RESEARCH PAPER

# Formulation and Evaluation of Nimodipine Floating Tablet By Solid Dispersion Using Microwave Irradiation Method

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**ABSTRACT**

Oral drug delivery remains the most preferred route of administration due to its convenience and patient compliance. The development of sustained and controlled release systems, which serve as drug reservoirs and allow the release of active pharmaceutical ingredients at a predefined rate, has advanced significantly in recent years. After reaching steady state, an ideal controlled release dosage form maintains constant plasma drug levels, simulating intravenous infusion. By extending the duration of residence in the stomach, gastric retention systems further improve therapeutic efficacy. This is especially advantageous for medications that act locally in the stomach, are mostly absorbed in the upper gastrointestinal tract, are poorly soluble at alkaline pH, or have a limited absorption window. The maximum quantity of solute that dissolves in a solvent at a given temperature is known as solubility, and it is a key factor in drug bioavailability. Solubility is greatly influenced by variables such molecular size, temperature, pressure, particle size, polarity, and polymorphism. Physical modification, particle size reduction, crystal habit modification, drug dispersion in carriers, complexation, surfactant-based solubilization, and chemical modification are some methods to improve solubility. Among these, complexation using microwave irradiation has become a new and effective method. Due to its speed, energy efficiency, and environmental friendliness, microwave-assisted synthesis is becoming more and more popular. Microwave irradiation, as opposed to traditional heating, heats materials directly, producing superheating effects, faster and more selective heating, and increased reaction efficiency. Dielectric heating is the process by which electromagnetic waves cause molecules to move through polarization and conduction, producing heat inside the substance. This technology offers better solubility enhancement and sustainable processing techniques, making it a promising development in pharmaceutical research.

**Keywords:** Oral Drug Delivery, Bioavailability, Solubility Enhancement, Complexation, Microwave Irradiation, Pharmaceutical Formulation.

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## Introduction [1,7]

Oral administration has long been the primary method for delivering drugs. Over the last twenty years, a variety of oral delivery systems have been created to serve as reservoirs for drugs, allowing the active ingredient to be released at a controlled and predetermined rate over a specific duration. From a pharmacokinetic perspective, the optimal sustained and controlled release dose form should resemble an intravenous infusion, which constantly delivers the quantity of medication required to sustain steady plasma levels after the steady state is established. For local action in the upper portion of the small intestine, such as the treatment of peptic ulcer disease, a prolonged residence period in the stomach may be beneficial. Gastric retentive devices may be beneficial for some medications. Among them are: [1,7]

• Acting locally in the stomach.

• Primarily absorbed in the stomach.

• Poorly soluble at an alkaline PH.

• Narrow window of absorption.

• Absorbed rapidly from the GI tract.

• Degrade in the colon.

**2. Solubility**[5-7]

The maximum amount of solute that may dissolve in a given amount of solvent or solution at a given temperature is known as its solubility. Bioavailability rises with increasing solubility.

**Factor affecting solubility:-**[5,6]

· Molecular size
· Nature of the solute and solvent
· Temperature
· Pressure
· Particle size
· Polarity
· Polymorphs

**Technique to enhance solubility**[1,4]

1) Physical modification
2) Particle size reduction
3) Modification of crystal habit
4) Drug dispersion in carrier
5) Complexation
6) Solubilization by surfactants
7) Chemical modification

**Complexation**

**Microwave irradiation method**[-]

One of the main functions of chemistry research is organic synthesis, which helps to improve everyone's quality of life by producing everything from plastics to medications. Many important developments in the practical aspects of organic chemistry over the past few decades have led to the development of a wide range of analytical tools as well as innovative synthesis strategies and procedures. These days, technological advancements are focused on cleaner, more ecologically friendly processes. As a result, modern chemists are no longer limited to employing thermal energy alone to drive chemical reactions; instead, they are now able to use a variety of sonochemical, microwave, and enzymatic techniques.

An emerging area of study is the application of microwave (MW) irradiation for chemical synthesis. The exponential development in the number of publications—roughly 1200 to date—and the number of process patents in this area of current study demonstrate the researchers' interest in the topic.

**Materials and methods Materials**

Nimodipine were obtained as a gift samples from Laksh Finechem pvt Ltd. Ahmadabad.β-cyclodextrin were obtained as a Gangwal Chemicals, Mumbai. Microcrystalline cellulose were obtained as a FMC Biopolymer, Mumbai.Sodium bicarbonate and dicalcium phosphate were obtained from Ranchem Chemicals, New delhi. Every other chemical and solvent utilized was of the grade of an analytical reagent.

**Phase solubility studies:**

Phase-solubility tests were conducted using the procedure described by Higuchi and Connors. Nimodipine (50 mg) was added to 15 ml of distilled water that contained 3–15 mM of βCD, and the mixture was then placed into 25 ml stopped conical flasks. A rotary flask shaker was used to shake the mixtures for 72 hours at ambient temperature (280C). Samples were taken out and filtered right away using a 0.45 μ nylon disc filter after 72 hours of equilibration. After an appropriate dilution, each sample's drug content was measured at 358 nm using an UV/Visible spectrophotometer. The solubility tests were carried out three times (n = 3). [5-7]

**Preparation of inclusion complexes**

**Microwave irradiation method**

This method uses a microwave oven to create a microwave irradiation reaction between the medication and complexing agent. A 1:1 molar ratio of nimodipine and β-cyclodextrin was dissolved in a predetermined ratio of water and methanol in a round-bottom flask. The combination was heated to 340 watts in a microwave oven for a brief period of time—roughly four minutes. The residual, uncomplexed free drug and β-cyclodextrin were removed from the reaction mixture by adding a sufficient amount of solvent mixture (methanol+water) after the reaction was finished The precipitate so obtained was separated using Whatman filter paper, and dried in vaccum oven at $40^0$C for 8 hrs.

**Preparation of Nimodipine Floating Tablet Blend :-**[9-10]

Nimodipine floating tablets were prepare using the wet granulation method in accordance with the formula. series of tablets (F1-F7). HPMCK4M at varying concentrations as a sustained release polymer and Pvp K30 as a binder. The effervescent agent was sodium bicarbonate. The formulation's

lubricant, glidant, and antiadherent components were magnesium stearate, talc, and aerosil.

1. Inclusion complex were prepared by weighed quantities of nimodipine with β-cyclodextrin in (1:1) ratio.
2. All the ingredients were accurately weighed, passed through sieve.60.
3. Inclusion complex (Nimodipine:β-cyclodextrin), microcrystalline cellulose& HPMCk4M were transferred to a clean porcelain mortar except magnesium stearate, talc & aerosil.
4. Binding solution was added to the powder mixture in small quantities, while mixing thoroughly after each addition until a coherent mass was formed.
5. Then it was passed through sieve no. 22 and the wet granules were dried in hot air oven at 60°C for 30 min.
6. Lastly mag. stearate, sodium bicarbonate, talc &aerosol were added to the dried granules and mixed.
7. Tablets were compressed on a CIP multitooling punching machine using round shaped standard concave punch.

**Estimation of Nimodipine**: [11]

Nimodipine content of the complexes was estimated by UV spectrophotometric method. Nimodipine from accurately weighed samples was extracted into methanol and the extracts were suitably diluted with 0.1N HCl and assayed for nimodipine content by measuring the absorbance at 358 nm using 0.1N HCl as blank.

**Drug carrier compatibility studies:-**

**Fourier Transform Infrared Spectroscopy (FTIR)**

Fourier transformed infrared technique is one of the most powerful technique to identify functional groups. The infrared spectra of pure nimodipine sample were recorded (Carry 630 FTIR spectrometer). The Agilent technology was used for preparation of sample. the infrared spectra of nimodipine, β - CD, nimodipine: β-CD(1:1),nimodipine: HPMC K4M(1:1). The spectrum was compared with the infrared spectra of plain drug and polymer and checked for the drug polymer interaction.[12]

**Differential Scanning Calorimetry (DSC)**

The thermal analysis can be used to investigate and predict any physicochemical interactions between components in a formulation and can therefore be applied to the selection of suitable chemically compatible excipients. Drug and excipients in the ratio 1:1 were analyzed for differential scanning calorimetry.[14-16]

**Powder X-ray Diffractometry**

X-ray diffraction spectroscopy has been used to assess of crystallinity of given drug substances. From the XRD study we conclude the crystallinity of sample. When complexation of nimodipine and β-cyclodextrin are formed, the overall number of crystalline structure is reduced and the number of amorphous structures is increased.[12]

**Table 1: Composition of nimodipine floating tablets and their betacyclodextrin inclusion complex.**

| **Ingredients** | **Batches** | | | | | | |
|---|---|---|---|---|---|---|---|
| | **F1** | **F2** | **F3** | **F4** | **F5** | **F6** | **F7** |
| Nimodipine | 50 | - | - | - | - | **-** | - |
| Nimodipine:β-Cyclodextrine | - | 190 | 190 | 190 | 190 | **190** | 190 |
| MCC | 115 | 15 | 35 | 55 | 75 | **95** | 115 |
| HPMCK4M | 240 | 200 | 180 | 160 | 140 | **120** | 100 |
| PVPK30 | 30 | 30 | 30 | 30 | 30 | **30** | 30 |
| Sodium Bicarbonate | 150 | 150 | 150 | 150 | 150 | **150** | 150 |
| Magnesium stearate | 6 | 6 | 6 | 6 | 6 | **6** | 6 |
| Talc | 6 | 6 | 6 | 6 | 6 | **6** | 6 |
| Aerosil | 3 | 3 | 3 | 3 | 3 | **3** | 3 |
| **Average weight** | **600** | **600** | **600** | **600** | **600** | **600** | **600** |

**Nimodipine-betacyclodextrin inclusion complex in 1:1 molar ratio equivalent to 50 mg of nimodipine.**

**Evaluation Parameters**

**1) Weight variation:-**

Weigh each of 20 randomly chosen units or the contents of 20 units in separate containers for a single dose preparation, then compute the average weight. None of the individual weights differ from the average weight by more than twice the percentage, and no more than two deviate by more than the percentage displayed in the table.[4-5]

**2) Thickness**

A Vernier caliper was used to measure the diameter and thickness homogeneity. The tablet's average thickness and diameter were computed. If there was no deviation of ± 5% from the average in any of the individual diameter and thickness values, the test was considered successful. [4-5]

**3)Hardness**

The tablet's hardness was assessed using a Monsanto hardness tester. The tablet was positioned vertically between the tester's jaws. A spring and screw gauge were used to tension the two jaws. The applied pressure from the spring was measured in kg/cm2 at collapse after the screw was turned to increase the load. [5-7]

**4) Friability**

For a tablet weighing 0.65 g or less on average, take a sample of 6.5 g of whole tablets; for a tablet weighing more than 0.65 g, take a sample of 10 entire tablets. Carefully dust the tablets and precisely weigh the necessary quantity. After inserting the tablets, turn the drum 100 times. Take out the tablets, clean them of any loose dust, and weigh them precisely. The test is only conducted once, unless the results are hard to understand or the weight loss exceeds the desired level, in which case it is repeated twice and the average of the three tests is calculated. A maximum loss of weight (from a single test or from the mean of the three tests) is not greater than 1.0% is acceptable for most tablets.[6-7]

**5) Drug Content**

The average weight of three floating tablets was calculated after they were chosen at random. Using a mortar and pestle, tablets were triturated. Tablet powder equal to 50 mg of nimodipine was first dissolved in 15 ml of distilled water, and the volume was then increased to 50 ml. Next, 1 milliliter of this solution was diluted with 10 milliliters of distilled water. A Shimadzu 1800 UV spectrophotometer was used to measure this solution at 238 nm against the corresponding reagent blank.[6-7]

**6) Buoyancy study/Floating behavior:**

The in vitro buoyancy was determined by floating lag time and floating time. The tablets were placed in dissolution test apparatus USP II(paddle type) containing 900 ml of 0.1 N HCl (pH-1.2) maintained at 37+ 0.5 $^0$ c. Paddle RPM was set to 50RPM. The time required for the tablet to rise to the surface of and float was determined as floating lag time. Buoyancy time/ floating time is the total time for which the tablets float in dissolution medium (including buoyancy lag time) before getting disintegrated or settling down.[11]

**7) Swelling index**

Each tablet was precisely weighed and stored in 50 milliliters of water. Tablets were taken out carefully after 60 minutes, blotted with filter paper to remove the water present on the surface and weighed accurately. The following formula was used to determine the percentage swelling index.[12]

**8) In – vitro dissolution study**

The release rate of nimodipine floating tablets was determined using USP dissolution testing apparatus II (paddle method). The dissolution test was performed using 900 ml of 0.1N HCl at 37°C ± 0.5°C and 50 rpm. Sample solution of 5 ml was withdrawn from the dissolution apparatus at intervals (30min, 1, 2, 4, 6, 8, 12 hrs). The withdrawn samples were replaced with fresh dissolution medium of same quantity. The withdrawn samples were filtered through what man filter paper and analyzed spectrophotometrically at 238nm.[11]

**Table:-2 Evaluation data of floating tablets of nimodipine and its inclusion complex with betacyclodextrin**

| Evaluation parameter | Batches | | | | | | |
|---|---|---|---|---|---|---|---|
| | F1 | F2 | F3 | F4 | F5 | F6 | F7 |
| Weight variation (mg) (n=6) | 599± 0.04 | 603± 0.02 | 602± 0.06 | 598± 0.03 | **600± 0.04** | 599± 0.02 | 599± 0.03 |
| Thickness (mm) (n=3) | 4.72± 0.13 | 4.69± 0.27 | 4.70± 0.24 | 4.70± 0.12 | **4.66± 0.13** | 4.66± 0.20 | 4.65± 0.08 |
| Hardness (kg/cm$^2$) | 5.2 ± 0.64 | 5.3 ± 0.68 | 5.1 ± 0.57 | 5.2 ± 0.80 | **5.4 ± 0.46** | 5.0 ± 0.57 | 5.3 ± 1.06 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| (n=3) | | | | | | | |
| Friability (%) (n=3) | 0.603 ± 0.31 | 0.593 ± 0.18 | 0.584 ± 0.43 | 0.543 ± 0.12 | **0.504 ± 0.06** | 0.614 ± 0.07 | 0.787 ± 0.05 |
| Content uniformity(%) (n=6) | 96.25 ± 0.42 | 98.64 ± 0.75 | 95.32 ± 0.68 | 93.67 ± 0.85 | **99.73 ± 0.61** | 94.23 ± 0.44 | 96.76 ± 0.69 |
| Swelling index | 0.771 ± 0.01 | 1.0453 ± 0.01 | 1.5026 ± 0.06 | 0.6215 ± 0.03 | **1.127 ± 0.10** | 1.4767 ± 0.018 | 0.9495 ± 0.01 |

**Table No. 3 Buoyancy study/Floating behavior**

| Batches | Total lag time (sec) | Total floating time (hrs) |
|---|---|---|
| B1 | 088 | 14.00 |
| B2 | 028 | 12.00 |
| B3 | 064 | 13.40 |
| **B4** | **054** | **12.50** |
| B5 | 039 | 12.20 |
| B6 | 038 | 12.10 |
| B7 | 044 | 12.40 |

**Table No. 8 Result of in vitro drug release study of Floating tablet of nimodipine**

| Time (hr) | Batches | | | | | | |
|---|---|---|---|---|---|---|---|
| | **F1** | **F2** | **F3** | **F4** | **F5** | **F6** | **F7** |
| 0 | 0 | 0 | 0 | 0 | 0 | **0** | 0 |
| 1 | 10.25 | 12.20 | 14.30 | 15.33 | 18.01 | **18.49** | 20 |
| 2 | 19.3 | 17.44 | 19.72 | 21.12 | 20.17 | **20.41** | 25 |
| 4 | 27.03 | 22.08 | 24.90 | 25.92 | 23 | **24** | 30 |
| 6 | 34.23 | 52.12 | 55.01 | 52.67 | 43.12 | **54** | 50 |
| 8 | 54.46 | 72.30 | 71.10 | 75.55 | 79.11 | **80.30** | 83.13 |
| 12 | 70.54 | 87.12 | 89.20 | 90.11 | 90.85 | **92.32** | 95.66 |

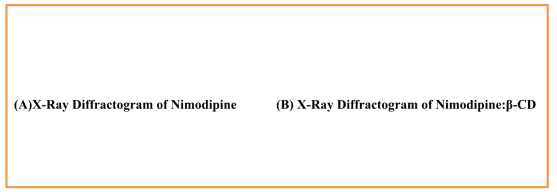


**Figure 1: X-ray diffractograms of nimodipine (A), nimodipine-βCD in 1:1M ratio (B)**

**Figure 2: DSC thermograms of nimodipine (A), nimodipine-βCD in 1:1M ratio (B).**

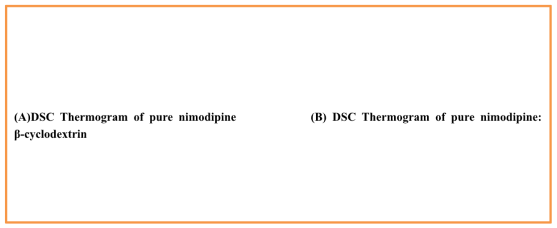


**Figure No:-4 FTIR Sprectum of β-Cyclodextrin**

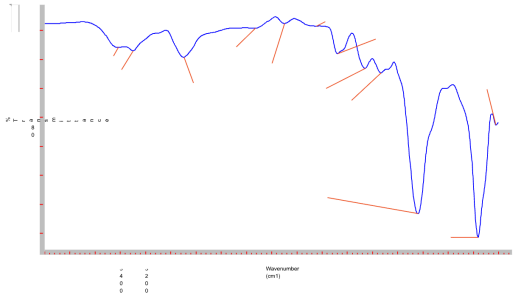

**Figure No:-4 FTIR Sprectum of nimodipine:β-Cyclodextrin**

**Figure No:-4 FTIR Sprectum of nimodipine:β-Cyclodextrin**

**Results and Discussions:** The phase-solubility diagram was of AL according to Higuchi and Connors. The aqueous solubility of nimodipine was increased linearly as a function of the concentration of βCD with a slope of 0.99. Dissolution rate constant were calculated from the slope of the first order linear plots of the dissolution data. The dissolution profiles are indicate that the inclusion complex gave fast and rapid dissolution of nimodipine when compared to nimodipine pure

drug. dissolution efficiency was observed with βCD in 1:1, 1:2 and 1:3 respectively. Thus both solubility and dissolution rate of nimodipine were markedly enhanced by

complexation with βCD. N-βCD(1:1) was taken for preparing floating tablets, physical parameters (thickness and diameter), hardness, buoyancy time and drug content of all the formulations are shown in Table 2. FTIR spectra analytical reports confirmed that there was no interaction between drug and excipients used (Fig No: 3). The drug release was shown to be dependent on the concentration and viscosity grades of HPMC based on the in-vitro release data. Different grades of HPMC were selected as swellable polymers because they are commonly used as low-density hydrocolloid systems; when they come into contact with water, a hydrogel layer forms to serve as a gel boundary for the delivery system; sodium bicarbonate is used as a gas-generating agent that causes the tablet to become floatable and stay in the stomach. When the sodium bicarbonate tablet comes into contact with the acidic dissolution liquid, carbon dioxide is created inside the tablet. The tablet floats thanks to hydroxypropyl methylcellulose's low density. Additionally, by trapping carbon dioxide gas in its gel network, HPMC's gelling ability aids in the tablet's ability to float. During the dissolving research, the tablet's disintegration is prevented by HPMC's gelling ability. Tablets containing lower viscosity grades of HPMC controlled the release but could not buoyant for longer time but tablets containing higher viscosity grade of HPMC controlled the release with good buoyancy time. Release from floating tablets of F0 was found to be very slow, 58.2% in 24 h. The poor dissolution and low release of nimodipine from F0 is due to the high crystalline nature and poor solubility of nimodipine. Whereas floating tablets formulated employing N-βCD inclusion complex gave slow, controlled and complete release spread over a period of 24 h. The drug release profile of the tablets having total buoyancy time of 22 h or more are shown. In conclusion, controlled release floating tablets of nimodipine could be developed using its inclusion complex with BCD.

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