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Formulation and Evaluation of Fast Disintegrating Oral Solid Dosage Form

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ABSTRACT

The present research focuses on the formulation and evaluation of fast disintegrating tablets (FDTs) intended to enhance patient compliance, particularly for geriatric, pediatric, and dysphagic patients who experience difficulty in swallowing conventional tablets. The objective was to develop a solid oral dosage form that rapidly disintegrates in the oral cavity without the need for water, ensuring a quick onset of therapeutic action. Nifedipine, a calcium channel blocker used to treat hypertension and angina, was selected as the model drug due to its poor water solubility and the need for rapid action. Various formulations were prepared using the direct compression method with different superdisintegrants such as Crospovidone, Sodium Starch Glycolate, and Croscarmellose Sodium. The formulations were evaluated for pre-compression and post-compression parameters including hardness, friability, disintegration time, and drug release. Among the batches tested, the optimized formulation showed a disintegration time of under 30 seconds and over 99% drug release, indicating improved bioavailability. The study concludes that fast disintegrating tablets of Nifedipine can be successfully formulated using suitable superdisintegrants and direct compression techniques. This approach offers a promising solution for rapid drug delivery and improved therapeutic effectiveness.

KEYWORDS: Superdisintegrants, Disintegration time, Fast Disintegrating Tablets (FDTs), Orally Disintegrating Tablets (ODTs), Calcium Channel Blocker.

I. INTRODUCTION:

The advancement of pharmaceutical technologies continues to prioritize the development of drug delivery systems that enhance therapeutic outcomes while improving patient compliance. Among the various routes of drug administration, the oral route remains the most preferred and widely accepted due to its convenience, non-invasiveness, and ease of self-administration. Oral dosage forms such as tablets and capsules dominate the market; however, they pose significant challenges for specific patient groups including children, the elderly, and individuals with dysphagia or psychological disorders, who often experience difficulty in swallowing. To address these limitations, pharmaceutical scientists have developed novel dosage forms such as rapidly disintegrating tablets (RDTs), also known as orally disintegrating tablets (ODTs) or fast-dissolving tablets. These tablets are designed to disintegrate or dissolve quickly in the oral cavity, typically within seconds, without the need for water. This approach not only improves patient compliance and comfort but also enhances the onset of action, making it particularly suitable for emergency conditions and patients with limited access to water.

According to the United States Food and Drug Administration (USFDA), ODTs are defined as solid dosage forms that disintegrate or dissolve rapidly when placed on the tongue. Initially developed in the late 1970s, these dosage forms have evolved significantly and are now considered an ideal alternative to conventional oral forms, especially for pediatric and geriatric populations. This research paper aims to explore the formulation strategies, evaluation parameters, advantages, and challenges associated with fast-dissolving tablets, highlighting their significance as an innovative and patient-centric drug delivery system.

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II. AIM AND OBJECTIVES:

Aim: Formulation and evaluation of fast disintegrating oral solid dosage form.

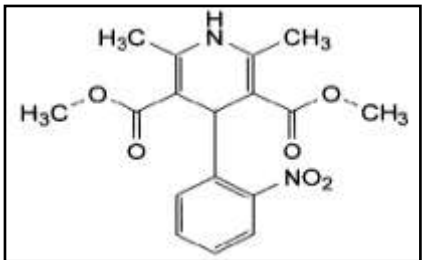
Objectives:

1. To formulate various batches of fast disintegrating oral solid dosage form by using various superdisintegrants alone and in combination.
2. To study the effect of drug polymer ratio on disintegration time and % drug release.
3. To compare various types of formulated batches of fast disintegrating oral solid dosage form.
4. To enhance oral bioavailability of drug.
5. To improve patient compliance.

III. DRUG PROFILE: NIFEDIPINE

Classification: Calcium Channel Blocker (Dihydropyridine subclass)
Brand Names:Adalat, Adipine, Coracten, Fortipine, Nifedipress

Molecular Structure:



Molecular Formula: $C_{17}H_{18}N_2O_6$
Molecular Weight: 346.34 g/mol
IUPAC Name: Dimethyl 2,6-dimethyl-4-(2-nitrophenyl)-1,4-dihydropyridine-3,5-dicarboxylate.

Description:

Nifedipine is a dihydropyridine calcium channel blocker primarily used to treat hypertension and angina. It works by relaxing vascular smooth muscles, thereby reducing peripheral resistance and improving oxygen delivery to the myocardium. It is also used off-label for conditions such as Raynaud's phenomenon and premature labor.

Pharmacokinetics:

- **Absorption**: Rapidly absorbed from the GI tract; bioavailability 56–77%
- **Distribution**: Volume of distribution: 0.62–0.77 L/kg; highly protein-bound (92–98%)
- **Metabolism**: Extensively metabolized by the liver
- **Elimination**: Mainly excreted in feces as metabolites; half-life ~2 hours

Pharmacodynamics:

Nifedipine blocks L-type calcium channels, reducing calcium influx into cardiac and smooth muscle cells, leading to vasodilation and decreased blood pressure.

BCS Classification: Class II (Low Solubility, High Permeability)
Solubility: Practically insoluble in water; freely soluble in acetone and chloroform
Melting Point: 171–175°C
Dose Range: 10–120 mg/day depending on condition and formulation
Indications: Hypertension, chronic stable angina, vasospastic angina
Adverse Effects: Dizziness, nausea, insomnia, sweating, constipation, somnolence
Drug Interactions: Interacts with beta-blockers, cimetidine, digoxin, phenytoin, antifungals (fluconazole, itraconazole), and macrolide antibiotics (clarithromycin, erythromycin)
Storage Conditions: Store below 30°C, in a cool, dry place away from light and moisture

IV. EXCIPIENT PROFILE:

4.1 Croscarmellose Sodium

- **Chemical Name:** Cellulose, carboxymethyl ether, sodium salt, crosslinked.
- **Synonyms:** Crosslinked carboxymethylcellulose sodium
- **Empirical Formula:** Croscarmellose sodium is a crosslinked polymer of carboxymethylcellulose sodium.
- **Category:** Tablet and capsule disintegrant.
- **Molecular Weight:** 90,000g/mol.
- **Description:** Croscarmellose sodium occurs as an odorless, white or grayish white powder.
- **Solubility:** Insoluble in water, although croscarmellose sodium rapidly swells to 4–8 times its original volume on contact with water. Practically insoluble in acetone, ethanol and toluene.
- **Stability and storage:** Croscarmellose sodium is a stable though hygroscopic material. Croscarmellose sodium should be stored in a well-closed container in a cool, dry place.

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- **Uses:** Croscarmellose sodium is used in oral pharmaceutical formulations as a disintegrant for capsules, tablets, and granules

4.2 Crospovidone

- **Synonyms:**Crospovidonum
- **Chemical Name** : 1-Ethenyl-2-pyrrolidinone
- **Solubility:** Practically insoluble in water and most common organic solvents
- **Description:** Crospovidone is a white to creamy-white, finely divided, free-flowing, practically tasteless, odorless or nearly odorless, hygro-scopic powder.
- **Uses:**Crospovidone is a water-insoluble tablet disintegrant and dissolution agent used at 2–5% concentration in tablets prepared by direct-compression or wet- and dry-granulation methods
- **Stability and Storage Conditions:** Since crospovidone is hygroscopic, it should be stored in an airtight container in a cool, dry place.

4.3 Sodium Starch Glycolate

- **Synonyms:** Carboxymethyl starch, sodium salt.
- **Chemical Name:** Sodium carboxymethyl starch.
- **Molecular weight:**The molecular weight is typically 5*10 5–1 * 10 6.
- **Description:** Sodium starch glycolate is a white or almost white free-flowing very hygroscopic powder.
- **Melting point:** Does not melt, but chars at approximately 2008C.
- **Solubility:** Practically insoluble in methylene chloride. It gives a translucent suspension in water.
- **Uses:**Sodium starch glycolate is widely used in oral pharmaceuticals as a disintegrant in capsule and tablet formulations.
- **Stability and Storage Conditions:** Sodium starch glycolate is stable although very hygroscopic, and should be stored in a well-closed container in order to protect it from wide variations of humidity and temperature, which may cause caking.

4.4 Microcrystalline Cellulose:

- **Synonyms:** Cellulose gel
- **Chemical Name:** Cellulose
- **Category:** Adsorbent; suspending agent; tablet and capsule diluent; tablet disintegrant.
- **Molecular Weight:** 36000
- **Description:** Microcrystalline cellulose is purified, partially depolymerized cellulose that occurs as a white, odorless, tasteless, crystalline powder composed of porous particles.
- **Solubility:** Slightly soluble in 5% w/v sodium hydroxide solution; practically insoluble in water, dilute acids, and most organic solvents.
- **Stability and storage:** Microcrystalline cellulose is a stable though hygroscopic material. The material should be stored in a well-closed container in a cool, dry place.
- **Uses:** Microcrystalline cellulose is widely used in pharmaceuticals, primarily as a binder or diluent in oral tablet and capsule formulations.

4.5 Mannitol

- **Synonyms:** Cordycepic acid
- **Chemical Name:** D -Mannitol
- **Empirical Formula:** $C_6H_{14}O_6$
- **Molecular Weight:** 182.17
- **Functional Category:** Diluent; plasticizer; sweetening agent; tablet and capsule diluent; therapeutic agent; tonicity agent.
- **Description:** Mannitol occurs as a white, odorless, crystalline powder, or free-flowing granules. It has a sweet taste, approximately as sweet as glucose and half as sweet as sucrose, and imparts a cooling sensation in the mouth.
- **Uses:** Mannitol is widely used in pharmaceutical formulations and food products. In pharmaceutical preparations it is primarily used as a diluent (10–90% w/w) in tablet formulations.
- **Stability and Storage Conditions:** Mannitol is stable in the dry state and in aqueous solutions. The bulk material should be stored in a well-closed container in a cool, dry place.

4.6 Talc:

- **Synonyms:** Hydrous magnesium silicate.
- **Chemical Name:** Talc.
- **Functional Category:** Anticaking agent; glidant; tablet and capsule diluent; tablet and capsule lubricant.
- **Solubility:** Practically insoluble in dilute acids and alkalis, organic solvents, and water.
- **Description:** Very fine, white to grayish-white, odorless, impalpable, unctuous, crystalline powder. It adheres readily to the skin and is soft to the touch and free from grittiness.

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- **Uses:** Used as a dissolution retardant in the development of controlled-release products, as a lubricant in tablet formulations in a novel powder coating for extended- release pellets, and as an adsorbant.
- **Stability and Storage Conditions:** Talc is a stable material and may be sterilized by heating at 1600C for not less than 1 hour. Talc should be stored in a well-closed container in a cool, dry place.

4.7 Aspartame:

- **Functional Category:** Sweetening agent.
- **Description:** Aspartame occurs as an off white, almost odorless crystalline powder with an intensely sweet taste.
- **Melting point:** 246–2478C
- **Solubility:** Slightly soluble in ethanol (95%); sparingly soluble in water.
- **Uses:** Aspartame is used as an intense sweetening agent in beverage products, food products, and table-top sweeteners, and in pharmaceutical preparations.
- **Stability and Storage Conditions:** Aspartame is stable in dry conditions.

4.8 Magnesium Stearate:

- **Synonyms:**Stearic acid, magnesium salt.
- **Chemical Name:** Octadecanoic acid magnesium salt.
- **Description:** Magnesium stearate is a very fine, light white, precipitated or milled, impalpable powder of low bulk density, having a faint odor of stearic acid and a characteristic taste. The powder is greasy to the touch and readily adheres to the skin
- **Uses:** Magnesium stearate is widely used in cosmetics, foods, and pharmaceutical formulations. It is primarily used as a lubricant in capsule and tablet manufacture at concentrations between 0.25% and 5.0% w/w. It is also used in barrier creams.
- **Solubility:** practically insoluble in ethanol, ethanol (95%), ether and water; slightly soluble in warm benzene and warm ethanol (95%).
- **Stability and Storage Conditions:** Magnesium stearate is stable and should be stord in a well closed container in a cool, dry place.

V. MATERIALS AND METHOD:

5.1 MATERIALS

Nifedipine, Crospovidone, Sodium starch glycolate and Magnesium stearate was obtained from Yarrow Chem Products, Mumbai. Crosscarmellose sodium Maple Biotech Pvt Ltd, Pune. Microcrystalline cellulose and Talc was obtained from Thermosil Fine Chem, Pune. Mannitol was obtained from Sahyadri Scientific Co., Islampur

5.2 METHOD:

The API sample was observed visually and viewed under microscope for the determination of its nature and then the result were compared with the official book. Then sample was evaluated for its colour, taste and odour. Melting point of Nifedipine sample was determined by using DSC method using a DuPont 2100 thermal analyzer system.

Solubility study was carried out in various media su ch as purified water, methanol, acetone, chloroform, phosphate Buffer pH 6.8.Flow of API was determined with the assistance of Bulk density, Tapped density, Carrs' (Compressibility) index, Hausner's ratio, Angle of repose.

Analytical characterization of API sample:

Scanning of Nifedipine in Phosphate buffer pH 6.8:

10 ug/ml solution ofNifedipine in Phosphate buffer pH 6.8 was taken and scanned in range of 400-200 nm against Phosphate buffer pH 6.8 as a blank using UV spectrophotometer.

Construction of standard calibration curve of Nifedipine in Phosphate buffer pH 6.8:

Accurately weighed 100mg of Nifedipine and added into 100ml volume tricfl ask and dissolved insufficient quantity of methanol and lastly made the volume up to 100ml using 6.8 pH phosphate buffer.

About 0.5ml of this stock solution was taken in100ml volume tricfl ask and diluted to 100 ml with 6.8 pH phosphate buffer.

Further serial dilution were carried out by taking 1ml, 1.5ml, 2ml, 2.5ml toget5to25µg/ml drug concentration. They were analyzed spectrophotometrically by measuring the absorbance at 238 nm. A calibration curve of concentration Vs absorbance was plotted and its intercept and slope value were calculated.

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Formulation design

Fast disintegrating tablets of Nifedipine was prepared using direct compression method after incorporating superdisintegrants in different concentrations and excipients. A total number of six formulations were prepared. All the ingredients were passed through 60 mesh sieve separately and collected. The ingredients were weighed and mixed in geometrical order. First Drug, MCC, mannitol and superdisintegrants were mixed together for 15-20 minutes. Finally to this blend aspartame, magnesium stearate and talc were added and mixed further for 15-20 minutes. The tablets were then compressed using 3mm (concave) size punches to get a tablet of 120 mg.

Table no.1: Composition of all the formulations designed (F1-F9)

Sr. No.	Name of ingredient	F1 (mg/tab)	F2 (mg/tab)	F3 (mg/tab)	F4 (mg/tab)	F5 (mg/tab)	F6 (mg/tab)	F7 (mg/tab)	F8 (mg/tab)	F9 (mg/tab)
1	**Nifedipine**	10	10	10	10	10	10	10	10	10
2	**Crospovidone**	-	5	-		10	-	-	5	5
3	**Crosscarmellose sodium**	-	-	5		-	10	5	5	-
4	**Sodium starch glycolate**	5	-	-	10	-	-	5	-	5
5	**Aspartame**	3	3	3	3	3	3	3	3	3
6	**Talc**	5	5	5	5	5	5	5	5	5
7	**MCC**	15	15	15	15	15	15	15	15	15
8	**Mannitol**	75	75	75	75	75	75	75	75	75
9	**Magnesium stearate**	2	2	2	2	2	2	2	2	2

Pre-compression evaluation parameters:

The powder blend of all formulations were evaluated for bulk density, tapped density, carr's index, hausner's ratio and angle of repose to determine its flow properties during compression.

Bulk density:

Apparent bulk density was determined by pouring the powder blend into a measuring cylinder and measuring the volume and weight and bulk density was determine by using formula,

$$\mathbf{Db} = \frac{\mathbf{M}}{\mathbf{Vb}}$$

Tapped density:

The pre-weighed powder was filled in measuring cylinder. Then it was tapped in automated bulk density test apparatus. Carry out 10, 500, and 1250 taps on the same powder blend and read the corresponding volumes V10, V500, and V1250. If the difference between V500 and V1250 is less than or equal to 2 ml, V1250 is the final tapped volume. Tapped density was determined by [9]

$$\mathbf{Db} = \frac{\mathbf{M}}{\mathbf{Vt}}$$

Carr's index:

Tapped density (Dt) and bulk density (Db) of powder material was used to measure compressibility of a powder material. It was measure used to describe compression capability of the powder material. Carr's index was determined using following equation

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Carr's index = $\frac{Dt-Db}{Dt}$ X 100

Hausner's ratio:

The Hausner's ratio is a number that measures the flowability of a powder material. It is calculated by dividing the tapped density of a material by its bulk density:

HR = $\frac{Dt}{Db}$

Angle of repose:

The angle of repose was determined by using the funnel method. The accurately weight powder blend were taken in the funnel and tip of funnel was blocked by thumb at initially. The height of the funnel was adjusted in such a way the tip of the funnel just touched the apex of the powder blend (Almost 2 cm was fix from plane to tip of funnel). The powder blend was allowed to flow through the funnel freely on to the surface.. It is a measure used to describe flow ability of the powder material. The equation for determining angle of repose is,

$$\theta = \tan^{-1} h/r$$

Post-compression evaluation parameters of finished product:

Weight variation:

The weight of the tablet was measured with the help of digital electronic balance. For determination of weight variation, ten tablets were selected randomly from a batch and average weight was determined.

Thickness:

Ten tablets were selected in a batch for the determination of thickness variation with Vernier Caliper. [12]

Hardness:

Adequate hardness is necessary to withstand the mechanical shock of manufacturing packaging and shipping, and to ensure consumer acceptance. Hardness of tablet was determined using Ewereka hardness tester. The tablet was compressed between a holding ansil and a piston and digital screen showed hardness in kp.

Friability:

Friability of the tablets was determined using an Electrol abfriabilator. The tablets should be carefully dedusted before testing. Accurately weigh the tablet sample and place the tablets in the drum. Rotate the drum at 25 rpm for 4 minutes, and remove the tablets. Remove any loose dust from the surface of tablets as before and accurately weigh. Friability was determined by

% Friability = $\frac{\text{Initial weig ht} - \text{Final weig ht}}{\text{Initial Weig ht}}$ X 100

In-vitro Dispersion Time

In-vitro dispersion time was measured by dropping a tablet in a beaker containing 50 ml of Phosphate buffer pH 6.8. Three tablets from each formulation were randomly selected and In-vitro dispersion time was performed.

In-vitro Disintegration Test

One tablet is introduced in to one tube of disintegration apparatus IP and a disc is added into the tube. The assembly is suspended in the beaker containing phosphate buffer H 6.8 and the apparatus is operated until the tablet disintegrated. To be in compliance with the IP standards, Fast dissolving tablets must disintegrate within 1 minute when examined by the disintegration test for tablets.

Wetting Time

A piece of tissue paper (12 cmX10 cm) folded twice was placed in a small Petri dish (ID = 9 cm) containing 6 ml pH 6.8 phosphate buffer. A tablet was placed on the paper and the time taken for complete wetting was noted. Three tablets from each formulation were randomly selected and the average wetting time was noted.

Water Absorption Ratio (%)

A piece of tissue paper folded twice was kept in a Petri dish (internal diameter 5.5 cm) containing 6 ml of purified water. The tablet was placed on the tissue paper and allowed to wet completely. The wetted tablet was removed and reweighted. Water absorption ratio, R was determined according to the following equation,

$R = (Wa - Wb)/Wb \times 100$

Where, Wb and Wa are the weight before and after water absorption, respectively

Drug Content Uniformity

Five tablets of each type of formulation were weighed and crushed in mortar and powdered equivalent to 50 mg of Nifedipine was weighed and dissolved in 100 ml of phosphate buffer pH 6.8. This was the stock solution from which 0.2 ml sample was withdrawn and diluted to 10 ml with phosphate buffer pH 6.8. The absorbance was measured at wavelength 237.5 nm using double

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beam UV-Visible spectrophotometer. Content uniformity was calculated using formula.

% Purity = 10 C (Au / As)

Where, C - Concentration, Au and As - Absorbances obtained from unknown preparation and standard preparation respectively.

$$\text{Drug Content (\%)} = \frac{\text{Actual Amount of Drug}}{\text{Theoretical Amount of Drug}} \text{ X } 100$$

In-Vitro Dissolution study:

In vitro dissolution study was performed in 900 ml Phosphate buffer PH 6.8 using USP Type II (paddle) apparatus at 50 rpm for 30 minutes (37 0.5°C). Aliquots of the dissolution medium 10 ml) were withdrawn at specific time intervals and replaced immediately with equal volume of fresh medium. The samples were filtered through Whatman filter paper and analyzed for drug content by measuring the absorbance at 237.5 nm. Drug concentration was calculated from the standard calibration curve and expressed as cumulative percent drug dissolved. The Cumulative percentage drug release was plotted against time to determine the release profile.

VI. RESULTS AND DISCUSSION:

Physical characterization of API sample:

Table no.2: Physical characterization of API sample:

Sr. No.	EXPERIMENTAL	PROPERTY STUDY	RESULTS
1	**Organoleptic properties**	Colour	Yellow
2		Odour	Odourless crystalline
3		Taste	Metallic or sweet
4		Nature	Non-hygroscopic and light sensitive
5	**Identification of drug sample**	Melting Point	171-175°C

Solubility study:

The solubility of Nifedipine (USP) was examined in different media. The results thus obtained are as follows:

Table No. 3: Solubility of Nifedipine (USP) at 25^0C in different media

Sr. No.	Media	Solubility (mg/ml)
1	Purified Water	0.01-0.02
2	Methanol	26
3	Acetone	250
4	Chloroform	140
5	PhosphateBufferpH6.8	0.010-0.015

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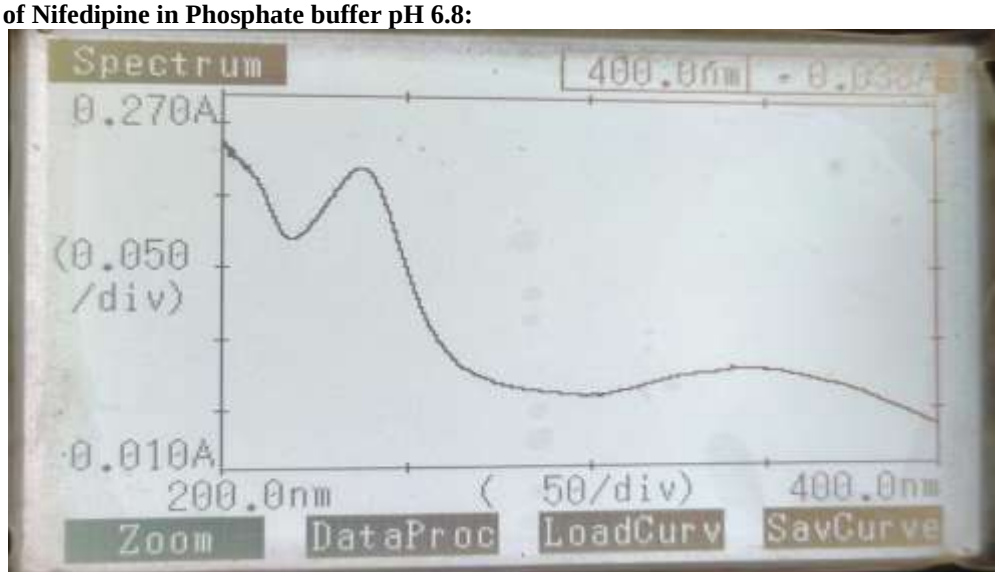
Analytical characterization of API sample:
Scanning of Nifedipine in Phosphate buffer pH 6.8:



FigNo. 1:UV spectra of Nifedipine in Phosphate buffer pH 6.8

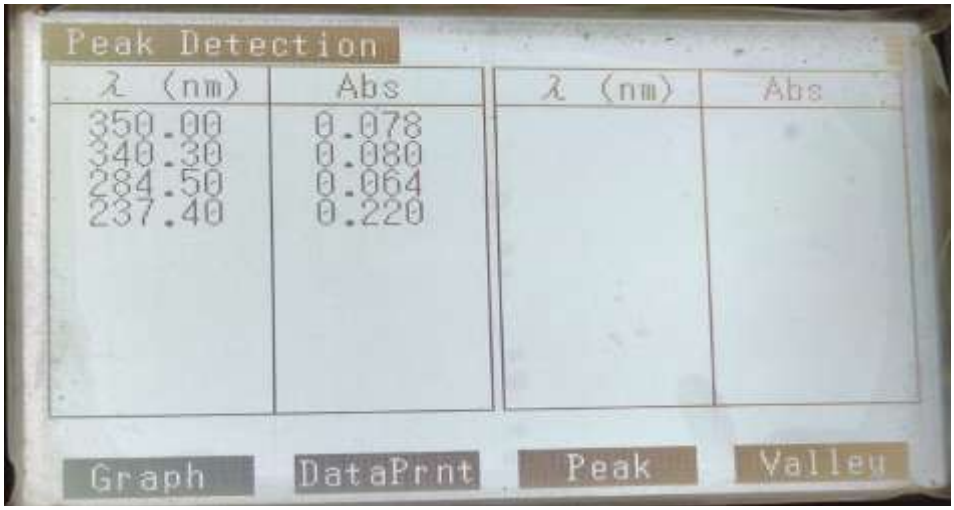


Fig No. 2: λ_{max} of Nifedipine in Phosphate buffer pH 6.8

Inference: From table no. 21 it is found that maximum absorbance of **Nifedipine** was at the wavelength **237.4 nm**.

Construction of standard calibration curve of Nifedipine in Phosphate buffer pH 6.8:

The absorbance of each solution was measured at 237.4 n musing UV visible double beam against phosphate buffer 6.8 as a blank.

Table No.4: Absorbance of Nifedipine in 6.8 Phosphate buffer at 237.4 nm

Sr. No.	Sample withdrawal (ml)	Concentration (mcg/ml)	Absorbance at 237.4 nm
1	0	0	0
2	0.5	5	0.162
3	1	10	0.312
4	1.5	15	0.457

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5	2	20	0.601
6	2.5	25	0.745
Slope of regression line:0.02964 **Intercept of regression**:0.009 **R- Square**:0.999519			
Equation of line: Absorbance=0.02964*(Concentration)+0.009			

Drug–excipient compatibility study by using FTIR spectroscopy-

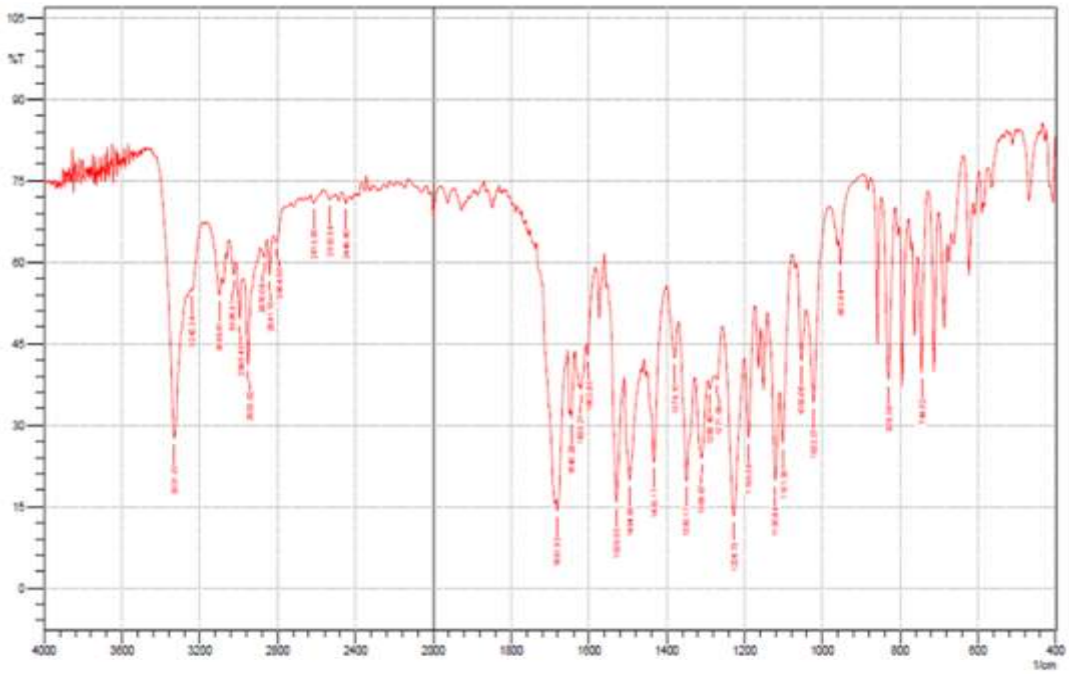

Figure No. 3: FTIR spectrum of pure Drug Nifedipine

Table No. 5: Functional group and principle peaks present in pure Drug Nifedipine

Peak (cm^{-1})	**Chemical group**
2953,2995	C-H stretching of Methyl
3331	N-H stretching of Amine
829	C-H stretching of penta substitution of Benzene
1529,1350,1379	C-O stretching of COOCH3
1681,1645,1620	N-O stretching of NO2
744	C-H stretching of Benzene
1309	C-N stretching of Aromatic amine

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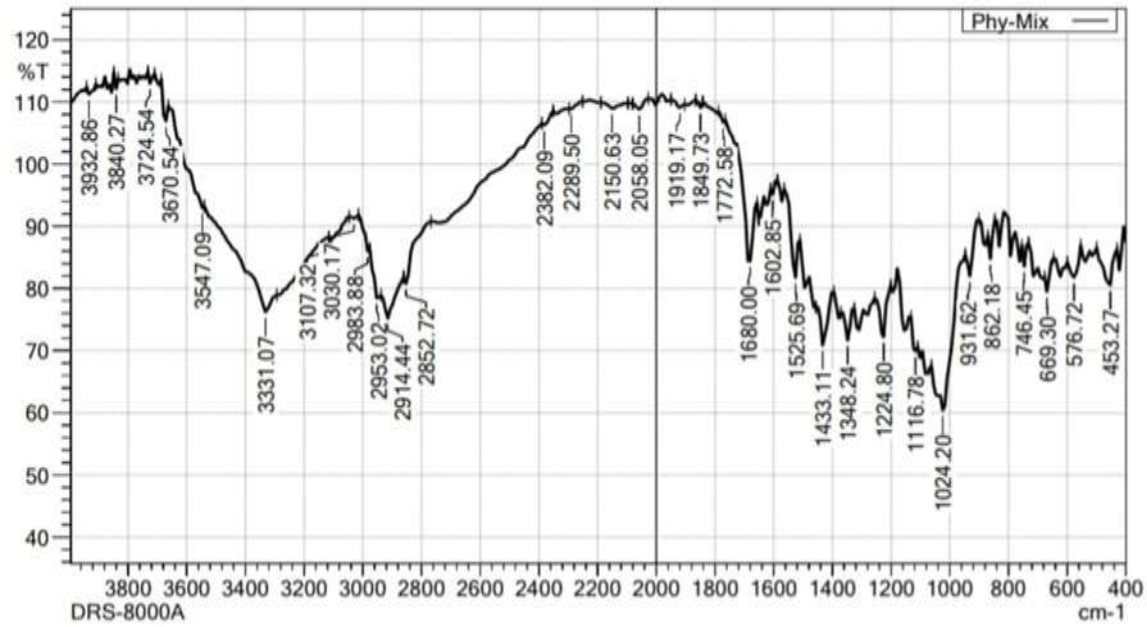

Figure No. 4: FTIR spectrum of pure Drug Nifedipine and and all excipients

Table No. 6: Functional group and principle peaks present in mixture of Nifedipine and all excipients

Wave Number (cm^{-1})	Functional Group / Bond Type	Characteristics
3932.86 – 3670.54	O–H stretch (free)	Strong, broad – alcohols, phenols
3547.09	N–H stretch	Primary amines
3331.07 – 3107.32	N–H or O–H stretch	Hydrogen bonding – amines or phenols
3030.17 – 2983.88	C–H stretch (aromatic/aliphatic)	Alkanes or aromatics
2953.02 – 2852.72	C–H stretch (alkanes)	Methyl/methylene groups
2382.09 – 2058.05	C≡C or C≡N stretch	Alkynes or nitriles (weak)
1919.17 – 1772.85	Overtone or combination bands	Aromatic compounds
1680.00 – 1602.85	C=O or C=C stretch	Carbonyl (ketones, esters), aromatic C=C
1525.09 – 1433.11	N–O asymmetric stretch, C–C stretch	Nitro compounds, aromatics
1383.24 – 1224.80	C–H bending, C–O stretch	Alkanes, alcohols, esters
1116.78 – 1024.20	C–O–C or C–O stretch	Ethers, esters
931.62 – 746.45	Aromatic C–H out-of-plane bend	Mono- or disubstituted aromatics
669.30 – 453.27	C–Cl, C–Br stretch	Halogenated compounds

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FTIR spectral analysis of pure Nifedipine and its physical mixture with all excipients (SSG, Crospovidone, Microcrystalline Cellulose, Talc, Aspartame, Magnesium Stearate), no significant peak shifts, new interactions, or degradation products were observed. Thus, Nifedipine is compatible with the selected excipients based on FTIR analysis, confirming its stability in the proposed formulation.

Pre-compression Evaluation Of Powder blend:

The evaluated powder blends (F1–F9) demonstrated varying flow properties based on their angle of repose, compressibility index, and Hausner's ratio. Most formulations exhibited passable to fair flow characteristics, indicating suitability for direct compression.

Table No. 7: Pre-compression evaluation parameters of the powder blend

Formulation code	Angle of repose (Degree)	Bulk density (g/ml)	Tapped density (g/ml)	Carr's index (%)	Hausner's ratio
F01	22.27	0.3112	0.3661	14.99	1.176
F02	23.34	0.3234	0.3832	15.61	1.185
F03	23.15	0.3184	0.3627	13.59	1.157
F04	24.56	0.3164	0.3638	13.03	1.150
F05	23.15	0.3269	0.3792	13.79	1.160
F06	24.58	0.3126	0.3648	14.31	1.167
F07	25.25	0.3111	0.3531	11.89	1.135
F08	23.80	0.3256	0.3749	13.15	1.151
F09	**22.13**	**0.3261**	**0.3863**	**15.58**	**1.185**

Post-compression evaluation parameters of finished product:
Physical parameters of batch from F1 to F9:

Table No. 8: Physical parameters of batch from F1 to F9

Formulation code	Dispersion time (sec)	Disintegration time (sec)	Wetting time (sec)	Water absorption ratio (%)	Drug content uniformity (%)
F1	52.10	58.16	69.62	59.20	92.96
F2	55.45	61.60	75.94	65.80	90.02
F3	51.28	59.24	78.28	67.65	92.16
F4	40.58	48.40	55.45	78.38	93.61
F5	39.25	47.39	53.50	82.50	94.08
F6	41.39	46.33	50.80	79.70	91.25
F7	35.68	42.27	44.70	88.45	97.71
F8	38.24	44.48	46.45	94.56	96.85
F9	**30.50**	**33.51**	**38.26**	**96.04**	**99.82**

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In-vitro Drug Dissolution Study

Table no. 9: Cumulative Percent Drug Release From F1-F9

Formulation code	Cumulative Percent Drug Release Time (min)						
	0	**5**	**10**	**15**	**20**	**25**	**30**
F1	0	65.28	67.71	72.87	74.39	78.04	76.82
F2	0	44.64	53.74	66.80	81.68	77.73	84.72
F3	0	46.46	50.10	61.34	73.48	69.53	74.70
F4	0	51.32	55.26	62.55	68.02	72.87	75.30
F5	0	55.57	58.91	63.77	64.98	72.57	73.48
F6	0	59.21	60.73	65.59	69.23	65.28	70.45
F7	0	62.45	63.77	68.62	75.30	78.04	85.02
F8	0	69.23	74.70	79.86	87.75	85.63	90.79
F9	**0**	**81.68**	**88.97**	**85.93**	**88.66**	**89.88**	**96.86**

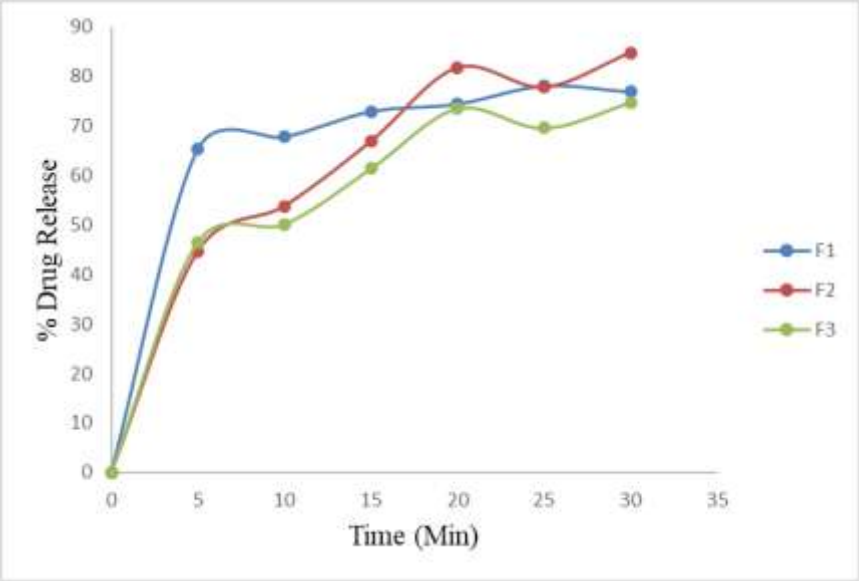

Fig no.5: Comparison Of Cumulative Percent Drug Release From F1-F3

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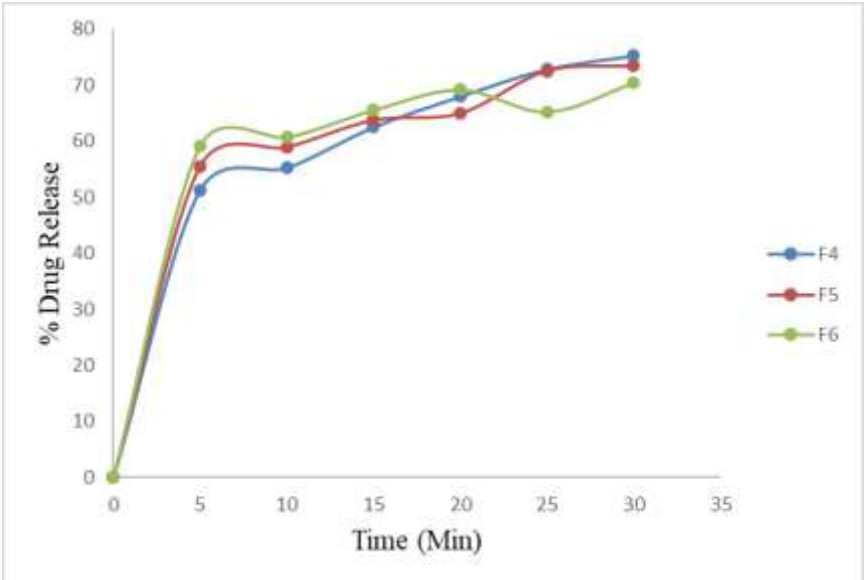

Fig no.6: Comparison Of Cumulative Percent Drug Release From F4-F6

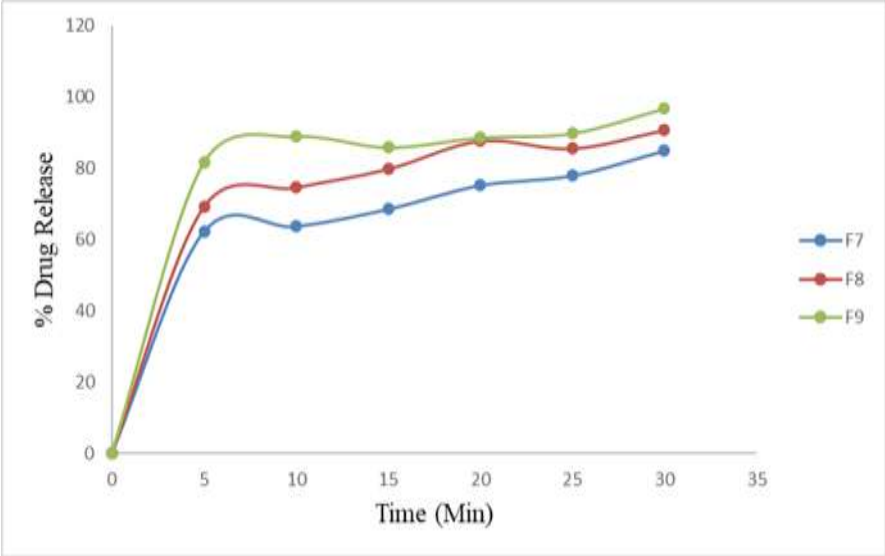

Fig no.7: Comparison Of Cumulative Percent Drug Release From F7-F9

From above results it is concluded that formulation F9 containing 5% Sodium starch glycolate and 5% Crospovidone shows better % Drug release within 15-20 minutes i.e. 96.86%. Also it shows less Disintegration time, Wetting time, Dispersion time, and fast dissolution of drug as compare to other formulations, it may be due to the combined effect of Sodium starch glycolate and Crospovidone as an superdisintegrants.

VII. SUMMARY AND CONCLUSION

A total of nine formulations (F01–F09) were developed using varying concentrations of synthetic superdisintegrants such as Sodium starch glycolate, Crospovidone and Crosscarmellose sodium at different concentrations (2.5-5%). To mask or enhance the slightly bitter taste of drug we add Mannitol and Aspartame, so it will be useful for diabetic patients. The drug-excipient compatibility studies confirmed no significant interactions, ensuring the stability of the formulation.

The formulations were prepared with different drug-superdisintegrant ratios:

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F1-F3: Contained Sodium starch glycolate, Crospovidone and Crosscarmellose sodium respectively in the concentration 5mg/tab. F3 showed slow drug release, necessitating an increase in superdisintegrant concentration in later formulations.
F4-F6: Included Sodium starch glycolate, Crospovidone and Crosscarmellose sodium, respectively ata higher concentrations 10mg/tab.
F7: Used combination of Sodium starch glycolate and Crosscarmellose sodium. The F7 batch showed better drug release within 30 minutes.
F8: Used combination of Crospovidone and Crosscarmellose sodium. The F8 batch showed better drug release within 20 minutes.
F9: Used combination of Sodium starch glycolate and Crospovidone. The F8 batch showed better drug release within 5 minutes.

Optimization and Selection of Batch F9:

Among all the developed formulations, batch F09 was identified as the optimized formulation based on its pre-compression and post-compression evaluation parameters and evolutionary results.

Conclusion:

The formulated Nifedipine fast disintegrating tablet (FDT) successfully achieved fast drug releaseand patient compliance. The study demonstrated that the selected polymer (superdisintegrant) concentration and excipient combination effectively controlled the drug release mechanism. The formulation enhanced patient compliance, particularly in populations with swallowing difficulties such as pediatric, geriatric, and psychiatric patients. The optimized formulation (F9) demonstrated rapid disintegration within seconds and improved dissolution characteristics, leading to potentially faster onset of action compared to conventional tablets. This approach also bypasses first-pass metabolism to some extent and ensures better bioavailability. Overall, the study confirms that FDTs of Nifedipine can be a promising alternative to conventional dosage forms for improved therapeutic efficacy and patient convenience.

Hence, the optimized formulation (F9) can serve as a promising alternative for the effective management of Hypertension and Angina.

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