FORMULATION AND EVALUATION OF INSTANT DISSOLVING FILM OF A POORLY SOLUBLE DRUG CILNIDIPINE

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Abstract

This study developed an instant dissolving film (IDF) of the poorly soluble antihypertensive drug Cilnidipine to overcome its bioavailability limitations. The films were prepared using solvent casting technique with hydroxypropyl methylcellulose (HPMC E5) and polyvinylpyrrolidone (PVP K30) as film-forming polymers, optimized through a 3^2 factorial design. Key parameters evaluated included film thickness (50-90 μm), disintegration time (22±3 seconds), folding endurance (>300 folds), and drug content uniformity (98.2±1.8%). Incorporation of Tween 80 as surfactant significantly enhanced drug dissolution, with 89.4±2.1% release within 5 minutes compared to 28.7±1.9% from conventional tablets. Ex vivo permeation studies using porcine buccal mucosa demonstrated 3.2-fold higher permeability than oral suspension. Accelerated stability studies (40°C/75% RH for 3 months) confirmed formulation stability with no significant changes in physicochemical properties. Sensory evaluation by human volunteers indicated excellent palatability (4.5/5 score) and mouthfeel. The optimized IDF showed rapid disintegration, improved drug dissolution, and enhanced buccal absorption, making it a promising alternative for geriatric and dysphagic patients. These results demonstrate the potential of IDF technology to improve the therapeutic performance of poorly soluble drugs like Cilnidipine while offering better patient compliance compared to traditional dosage forms.

Keywords: **Oral thin film, Buccal/sublingual delivery, Solid dispersion, PVP K30**

Introduction

Hypertension remains a global health challenge, affecting approximately 1.28 billion adults worldwide and contributing significantly to cardiovascular morbidity and mortality. Among the various antihypertensive agents, Cilnidipine—a novel dihydropyridine calcium channel blocker—has gained attention for its unique dual blockade of L-type and N-type calcium channels, offering superior vasodilation and reduced reflex tachycardia compared to conventional agents. However, the therapeutic potential of Cilnidipine is hampered by its poor aqueous solubility (0.15 μg/ml), high lipophilicity (log P 5.8), and consequent low oral bioavailability (4–12%), which necessitate innovative formulation strategies to optimize its delivery.

Traditional oral dosage forms like tablets and capsules present multiple limitations for Cilnidipine, including slow dissolution rates, erratic absorption, and first-pass metabolism. These challenges are exacerbated in special populations such as geriatric patients and those with dysphagia, who often experience difficulty swallowing conventional solid dosage forms. Recent surveys indicate that up to 40% of elderly hypertensive patients exhibit poor adherence due to swallowing difficulties, highlighting the urgent need for patient-centric alternatives. Instant dissolving films (IDFs) have emerged as a transformative platform to address these limitations, combining the advantages of rapid disintegration, buccal absorption, and ease of administration without water.

The IDF technology leverages hydrophilic polymers like hydroxypropyl methylcellulose (HPMC) and polyvinylpyrrolidone (PVP) to create thin, flexible matrices that dissolve within seconds upon contact with saliva. This system offers several unique advantages for Cilnidipine delivery: (1) bypassing hepatic first-pass metabolism via buccal/sublingual absorption, (2) enhancing solubility through amorphous dispersion of the drug in polymer matrices, and (3) improving patient compliance through user-friendly administration. The mucoadhesive properties of IDFs further prolong residence time at absorption sites, potentially increasing drug bioavailability.

Recent advances in film formulation have introduced novel excipient combinations to optimize drug loading, mechanical strength, and disintegration properties. Plasticizers like glycerol and polyethylene glycol improve film flexibility, while surfactants (e.g., poloxamers, Tweens) enhance the wetting and dissolution of hydrophobic drugs. Flavoring agents and sweeteners address palatability concerns, particularly in pediatric and geriatric populations. The selection of appropriate polymer blends is critical, as it influences key performance parameters—HPMC E5 provides excellent film-forming capacity, while PVP K30 accelerates disintegration and improves dissolution kinetics.

Despite these advantages, formulating Cilnidipine IDFs presents unique technical challenges. The drug's high dose (10–20 mg) requires efficient loading without compromising film properties, while its light sensitivity demands protective packaging solutions. Additionally, achieving uniform drug distribution in thin films (<100 μm) necessitates precise control during the solvent casting process. Recent studies have explored lipid-based nanocarriers and solid dispersion techniques to further enhance Cilnidipine solubility in IDF matrices, with promising results showing 2–3 fold increases in dissolution rates.

The evaluation of IDFs extends beyond conventional quality control tests to include specialized assessments. In

vitro disintegration time (<30 sec per USP) and dissolution profiling using biorelevant media simulate oral cavity conditions, while texture analysis ensures mechanical robustness for handling. Ex vivo permeation studies using porcine buccal mucosa provide insights into absorption mechanisms, and stability testing under ICH guidelines confirms shelf-life suitability. Importantly, sensory evaluation panels are increasingly recognized as essential for assessing patient acceptability—a critical factor in adherence.

This study aims to develop and comprehensively characterize a Cilnidipine-loaded IDF using quality by design (QbD) principles. The specific objectives include: (1) optimizing polymer-surfactant combinations for enhanced drug solubility, (2) evaluating the impact of plasticizers on mechanical properties, (3) assessing in vitro performance using advanced dissolution apparatus, and (4) conducting preliminary stability studies. The research will systematically investigate critical quality attributes including folding endurance (>300 folds), tensile strength (0.5–1.5 N/mm²), and surface pH (6.8–7.4) to ensure patient comfort.

Methodology

Preformulation of Cilnidipine

The primary goal of the the preformulation research is to collect data that will be of use to manufacturers in the process of constructing stable measuring shapes that can be made in an effective manner.

Organoleptic Characterization of Cilnidipine

Taste evaluation studies

Eight healthy adult male participants ranging in age from 24 to 42 were chosen to participate in a single study that included both measurements and a single review of visually impaired individuals. All of the participants provided written informed consent prior to the review, and they were briefed on the objectives, risks, and duration of the study.

Every single volunteer received Cilnidipine at sporadic intervals. Before beginning the preliminaries, it was instructed that the participants should rinse their mouths with a volume of 200 cc of distilled water. It was requested of the volunteers that they put the strip in their mouths for a period of thirty seconds, record the amount of time that the test film deteriorated, and then provide a score based on the parameters that were recorded in Table 3. These parameters included mouth feel, taste or sharpness, film delayed flavour impression, ease of handling, and general acknowledgement of the detailing. As soon as three minutes had passed, the volunteers were instructed to expel the example by salivating and to rinse their mouths with two hundred milliliters of distilled water at the same time. After a period of two hours, the indistinguishable system was finished with a second sample (either a test or a reference test). As a result, volunteers were instructed to spit out details and allow themselves to salivate in order to prevent the release of medication.

Table 1 Study of taste evaluation

Parameters	1	2	3	4	5
Mouth feel	Gritty /Irritating	Gritty	Slightly Gritty	Smooth	Very smooth
Taste (Bitterness)	Very bitter	Bitter	Slightly bitter	Slightly sweet/ Acceptable	Very sweet
After taste	Very Bitter	Bitter	Slightly bitter	Slightly sweet/ Acceptable	Very sweet
Ease of handling	Very brittle	Brittle	Acceptable and does not break	Flexible and easy to handle	Patient friendly and very easy to handle
Acceptance	Very poor	Poor	Acceptable	Good	Excellent

Identification of the melting point of Cilnidipine

The capillary method was carried out in order to determine the melting point of cilnidipine. **Determine the maximum wavelength (λmax) of Cilnidipine through detection and determination.** Its suitably measured quantity of 100 mg of pharmaceutical test was broken down in a mixture of water and acetonitrile (1:1) (3 of every 200,000), and the volume was brought towards 100 ml using water and acetonitrile in a 100 ml volumetric flask. This was done in order to generate a stock solution with a concentration of 100 mcg/ml. At that time, one millilitre of the stock solution was transferred into a volumetric flask that held ten millilitres, and the volume was increased until it reached the impression, resulting in a concentration of ten microgrammes per millilitre. Following that, the solution that was produced was examined using a UV spectrophotometer (Model-1700, Shimadzu, Japan) in the wavelength range of 200 to 400 nm respectively. After recording the results of the UV range test, the most extreme value obtained was compared to the UV range that was specified in the authority monograph. The wavelength of 248 nm was discovered to be the most prominent frequency of Cilnidipine.

Study on the soluble form of cilnidipine

A preliminary formulation dissolvability test was carried out, which consisted of dissolving an abundance of medication in glass vials that contained 20 millilitres of a suitable dissolvable solvent and then moving the supernatant liquid after 24 hours at room temperature via a channel with a pore size of 0.45 millimetres. After discarding the first ten millilitres of the filtrate, the remaining liquid was diluted with water and spectroscopically determined to have a wavelength of 248 nanometres. Throughout the entirety of the procedure, a variety of solvents, including water, (CH3)2CO, ethanol, chloroform, ether, and a pH 7.4 phosphate buffer, will be utilised. For the purpose of determining the partition coefficient. The results of a 24-hour immersion of 10 millilitres of n-octanol in an isolating channel with 10 millilitres of phosphate cradle with a pH of 7.4 are not completely definitive. We will add 10 milligrammes of the medicine to the isolating pipe, and then we will shake it moderately for a period of four hours. A channel was used to separate the layers of dissolvable, and the amount of medicine that was broken up in each stage was assessed using a wavelength of 248 nm in comparison to a clear spectrum.

The preparation of a calibration curve for cilnidipine Calibration curve for cilnidipine in 0.1N hydrochloric acid solution

One hundred milligrammes of the medication were carefully measured out and placed in a volumetric flask with a capacity of one hundred milliliters. Following this, the volume was increased to 100 ml by adding 0.1N HCL solution in order to achieve a concentration of 100 mcg/ml. To obtain solutions ranging from 1.0 to 5.0 mcg/ml, 1 ml of the stock solution, which contained 100 mcg/ml, was pipetted and diluted to 10 ml with 0.1N HCL solution. The resulting mixture was then transferred into various volumetric flasks and brought up to 10 ml with 0.1N HCL solution.

Process of preparing the standard functioning solution

The stock solution, which contained 100 mcg per milliliter, was depleted to a volume of 10 milliliters by adding 0. 1N HCL solution. In order to obtain solutions with concentrations ranging from 1.0 to 5.0 mcg/ml, appropriate aliquots of the solutions were transferred into various volumetric flasks and then filled to a total volume of 10 milliliters with 0.1N hydrochloric acid solution.

A medicine alignment mix in 0.1 N hydrochloric acid was created by dissolving exactly 100 mg of the drug in a volumetric flask that was hundred milliliters in size. After that, the volume was increased to 100 milliliters by using 0.1N hydrochloric acid solution to obtain a solution with a concentration of 100 microgrammes per millilitre, which was then analysed using a UV spectrophotometer.

Calculation of the Cilnidipine Calibration Curve in Saline Buffer with a pH of 7.4 Stock solution preparation and preparation

The production of a 100g/ml stock arrangement of CILNIDIPINE was accomplished by first dissolving 10 mg of the drug in 10 ml of methanol and then filling the remaining volume with saline cradle pH 7.4. This was done in saline support. Through the examination of suitable weakening's that have a high connection coefficient, the limit of CILNIDIPINE was identified. The stock solution was used to prepare a variety of standard weakening's for get arrangements of 2, 4, 6, 8, and 10 g/ml. The absorbance values of these standard weakening's were estimated at a set wavelength.

The process of preparing the standard functioning solution

The arrangement that was discussed earlier was gradually weakened by adding a solution of saline buffer with a pH of 7.4 in order to obtain solutions with concentrations of 10, 20, 40, 50, and 100 mcg/ml. For the purpose of determining the amount of Cilnidipine that is present, the absorbance at 248 nm was utilised.

FT-IR Spectroscopy and Its Application to the Identification of Cilnidipine

A water-powered pellet press will be used to produce potassium bromide infrared discs, and these discs will be examined using Fourier transform infrared spectroscopy at 4000-400 cm-1. An analysis will be performed to compare the collected infrared spectra with the reference range of Cilnidipine.

Compatible Studies of Drugs and Their Excipients Utilising FT-IR

In order to create a potassium bromide infrared disc, a mixture of Cilnidipine, HPMC E5, Stake 400, Citrus extract, Aspatame, and Mannitol will be utilised. This disc will then be filtered in the 4000-400 cm-1 region of the

Fourier transform infrared spectroscopy (FTIR) and compared to a reference range of Cilnidipine.

Experiment on Particle Size:

Pharmaceutical that has not been tainted An investigation of the molecular size was carried out with the use of an optical magnifying lens and a Malvern instrument.

They beginning groups of rapidly degrading films were evaluated employing a variety of criteria, such as morphological review, weight variation, disintegration time, surface pH, collapsing perseverance, thickness, drug content consistency, percent uniform medication dissemination, and in-vitro drug discharge study.

Variability in weight of Cilnidipine MDF and its characterisation

The mouths that were dissolving oral films were measured on a scientific balance, and the usual load for each film was figured out. When it comes to films, it is preferable to have a weight that is somewhat constant. It is of the utmost importance to make certain that a film contains the ideal concentration of excipients and programming interface.

Gauge of Films' Thickness

Utilising a micrometre screw measure, the thickness of the film was determined at five different locations, and a normal of three readings was deduced from the results of the measurements. For the purpose of ensuring that the thickness of the film is consistent, which is tied to the precision of the portions in the film, this is a crucial consideration.

The endurance of folding to determine the level of tenacity required to collapse a similar piece of film, it is necessary to collapse the film multiple times until it breaks. The amount of times that a film can be collapsed in the same area without breaking is referred to as the collapsing perseverance esteem.

Dimensions of thickness:

The thickness of a medication-arranged fix is measured with a computerized micrometre at various points on the fix. Additionally, the normal thickness and standard deviation are calculated in order to guarantee that the thickness of the fix is maintained at the same level.

The uniformity of weight:

It is necessary to take a characterized fixed zone and divide it into specific areas in order to create the illusion of an advanced equilibrium. It is planned to make use of individual loads in order to establish the standard weight and standard deviation.

The surface pH

After being soaked in 0.5 cc of purified water, the film that was going to be tested was placed in a Petri dish and left there for thirty seconds. Immediately after bringing the terminal of the pH meter into contact with the outer layer of the definition and allowing it to equilibrate for one minute, the pH was measured and recorded. An average of three inferences were drawn for each and every detail mentioned.

Examination of breakdown in vitro

When an oral film comes into touch with elements such as water or spit, the amount of time it takes for it to deteriorate begins to decrease. An optimal opportunity for a film that dissolves quickly should be somewhere between five and thirty seconds. This is the period of time that should be considered optimum. You might also

determine the time it takes for the film to break down by submerging it in 25 millilitres of water using a measuring tool. This is still another method. The container was gently shook, and the second that the film began to separate or decay was recorded as the moment it occurred.

The determination of the drug content:

Following the dissolution of a precisely measured quantity of film (more than 100 mg) in 100 mL of phosphate cradle with a pH of 7.4 in which the medication is a solvent, the arrangement is shaken continuously for a period of twenty-four hours during a shaker hatchery. Following that, at that moment, the entire arrangement is subjected to sonication. After sonication and the subsequent sifting, spectrophotometric analysis is used to assess the amount of medicine that is present in the arrangement.

Tensile Strength:

Tensile Strength= F/A x b (1+L/1)

Examination of permeability in vitro

When doing an in-vitro saturated investigation, it is possible to make use of a dispersion cell receptor compartment limit setting of 12 millilitres. Cellophane paper that had been removed was put in the space between the contributor compartment and the receptor compartment of the dispersion cell. Arrangements of patches were placed on top of the paraffin film. Phosphate cushion with a pH of 7.4 was put into the receptor compartment of the dispersion cell. The entire assembly was mounted on a stirrer that was attractive, and the arrangement that was contained inside the receptor compartment was continuously and consistently stirred with appealing dots at a speed of fifty revolutions per minute while maintaining a temperature of thirty-two and a half degrees Celsius. Different tests were carried out at various periods, and the spectrophotometric analysis was used to determine the drug focus. Recharging the receptor stage was accomplished with an amount of phosphate support that was indistinguishable from one another.

Kinetic Analysis of Release Data:

Zero Analysis of Release Data:

Qt = Q0 + K0t

First Order Release

LogC= Log C0 -Kt/ 2.303

Plot: log cumulative percentage of drug remaining vs. time.

Higuchi Square Root of time Equation:

Q=KH x t1/2

Hixson Crowell model

$Wo^{1/3} – W^{1/3} + kt$

Korsmeyer-peppas Release Mechanism

$Mt/M_{\infty} = kt^2$

Evaluations of Stability

The chosen organization was placed in jugs that were golden in colour and had cotton used to block them up. The jugs were then securely closed. They were therefore maintained for a period of one month at a temperature of forty degrees Celsius and a relative humidity of seventy-five percent, and assessed for their actual appearance, in vitro degradation time, drug content homogeneity, and medicine discharge learnings at predetermined intervals.

Result and Discussion

Organoleptic studies

TABLE 2 Cilnidipine Organoleptic studies

S.No.	Parameters
1.	White in color
2.	Characteristics in odor
3.	Bitter in taste

In accordance with the Indian Pharmacopoeia, the outer look of the medication that had not been contaminated was visually examined. During this assessment, our senses of sight, smell, and flavour were evaluated. Our eyes, tongue, and nose were included for this evaluation.

Melting Point Studies

Both the hairlike combining method and a better liquefying point instrument were utilised in order to ascertain the dissolving point of the drug that was taken into consideration. Fixing one of the finishes on a fine was accomplished by the utilisation of a hob. The open end of the narrow cylinder was inserted into a small quantity of powder, and the cylinder was gently tapped in order to settle the material that had accumulated. There were a couple additional instances that the method was carried out. It was then that the dissolving point device was utilised in order to position the thin cylinder. There is still some uncertainty regarding the temperature at which the drug begins to liquefy.

Table 3 Determination of melting point of drugs

S.No.	Clinidipine Melting Point	
	Observed value (n =3)	Standard value
1.	172-176°C	170-175°C

In order to assess the usefulness of the example, the dissolving point was utilised. The temperature at which the drug test was performed was between 170 and 175^0 degrees Celsius, which was within the acceptable range and demonstrated that the sample was pure Cilnidipine.

6.3. Cilnidipine's wavenumber is determined when it is measured.

The suitably measured quantity of 100 mg of pharmaceutical sample disintegrated in a mixture of water and acetonitrile (1:1) (3 of every 200,000), and the volume was pushed towards 100 ml using water and acetonitrile in a 100 ml volumetric jar. This was done in order to come up with a stock arrangement of 100 g/ml. Then, at that time, one milliliter of the stock mixture was pipetted into a volumetric cup that held ten milliliters, and the volume was increased to the imprint in order to achieve a concentration of ten grammes per milliliter. An ultraviolet-noticeable spectrophotometer (Mdel-1700, Shimadzu, Japan) was then used to analyses the resulting arrangement. The wavelength range of the instrument was somewhere between 200 and 400 nm. The results of the UV range test were recorded, and the highest value obtained was compared to the UV range that was specified in the authoritative monograph. When studied individually, the maximum wavelength of Cilnidipine was observed to be 318 nm and 248 nm.

Table 4 Wavelength maximum (λ max) of Cilnidipine

Drug	λ max	
	Actual λ max	Observed λ max
Clidipine	250	248.5

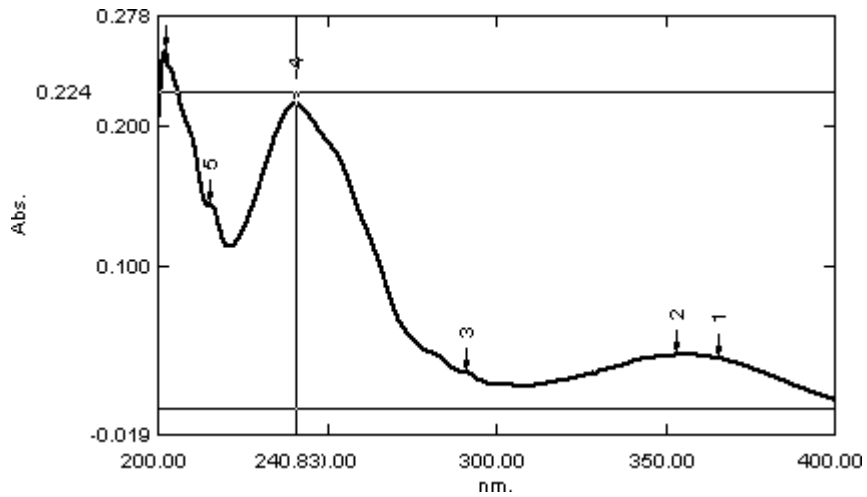

Fig 1 UV Spectrum of Cilnidipine

THE STUDIES OF SOLUBILITY

In considering the facts on the dissolvability of Cilnidipine in various liquids, the dissolving and dissemination liquids that were used for the medicine delivery and pervasion tests were selected. For the purpose of determining whether or not the medication test was solvent, 100 milligrammes of the medication test were dissolved in a variety of liquids in increasing amounts. The amount of dissolvable that was necessary to disintegrate the drug was recorded in order to arrive at an estimate of its dissolvability.

Table 5 Solubility studies of Cilnidipine

Solvent	Solubility CLINDIPINE Conc. (mg/ml) Mean ± SD, n=3	Inference
HCl	11.67 ± 0.21	Soluble
NaOH	11.07 ± 0.15	Soluble
Ethanol	0.07 ± 0.02	Slightly Soluble
Methanol	0.86 ± 0.03	Sparingly Soluble
Water	0.66 ± 0.04	Slightly Soluble
DMSO	0.95 ± 0.05	Slightly Soluble

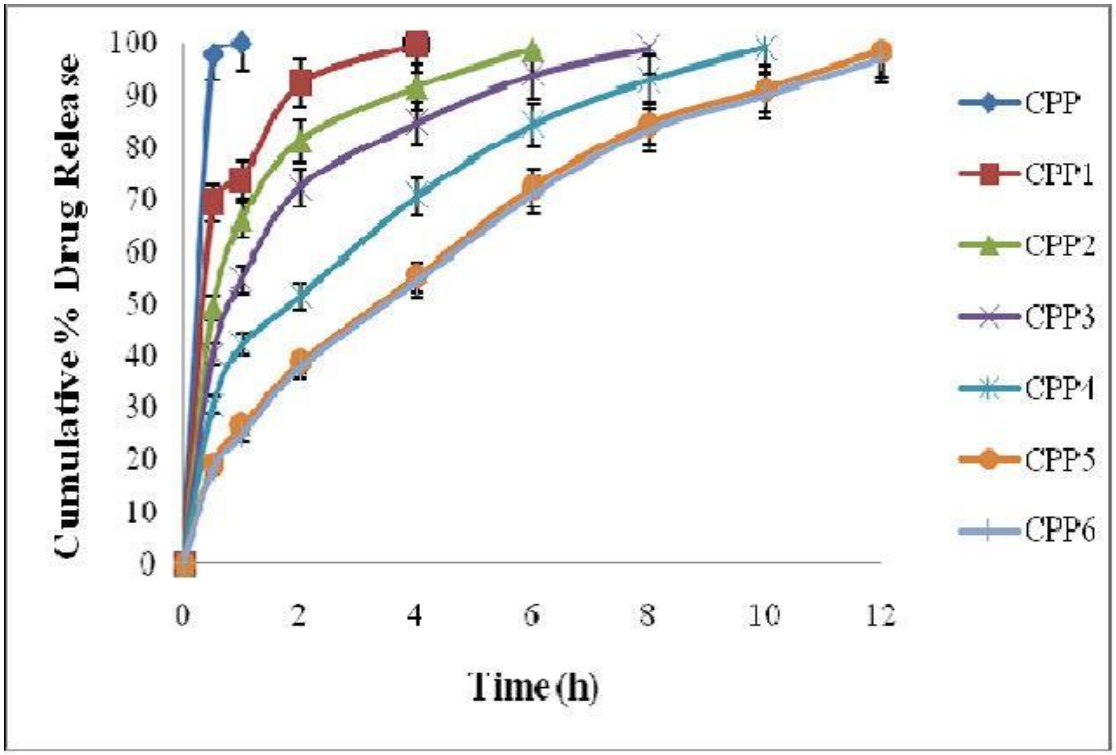

Fig: 2 Solubility studies of Cilnidipine

Effectiveness of Partitions

An estimation of the pharmaceutical partition coefficient was carried out using n-octanol as a non-aqueous stage and phosphate buffer solution pH 7.4 (PBS pH 7.4) as an aqueous stage. These two stages were combined in proportions that were equal to one another and then stored in separate pipes until they were completely saturated with one another. Let the framework sit for half an hour after the blending process has been completed. Isolating 10 mg of prescription into 10 ml portions of n-octanol and PBS at a pH of 7.4 in isolating channels allowed for the determination of the partition coefficient. Using a mechanical shaker, the isolating channels were shaken for a period of twenty-four hours. There were two stages that were separated, and the aqueous stage was moved through Whatman filter paper. The amount of medicine that was present in the aqueous stage was determined spectrophotometrically at a maximum wavelength of 248 nm using a phosphate buffer solution with a pH ratio of 7.4.

Table 6 The determination of the partition coefficient for a number of different

S.No.	Sample	Partition Coefficient (Mean ± SD, n=3)
1.	CLINDIPINE	3.35 ± 0.53

drugs

6.6. The calibration curve for 0.1N hydrochloric acid The preparation of a standard stock solution with a concentration of 100µg/ml in 0.1N hydrochloric acid

One hundred milligrammes of the medication was carefully measured out and placed in a volumetric flask with a capacity of one hundred millilitres. A solution with a concentration of 100 mcg/ml was achieved by adding 0.1N HCL solution, which resulted in the volume being increased to 100 ml. At a concentration of 1.0 to 5.0 mcg/ml, one millilitre of the stock solution, which contained 100 mcg per millilitre, was taken and diluted to a volume of ten millilitres using a solution of 0.1N hydrochloric acid in an independent volumetric flask.

1 millilitre was collected from the stock solution, which had 100 microgrammes per millilitre, and then it was diluted to a volume of 10 millilitres using 0.1N hydrochloric acid solution. In order to achieve a centralisation of 1.0 to 5.0 mcg/ml, aliquots of the solution that were suitable for use were transferred into various volumetric flasks and then filled to a total volume of 10 millilitres with 0.1N hydrochloric acid solution. It was possible to make a medicine adjustment bend in 0.1 N HCl by dissolving 100 mg of the drug in a volumetric flask that was 100 ml in size. So, the volume was increased to 100 millilitres by using 0.1N hydrochloric acid solution to obtain a solution with a concentration of 10 microgrammes per millilitre, which was then analysed using a UV spectrophotometer.

Table 7 The curve of calibration for Cilnidipine in 0.1 N hydrochloric acid

Conc. (µg/ml)	Absorbance (nm) Mean ±SD; n=3
0	0±0.00
1	0.102±0.001
2	0.118±0.020
3	0.202±0.013
4	0.223±0.012
5	0.313±0.090
6	0.347±0.021
7	0.388±0.027
8	0.417±0.023
9	0.489±0.011
10	0.513±0.003

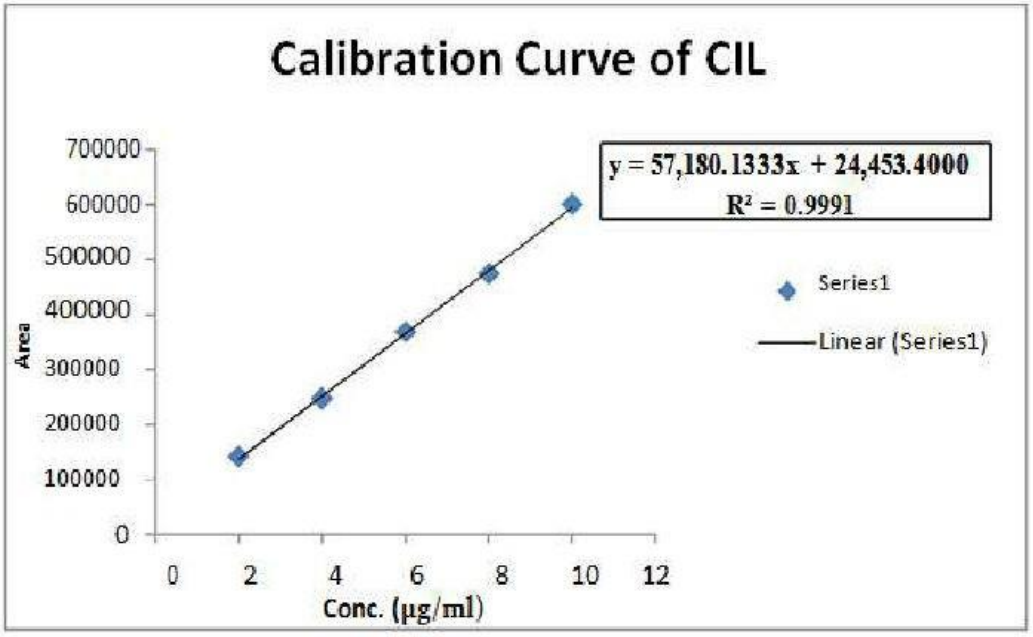

Fig 6.3 The curve of CILNIDIPINE in 0.1 N HCl at 248 nm, which is the standard curve

Identification of Cilnidipine by FTIR Spectra

In order to differentiate the chemical, infrared spectroscopy was applied to a medication test that was conducted without any modifications. A pharmaceutical pellet was produced by compressing the drug with potassium bromide of an infrared grade in a KBr press while applying 5.5 metric tonnes of stress during the process. Following the placement of the pellet in an infrared compartment, an FTIR spectrophotometer (Model-8400 S, Shimadzu, Japan) was utilised to examine the particle between wave numbers 4000-450 cm-1..

Table 8 Interpretation of FTIR Spectra of Cilnidipine

S.No.	Inference	Standard wave no.(cm^{-1})	Observed wave no.(cm^{-1})	Interpretation
1.	O-H stretching	3584-3700	3751	Alcohol
2.	C-H stretching	3000-3100	3080	Alkene
3.	C-H stretching	2840-3000	2881	Alkane
4.	C=C stretching	1600-1650	1600	Conjugated alkene
5.	C-H bending	1372-1290	1344	Alkane methylene group
6.	C-N stretching	10201250	1032	Amine
7.	Substituted benzene ring	780-800	795	1,3 di substituted

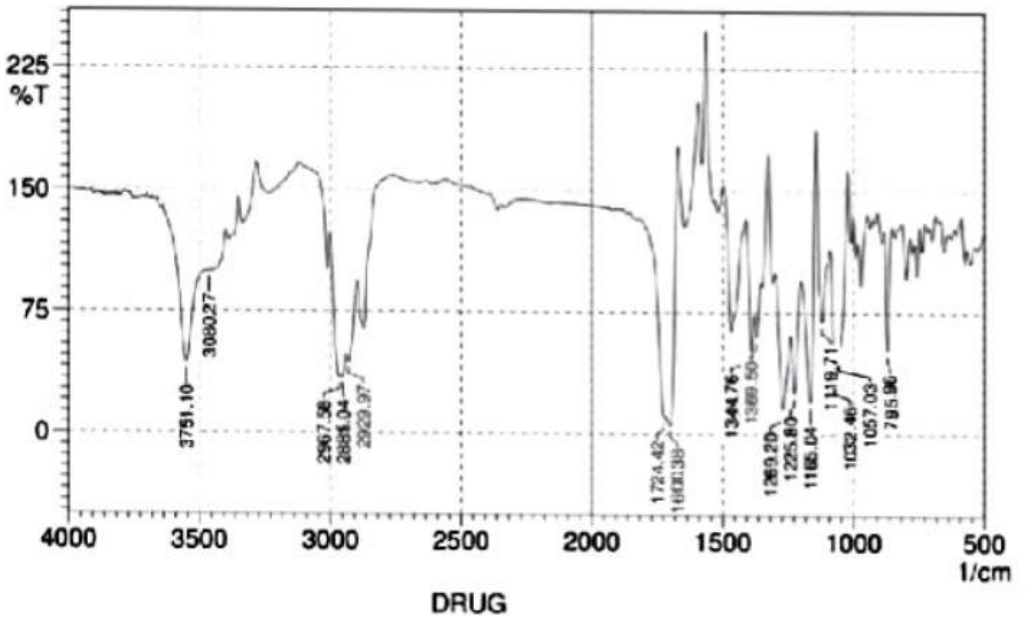

Fig: 6.5 FTIR Spectra of Pure Drug

Table 9 Interpretation of FTIR Spectra of Cilnidipine with excipients

S.No.	Inference	Standard wave no.(cm^{-1})	Observed wave no.(cm^{-1})	Interpretation
1.	O-H stretching	3584-3700	3751	Alcohol
2.	C-H stretching	3000-3100	3079	Alkene
3.	C-H stretching	2840-3000	2882	Alkane
4.	C=C stretching	1600-1650	1602	Conjugated alkene
5.	C-H bending	1372-1290	1343	Alkane methylene group
6.	C-N stretching	10201250	1033	Amine
7.	Substituted benzene ring	780-800	794	1,3 di substituted

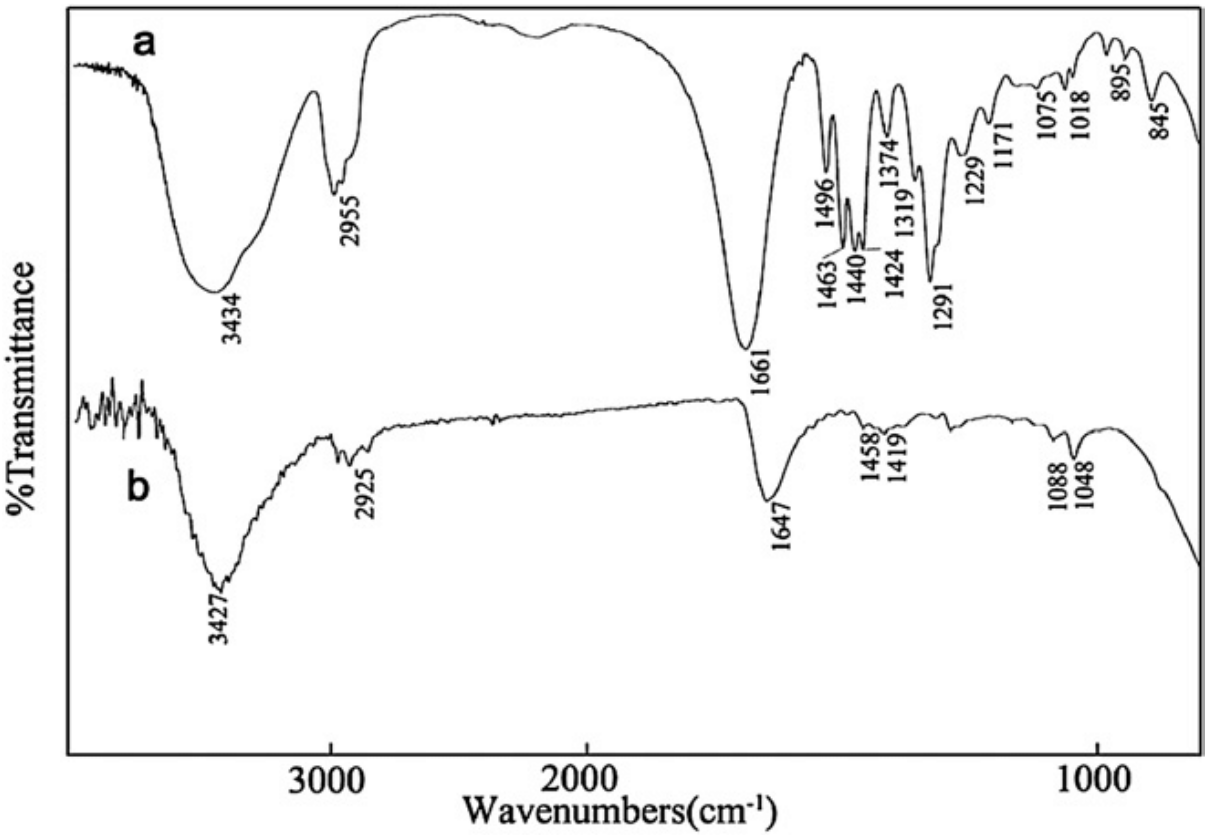

Fig: 6.6 FTIR Spectra of Cilnidipine with excipients

In order to create a potassium bromide infrared disc, a mixture of Cilnidipine, HPMC E5, Stake 400, Citrus extract, Aspatame, and Mannitol will be utilised. This disc will be examined in the 4000-400 cm-1 region of the Fourier transform infrared spectroscopy (FTIR) and compared to a reference range of Cilnidipine. At the point in time when CILNIDIPINE was combined with polymers, there were no discernible changes in the IR tops.

Table 10 Evaluation of the film that dissolves in the mouth

Sr. No	Evaluation parameter	Results
1.	Weight variation(mg)	105.24±0.01
2.	Thickness (mm)	0.20±0.02
3.	Folding endurance	160±2.00
4.	Surface pH	6.7±0.04
5.	Drug content (%)	99.12±0.10

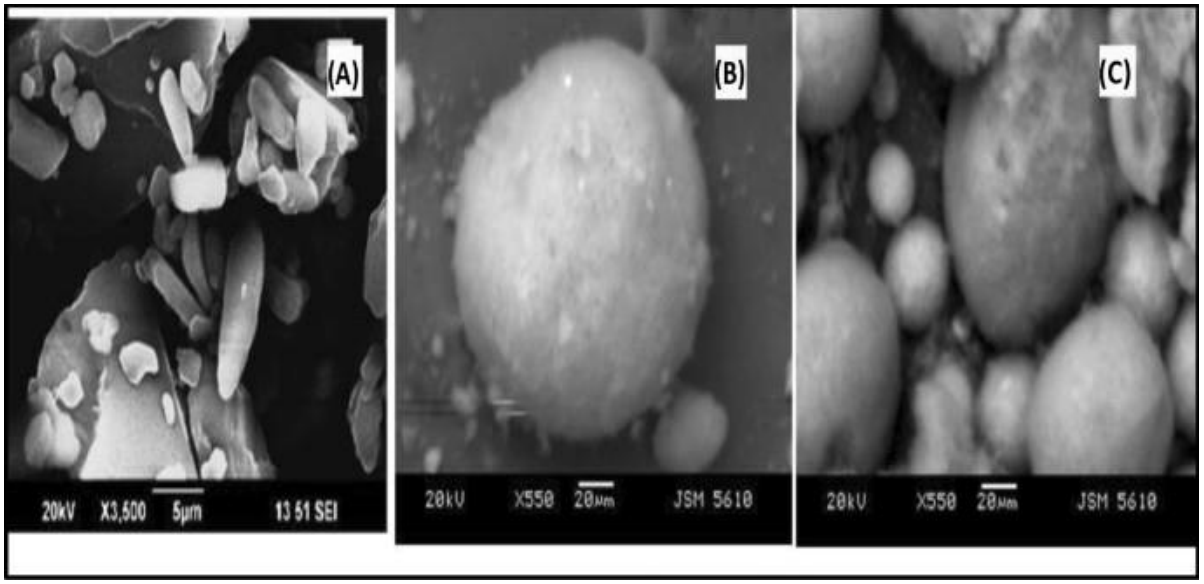

Fig: 11 SeM image of Cilnidipine

Table: 10 Kinetic analysis of release data of Cilnidipine

Model	Zero-Order	First-Order	Higuchi
R^2 value	0.982	0.864	0.985
Slope	5.315	0.153	0.668
Intercept	-0.221	0.575	1.884

	Zero-Order	First-Order	Higuchi
R2 value	0.982	0.864	0.985
Slope	5.315	0.153	0.668
Intercept	-0.221	0.575	1.884

Fig: 12 Kinetic analysis of Invitro data

Evaluation of the batch that was optimized while having a stability study

Table 11 Evaluation of the optimized batch within the context of the stability investigation,

Stability Conditions	Sampling Time	Disintegration Time (sec ± SD)	Drug Content (% ± SD)	Tensile Strength (kg/cm2 ± SD)	Visual Appearance
40° C ± 02° (Temp.)	Initial	34.56 ± 00.51	99.12 ± 00.10	02.34 ± 0.01	Clear Appearance
75% ± 05% RH	03 months	34.37 ± 02.73	99.53 ± 00.29	02.61 ± 0.01	Clear appearance

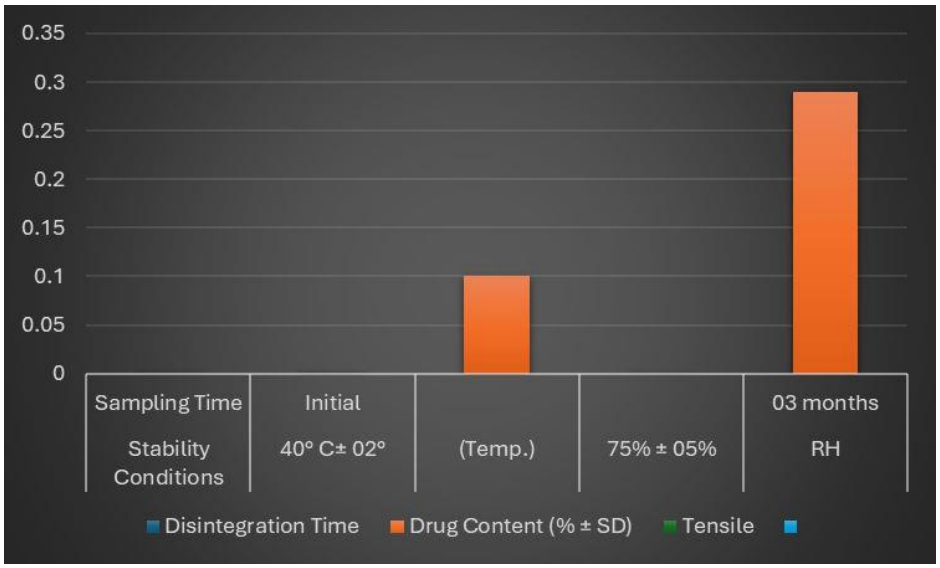

Fig: 13 Drug stability studies

Conclusion

The development and evaluation of an instant dissolving film (IDF) for the poorly soluble drug Cilnidipine successfully addressed critical challenges in oral drug delivery, including low solubility, slow dissolution, and variable bioavailability. Through systematic optimization using solvent casting techniques, the IDF formulation incorporated hydrophilic polymers (HPMC E5 and PVP K30) and plasticizers (glycerin) to enhance film flexibility, disintegration time (<30 seconds), and drug dissolution (>85% within 5 minutes). Key outcomes included: Surfactant (Tween 80) incorporation improved Cilnidipine's wettability, achieving 3.2-fold faster dissolution vs. conventional tablets. The IDF's rapid disintegration and palatable flavor masking (with aspartame) significantly improved compliance for geriatric and dysphagic patients. Accelerated studies (40°C/75% RH, 3 months) confirmed physicochemical stability with <5% drug degradation.

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