F5(mg)	F6(mg)
Nicardipine Hydrochloride	50	50	50
PEG 6000	100	100	100
Chitosan highly viscous	200	100	0
Lactose	Qs	Qs	Qs
Total	400	400	400

Table 3: Nicardipine Hydrochloride solid dispersion formulation by altering the proportions of Poloxamer 188 with PEG 6000.

Components	F7(mg)	F8(mg)	F9(mg)
Nicardipine Hydrochloride	50	50	50
PEG 6000	100	100	100
Poloxamer 188	200	100	0
Lactose	Qs	Qs	Qs
Total	400	400	400

2.3Characterization of Solid Dispersion

2.3.1 Micrometric properties:

2.3.1.1Bulk density and bulkiness: The inverse of bulk density was known as bulkiness. For bulk density determination, an accurately weighed quantity of sample (1 gm) was placed in a measuring cylinder. The cylinder was fixed on the bulk density apparatus and the volume occupied by the crystal was noted. Bulk density was calculated by the equation 1:

Equation 1 $$\text{Bulk Density} = \frac{\text{Weight of crystal}}{\text{weight of apparent volume}}$$

2.3.1.2Compressibility (Carr's Compressibility index): Fine cellulose crystal (1 g) was taken and transferred into a measuring cylinder and calculations were done using bulk density apparatus. Carr's index was calculated using the equation 2:

Equation 2

$$\text{Carr's index} = \frac{\text{Tapped density} - \text{bulk density}}{\text{tapped density}} \times 100$$

2.3.1.3 Flow property: Flow characteristics were measured by the angle of repose. Cellulose crystal (1 gm) was poured from a funnel which was kept at a distance of 5cm from the surface. The cellulose crystal formed a heap of piles on the surface from where the radius can be calculated. The angle of repose can be determined using the equation 3:

Equation 3 $$\tan\theta = h/r$$

Where,

h=height of pile

r= radius of pile

2.3.2 Solubility: The solubility of Nicardipine Hydrochloride was checked in different solvents: water, methanol, and phosphate buffer pH 6.8 of was added to 10 mg of Nicardipine Hydrochloride separately and shaken vigorously for 5 minute and placed in a constant temperature bath for 15minutes.

2.3.3 Drug Content Investigation: For the medication content investigation, solid dispersion containing 50mg was collected. It was dissolved in a 10ml volumetric container covering 10 ml of methanol as a solvent, and the elucidation was maintained to certify comprehensive solubility. The elucidation was then strained, & 5 mL of it was diluted up to 10 ml using methanol before the absorbance was dignified at a max of 236.0 nm. The percentage of medication contented was designed employing the standard curve.

Equation 4 $$\%\ \text{drug content} = \frac{C}{D} \times 100 \times \text{D. F.}$$

Where,

C = concentration Obtained by spectrophotometric method

D = dose of the drug

D.F. = Dilution Factor

2.3.4 In-Vitro Drug Release: The suggested constructions' dissolving investigations remained conceded out utilizing a USP II dissolution equipment (paddle type) and solid dispersion containing 50 mg of the drug nicardipine hydrochloride. The dissolving media employed was 900 ml of 0.1 NHCl& 6.8 phosphate buffer at 37 ± 0.5°C and 50 rpm. The dissolving experiment lasted 90 min. A 10 ml taster was extracted at predetermined recesses and sieved. The amount of dissolving fluid was reduced to 900ml by removing 10 ml of 0.1 N HCl&6.8 phosphate buffers after each sampling to maintain a consistent volume. At 236.0 nm (max), the material was spectrophotometrically examined. The drug nicardipine hydrochloride concentration was calculated using cumulative release per cent.

2.3.5 Drug Release Kinetics of optimized Formulations Parameters: To examine the in-vitro release record, multiple dynamic simulations have been applied to characterize the proclamation rates. The zero-order equation (j) represents the structure in which the medication release rate is independent of its conc. The first-order equation (ii) describes the intensity release rate. Higuchi depicts the release of the medication from an inert carrier by way of a square root of stage-dependent approach established on the fiction diffusion equation (iii), the Hixson-Crowell cube root law equation (iv) describes the release of the medication after a medium wherever its surface area and diameter fluctuate.

Equation 5 $$C = k_0 t$$

Where,

k is the zero-order rate constant communicated in units if conc. / time and t is the time.

Equation 6 $$\text{Log } C = \text{Log } C_0 - kt/2.303$$

While,

C symbolizes the preliminary drug conc. And k represents the first-order constant.

Equation 7 $$Q = Kt_{1/2}$$

Where,

K is a constant that represents the system's strategy variable.

The plots listed below were created: Log cumulative of% drug remaining v/s time (first-order kinetic model); log cumulative of% drug release v/s square root of time (Higuchi model), and log cumulative% drug release v/s log time (Korsemeyer model).

2.3.6 Scanning Electron Microscopy: The exterior & interior morphology of the solid dispersion was inspected consuming scanning electron microscopy SEM (GSM 6510 LV, JEOL, JAPAN). SEM taster was made by gluing the granules of a dual gum adhesive tape arranged on an aluminium stump. The stubs were then layered with silver using a high vacuum evaporator (polar on SEM coating machine) in an argon environment. The crusted illustration was then casually perused and photographed using a scanning electron microscope.

3. RESULT AND DISCUSSION

3.1 Micrometric Properties:

The various physical parameters of the solid dispersion are illustrated in Table 4.

Table 4: Physical Parameters of solid dispersion

Property		Average
Bulk Density (g/cm^2)		0.551 ± 0.011
Tapped Density (g/cm^2)		0.519 ± 0.0115
Carr's Index		14.8 ± 0.057
Angle of repose (θ)		39.98 ± 0.035
Solubility (mg/ml)	Distilled water	64.35 ± 0.67
	PBS pH 6.8	87.95 ± 0.73
	Methanol	28 ± 0.79

3.2 Drug Content:

The maximum drug content was found in the case of formulation F8 (99.1±1.98) while minimum in the formulation F3 (93.8±1.18).

Table 5: Drug content of solid dispersion of Nicardipine hydrochloride

S. N.	Formulation	% drug content
1	F1	94.2±1.21
2	F2	95.6±1.37
3	F3	93.8±1.18
4	F4	98.4±2.03
5	F5	97.2±2.01
6	F6	95.2±1.38
7	F7	96.0±1.41
8	F8	99.1±1.98
9	F9	95.2±1.35

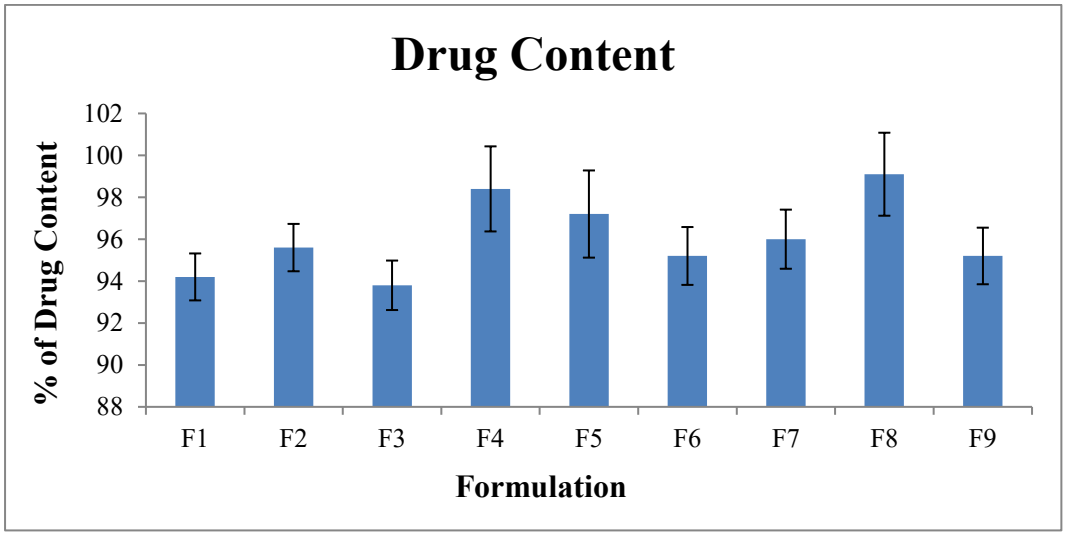

Figure 1: Graph of Drug content of solid dispersion

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3.3 Drug release

Table 6: Drug release study of 0.1N HCl

Time (min)	Cumulative drug release (%)								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
10	10.80 ± 0.25	9.10 ± 0.19	11.73 ± 0.21	14.43 ± 0.19	12.63 ± 0.39	8.14 ± 0.32	7.23 ± 0.45	18.02 ± 0.25	5.48 ± 0.29
20	22.38 ± 0.43	20.70 ± 0.34	22.53 ± 0.52	23.54 ± 0.48	20.82 ± 0.55	20.73 ± 0.52	18.32 ± 0.61	25.31 ± 0.58	18.98 ± 0.61
30	25.37 ± 0.62	25.71 ± 0.58	26.74 ± 0.69	27.21 ± 0.63	28.23 ± 0.69	27.16 ± 069	25.35 ± 0.73	27.98 ± 0.67	25.67 ± 0.74
40	29.90 ± 0.79	32.50 ± 0.77	30.74 ± 0.81	31.77 ± 0.78	31.57 ± 0.81	36.98 ± 0.75	30.69 ± 0.84	35.31 ± 0.81	28.98 ± 0.86
60	33.90 ± 0.86	37.82 ± 0.89	39.83 ± 0.91	43.74 ± 0.86	38.98 ± 0.90	41.43 ± 0.89	36.24 ± 0.91	40.57 ± 0.89	39.78 ± 0.94
90	47.12 ± 0.97	46.93 ± 0.98	45.30 ± 0.99	46.10 ± 0.96	45.83 ± 0.98	45.98 ± 0.90	45.97 ± 1.06	47.97 ± 1.08	45.29 ± 1.15

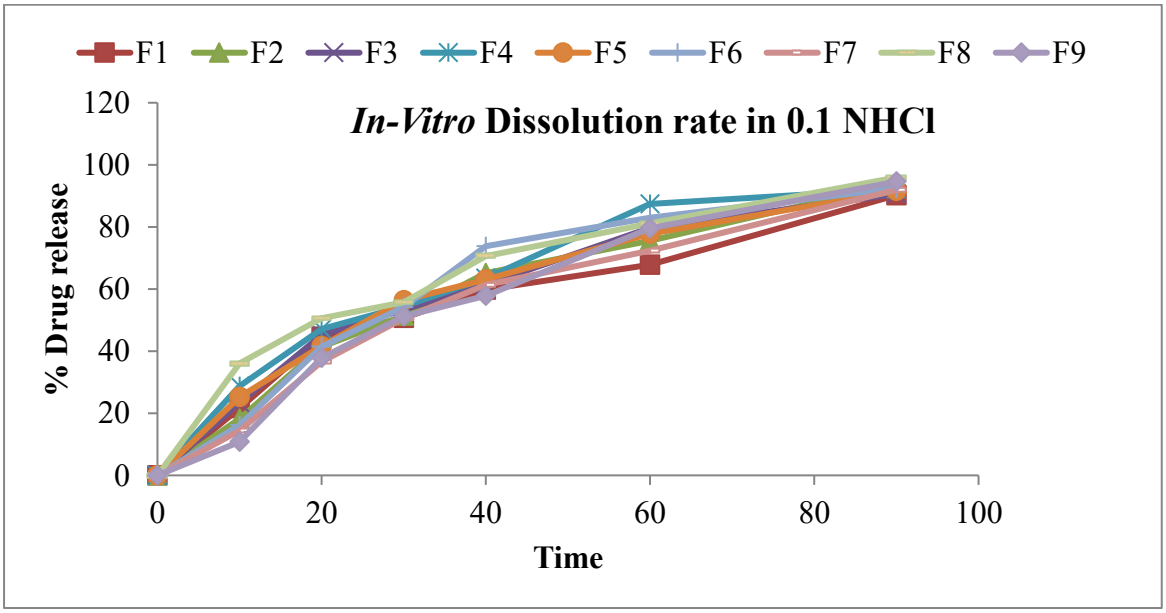

Fig 2: In-vitro dissolution study of Solid dispersion in 0.1N HCl

From the in-vitro study, it was observed that the maximum dissolution rate found to be F8 formulation and minimum dissolution rate found to be F9 formulation in 0.1N HCl.

Table 7:Drug release study of Phosphate buffer pH 6.8

Time (min)	Cumulative drug release (%)								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
10	9.50 ± 0.15	4.59 ± 0.19	6.32 ± 0.11	5.33 ± 0.21	8.19 ± 0.23	10.87 ± 0.17	10.80 ± 0.18	13.91 ± 0.22	9.91 ± 0.24
20	18.93 ± 0.35	9.61 ± 0.29	10.20 ± 0.31	18.98 ± 0.28	13.58 ± 0.34	15.37 ± 0.32	17.12 ± 0.27	21.63 ± 0.30	15.36 ± 0.25

30	24.23 ± 0.43	11.89 ± 0.48	19.36 ± 0.37	25.27 ± 0.41	21.69 ± 0.39	22.59 ± 0.42	25.20 ± 0.36	26.19 ± 0.49	23.40 ± 0.45
40	29.96 ± 0.54	19.35 ± 0.57	29.52 ± 0.63	27.98 ± 0.53	30.67 ± 0.61	28.82 ± 0.57	30.65 ± 0.58	32.48 ± 0.66	30.60 ± 0.63
60	37.29 ± 0.76	32.10 ± 0.79	37.69 ± 0.81	41.49 ± 0.83	36.92 ± 0.80	37.85 ± 0.84	37.88 ± 0.72	42.39 ± 0.75	43.28 ± 0.74
90	48.74 ± 0.96	48.52 ± 0.93	47.97 ± 0.90	48.99 ± 0.89	48.96 ± 0.91	49.02 ± 0.94	48.01 ± 0.93	49.58 ± 0.99	47.99 ± 0.92

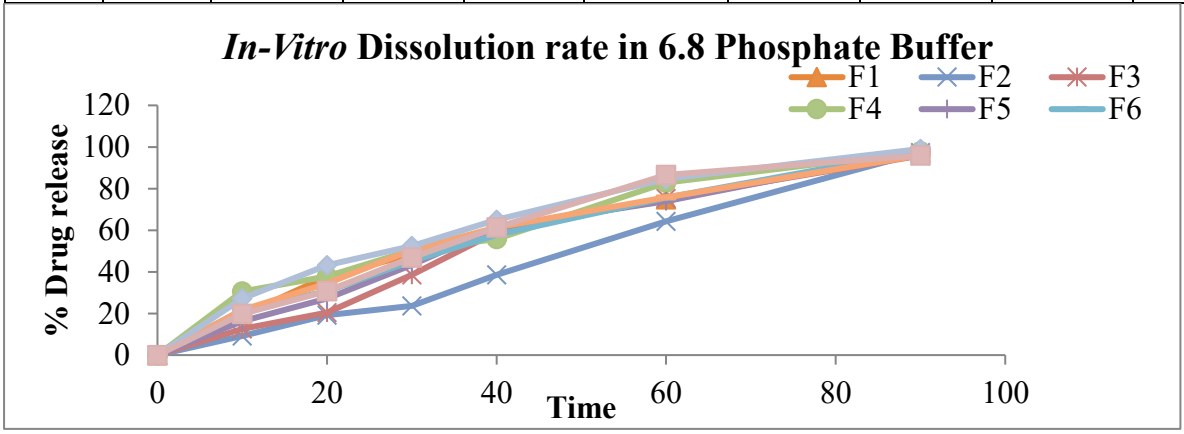

Fig 3: In-vitro dissolution study of Solid dispersion in Phosphate buffer pH 6.8

From the in-vitro study, it was observed that the maximum dissolution rate found to be F8 formulation and minimum dissolution rate found to be F2 formulation in phosphate buffer pH 6.8.

Table 8: Comparative drug release study of F8 in Phosphate buffer pH 6.8 and 0.1N HCl

Time (min)	Cumulative drug release (%) of F8 Formulation	
	0.1N HCl	Phosphate buffer pH 6.8
0	0	0
10	18.02±0.25	13.91±0.22
20	25.31±0.58	21.63±0.30
30	27.98±0.67	26.19±0.49
40	35.31±0.81	32.48±0.66
60	40.57±0.89	42.39±0.75
90	47.97±1.08	49.58±0.99

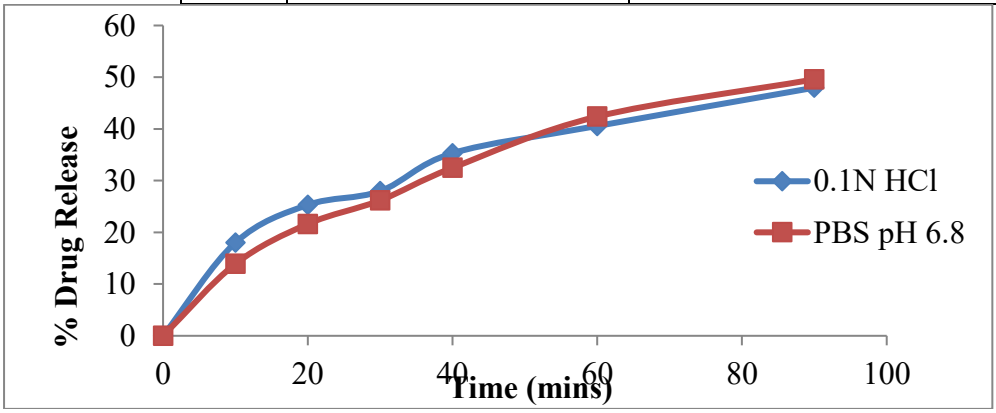

Fig 4: Comparative study of F8 formulation in 0.1N HCl and Phosphate buffer pH 6.8

From above comparative study, it was found that the solid dispersion of Nicardipine hydrochloride is dissolve in 0.1N HCl as compare to phosphate buffer pH 6.8 in large amount.

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3.4 Kinetic Drug Release

Table 9: Comparative study of drug kinetic release of outstanding formulation F8

Time (hr)	Log Time	Square root	F8 % CDR	Log F8 % CDR	Drug remain	Log drug remain
0.167	-0.78	0.41	27.16	1.43	98.57	1.99
0.333	-0.48	0.58	43.26	1.64	98.36	1.99
0.5	-0.3	0.71	52.38	1.72	98.28	1.99
0.66	-0.18	0.81	64.96	1.81	98.19	1.99
1	0	1	84.78	1.93	98.07	1.99
1.5	0.18	1.22	99.04	2.00	98.00	1.99

Table 10: Comparative study of drug kinetic release R^2 value of best formulation.

Formulation	Zero order	First order	Higuchi model	Korsmeyer-pappas model
	R^2	R^2	R^2	R^2
F8	0.8211	0.8727	0.9874	0.9937

Zero-order kinetics release.

In zero order graph plotted between time (hr) & Formulation CDR.

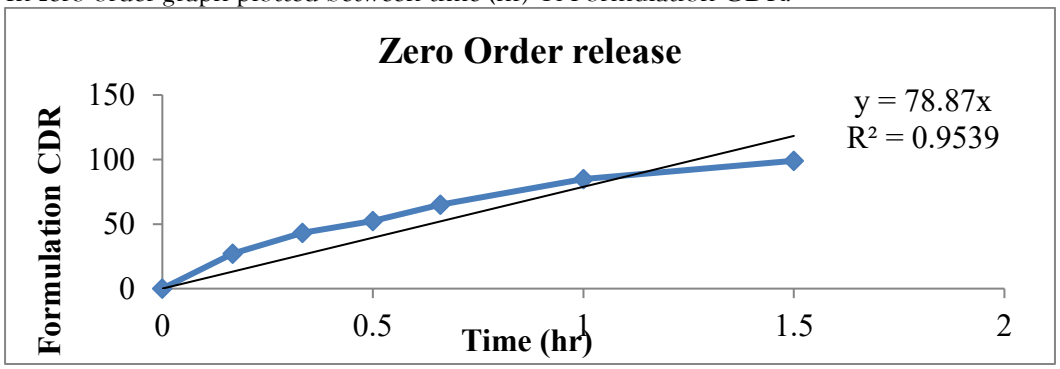


Fig 5: Comparative study of drug kinetic parameter of outstanding formulation

First Order Kinetic Release.

In first order graph plotted between time (hr) & Drug Remaining.

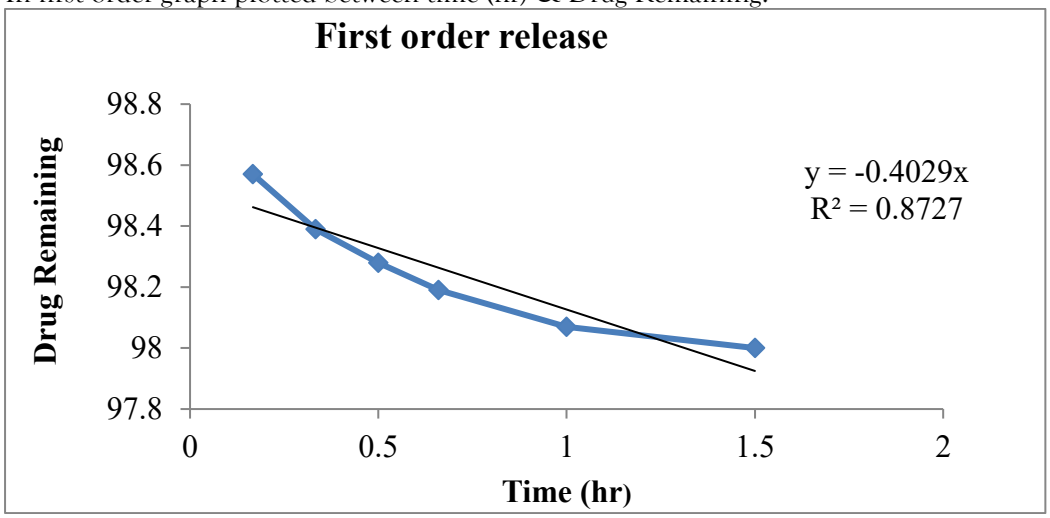


Fig 6: Comparative study of drug kinetic parameter of outstanding formulation

Higuchi Order Kinetic Release

In Higuchi order graph plotted between square root & Formulation % CDR.

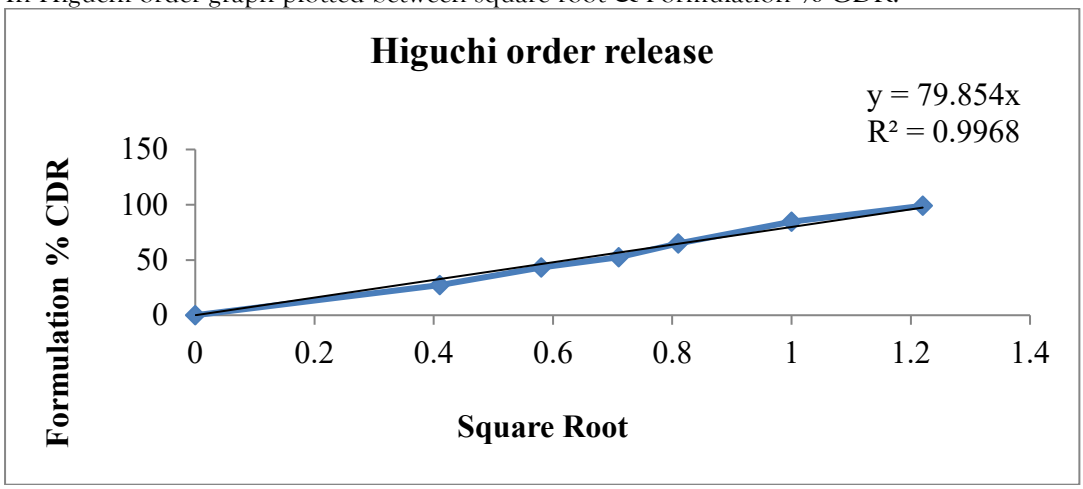


Fig 7: Comparative study of drug kinetic parameter of outstanding formulation

Korsemeyer Pappas Order Kinetic Release

In Korsemeyer Pappas order graph plotted between Log Time & Log Formulation % CDR.

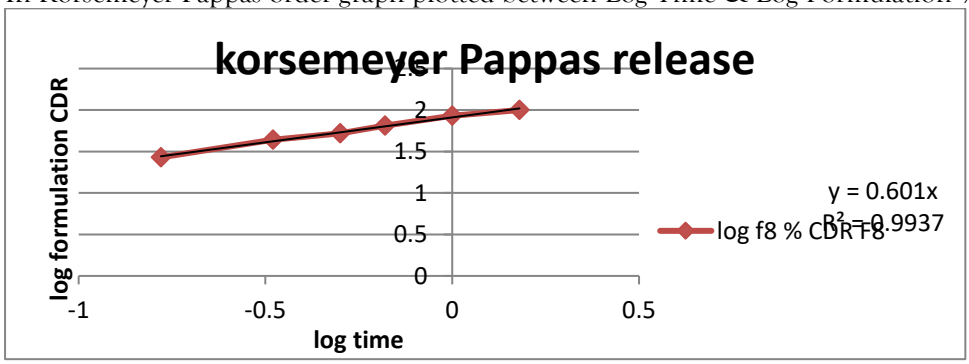
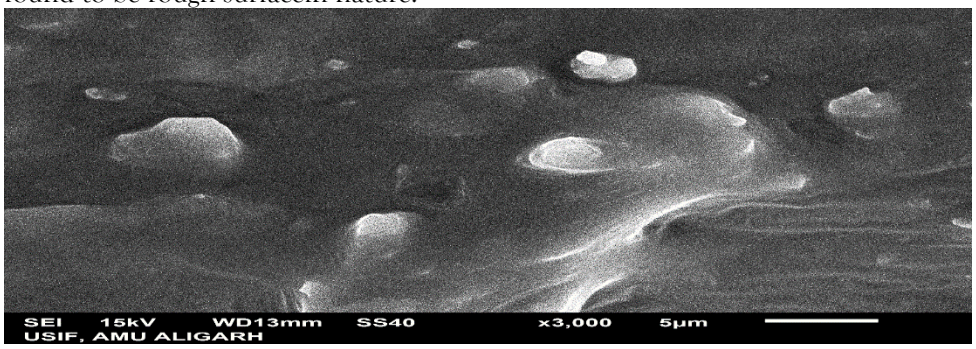


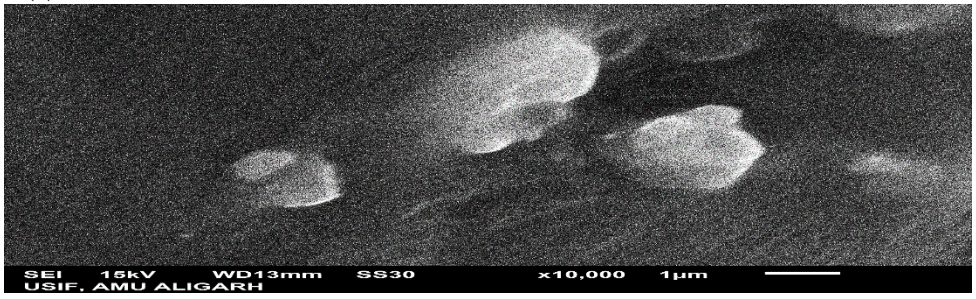
Fig 8:Comparative study of drug kinetic parameter of outstanding formulation

3.5 SEM

The surface morphology of the pure drug and pure drug with polymer was shown in figure 9 (a) & 9 (b) respectively. The pure drug surface was found to be porous and whereas a pure drug with polymer was found to be rough surfacein nature.



9 (a)



9(b)

Fig 9: SEM of (a) Nicardipine hydrochloride and (b) Nicardipine hydrochloride with polymer

CONCLUSION:

The work aimed to boost the solubility or increase the dissolution rate by utilizing the solvent evaporation approach on the active drug. Solvent evaporation methods have been used to increment the dissolution rate,

Solid dispersion is prepared from the hydrophilic polymer using the differences in improving the solubility & drug dissolution. The ternary mixture (Drug + PEG 6000+ Poloxamer 188) was formulated, and it was founded that Poloxamer 188 to be most efficient polymer compared to Mannitol and chitosan because Poloxamer 188 in higher concentration was proving to be denser than that of Mannitol and chitosan. Hence from the increased solubility & dissolution profile of each batch solid dispersion by the solvent evaporation approach. It was concluded that whenever the concentration of Poloxamer 188 is higher compared to Mannitol and chitosan, it has also been shown to raise the dissolution rate. Among all the methodologies performed, the final outstanding batch gives F8 formulation as the rise in solubility & dissolution rate of the medication. Either mainly due to reduced particle size or aggregation between the drug carriers in a different ratio. The final optimized batch is the F8 formulation of solid dispersion through the solvent evaporation method.

SEM report of F8 formulation batch showed that the particle size had been either reduced or it may have from a complex between the drug and carriers, which may attribute to increasing in dissolution rate of the medication

The solubility studies also concluded the maximum % solubility in dissimilar ratios of both the carrier with the constant amount of drug. As the encouraging result was obtained by dissolution profile 99.04% that was found through a solvent evaporation method

The drug content in the prepared solid dispersion by solvent evaporation technique was determined and found in the range of 92.08 to 99.1, showing no or less wastage or deterioration of the drug in the solvent evaporation method formulation.

The Drug Kinetic Release in the prepared solid dispersion by solvent evaporation approach was followed Korsmeyer Pappas model their range of R^2 value is 0.9987.

From this profile, we can conclude that each polymer and combination of polymers, however, aim to boost the solubility & dissolution rate of the medication. This method will be easily applicable at an economic level in the pharmaceutical industry as there was no solvent utilization to enhance the dissolution rate. We can conclude that there is no wastage of solvent, decreased chances of toxicity due to the presence of the solvents, and reduced stakes of reciprocal action among medication and polymer.

Hence, it can be ensured that solvent evaporation is undertaken as this technique, with lower cost, quicker, readily, scalable alternative for the invention of common aqueous soluble medications.In the future, an in vivo study has to be undertaken to correlate the relation with in vitro dissolution studies for the solid dispersion of the outstanding batch of Nicardipine Hydrochloride.

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