RESEARCH PAPER

# Enhancement of solubility of nimodipine for design and development of floating drug delivery system

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***ABSTRACT***
The present study deals with preparation and evaluation of floating tablets of Nimodipine with the help of β-Cyclodextrin for solubility and bioavailability enhancement. Nimodipine, a calcium channel blocker for the therapy of subarachnoid hemorrhage and cerebral vasospasm, is affected by poor solubility in water and low oral bioavailability being subjected to significant first-pass metabolism. In order to overcome these limitations, the complexing agent β-Cyclodextrin was used and a floating drug delivery system was designed to increase gastric residence time and absorption in the upper gastric tract. The prepared inclusion complex of Nimodipine with β-Cyclodextrin was made through kneading and co-evaporation and its solubility enhancement was determined. Floating tablets were developed using direct compression technology using suitable polymers such as Hydroxypropyl Methylcellulose (HPMC) and gas-generating agents such as sodium bicarbonate. The tablets were studied with respect to pre-compression parameters, post compression characteristics, floating behavior, drug content, in vitro drug release and stability. The tested results revealed a meaningful increase in solubility of Nimodipine in the presence of β-Cyclodextrin. The optimized formulation demonstrated acceptable floating lag time and total floating time over 12 hours. The in vitro release studies demonstrated sustained drug release for a period of 12 hours following non-Fickian diffusion kinetics. The formulation showed improved dissolution properties as compared to plain drug and market formulations-inferring enhanced bioavailability. Finally, the combination of β-Cyclodextrin with floating drug delivery systems appears to be a promising approach for increasing the therapeutic efficacy of poor soluble drugs such as Nimodipine.
**Keywords:** Nimodipine, Floating drug delivery system (FDDS), β-Cyclodextrin inclusion complex, Solid dispersion, Solubility enhancement, Oral bioavailability.
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**Introduction**[1-3]
Drug distribution via oral administration has been the most common method. Many oral delivery systems have been developed during the past 20 years to serve as drug reservoirs from which the active ingredient can be delivered at a predefined and controlled rate over a predetermined length of time. From a pharmacokinetic perspective, an intravenous infusion, which constantly administers the amount of medication required to maintain consistent plasma levels once the steady state is attained, should be comparable to the ideal sustained and controlled release dosage form. 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 are beneficial for some medications. Among them are:
• Having a local effect in the stomach.
• Mostly taken up in the stomach.
• Insoluble at alkaline pH levels.
• A limited absorption window.
• Quickly absorbed from the GI tract.
• Break down in the colon.

**Floating drug delivery system:**[4-6]
Since their bulk density is less than that of gastric fluid, floating systems—which Davis originally characterized in 1968—remain buoyant in the abdomen for extended periods of time. Drugs that are unstable or poorly soluble in intestinal fluids can benefit from floating drug delivery systems (FDDS), which are designed to keep the medication in the stomach. Making the dose form less thick than the stomach fluids so it can float on them is the basic idea. By adding various low density fillers, such as hydroxyl cellulose, lactates, or microcrystalline cellulose, the system's density can be decreased. This system's function is heavily reliant on the presence of food and liquid in the stomach, which makes it less than optimal. Because the drug dose does not disintegrate, the underlying goal behind the invention of such a device was to maintain a consistent level of drug in the blood plasma. To release the medication from the dosage form and maintain steady drug levels in the blood, the

medication typically floats in the stomach fluid and gradually dissolves at a set rate.

**Solubility**[7,8]

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.

Method for improving solubility

1) Physical alteration
2) Diminished particle size
3) Crystal habit modification
4) Dispersion of drugs in carriers
5) Complexity
6) Surfactant-induced solubilization
7) Chemical alteration

**Materials and methods :-**Nimodipine were obtained as a gift samples from Laksh its Finechempvt 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 mixed with 15 milliliters 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).

**Formulation**

**Improvement of solubility of Nimodipine**

**By inclusion complex formation.**[1-3]

Inclusion complexes of nimodipine with β-cyclodextrin (βCD) were prepared by triturating nimodipine and βCD in a mortar at 1:1, 1:2 and 1:3 ratios, using a solvent mixture of water and methanol (6:4, 10 ml). The resulting thick slurries were kneaded for 45 minutes, dried at 55°C, ground into a fine powder, and then sieved through a #100 mesh.

**By Microwave-Assisted Solid Dispersion.** [6,10]

Solid dispersions in ratios of 1:1, 1:2 and 1:3 w/w ratio of Nimodipine to PEG 6000 were prepared using microwave irradiation. A fixed amount of the physical mixture (1 g) was placed in a glass beaker and subjected to microwave energy for 5 minutes at a power of 600 W using a domestic microwave oven. Only one beaker was placed in the microwave oven at a time, ensuring precise placement. After irradiation, the solid dispersions were ground in a glass mortar and passed through a 100-mesh sieve to achieve a uniform particle size.

**Table 1.1: Results of improvement in quantitative solubility of Nimodipine using different solubility techniques**

| S. | Solvent | Nimod | N-βC (1:1) | N-βC | N-βCD |
|---|---|---|---|---|---|
| 1 | Water | 0.06 | **0.56** | 0.36 | 0.18 |
| 2 | Ethanol | 2.02 | **4.22** | 1.44 | 2.56 |
| 3 | Acetone | 1.98 | **3.98** | 2.12 | 2.78 |
| 4 | Methan | 1.12 | **2.14** | 1.38 | 1.72 |
| 5 | DMSO | 79 | **178** | 89 | 91 |
| 6 | PBS 1.2 | 1.02 | **2.02** | 1.21 | 1.78 |

**Preparation of Nimodipine Floating tablet (Using improved solubility of Nimodipine)**

The direct compression method was used to create nimodipine floating tablets in both its pure form and as an inclusion complex with β-cyclodextrin (βCD). In order to accomplish extended floating for more than 12 hours, the formulation was created using a variety of swellable polymers based on trial trials. To guarantee floating, HPMC was chosen as the swellable polymer. In a glass mortar, every ingredient—aside from magnesium stearate—was well combined. Magnesium stearate was added once the medicine and excipients had been sufficiently mixed, and the combination was then blended for a further 2-3 to minutes.The resulting powder was then compressed into tablets using tablet punching machine with a 12 mm flat-faced punch. Design Expert software version 13 with Central Composite Design was used to create the tablet formula. Based on various ratios of polymer concentration (HPMC k4m and HPMC k15M), the software produced thirteen formulations with five center points. The necessity to maximize the tablet's buoyancy and release profile usually justifies the inclusion of both HPMC K4M and HPMC K15M in a floating tablet formulation. Every grade of HPMC has unique qualities that affect various facets of the tablet's functionality. Sustained release: K15M optimizes medication release, while HPMC K4M slows it down. Both grades contribute to the tablet's ability to float, with K4M offering more robust gel formation and K15M improving buoyancy. Gel integrity: K15M provides flexibility and control, while K4M guarantees a robust gel. Flexibility in formulation: This combination enables formulators to adjust the tablet's release profile and other important characteristics. [8-10]

| Fo io | Percentage Cumulative drug relea respect to time (in hours) | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 1( | 1 | 1 |
| N | 0 | 6. | 1 | 2 | 2 | 3 | 4 | 5 | 6 | 7 | 7( | 7 | 8 |
| N | 0 | 6. | 1 | 2 | 2 | 3 | 4 | 4 | 5 | 6 | 7( | 7 | 8 |
| N | 0 | 5. | 1 | 1 | 2 | 4 | 5 | 6 | 6 | 7 | 7 | 7 | 7 |
| N | 0 | 6. | 1 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 7 | 8 | 8 |
| N | 0 | 7. | 1 | 2 | 2 | 3 | 4 | 4 | 5 | 6 | 7( | 7( | 8 |
| N | 0 | 8. | 2 | 3 | 4 | 5 | 5 | 6 | 7 | 8 | 8 | 9 | 9 |
| N | 0 | 4. | 7. | 1 | 2 | 3 | 4 | 5 | 6 | 6 | 6 | 7 | 7 |
| N | 0 | 7. | 1 | 2 | 2 | 3 | 5 | 5 | 6 | 7 | 8 | 8 | 9 |
| N | 0 | 3. | 9. | 1 | 2 | 3 | 4 | 6 | 6 | 7 | 7 | 7 | 7 |

**Table 1.2: Formulation table for Nimodipine-βCD (inclusion complex) tablet**

| Ingredient | N | N | N | N | N | N | N | N | N |
|---|---|---|---|---|---|---|---|---|---|
| N-βCD(1:1) | 19 | 19 | 19 | 19 | 19 | 19 | 19 | 19 | 19 |
| HPMC k4m | 90 | 30 | 90 | 5. | 15 | 15 | 30 | 17 | 90 |
| HPMC 15m | 90 | 30 | 5. | 90 | 15 | 30 | 15 | 90 | 17 |
| Sodium bica | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| Talc | 12 | 24 | 20 | 20 | 5 | 12 | 12 | 40 | 40 |
| Magnesium | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| Total Weigh | 60 | 60 | 60 | 60 | 60 | 60 | 60 | 60 | 60 |

**Evaluation**

**Weight variation**[1]

Twenty tablets were chosen at random, and the average weight was calculated. The weight of each tablet was then measured and compared to the average weight.

**Thickness**[1-3]

The prepared floating tablets were evaluated thickness using Verniercalipers.

**Hardness**[1-3]

Hardness of tablets (n=3) was determined using Monsanto hardness tester.

**Friability**[5,6]

The Roche friabilator was used to assess the tablets' friability. A preweighed sample of ten pills was put in the friabilator and run for one hundred rotations. After that, the tablets were powdered and weighed again. Three iterations of the experiment were conducted.

**Drug content**[5,6]

Weighing and powdering twenty tablets of each formulation was done. A 100 ml volumetric flask was filled with the amount of powder equal to 100 mg of medication, agitated with 70 ml of distilled water, and its volume was corrected to 100 ml using water. A UV spectrophotometer set to 239 nm was used to measure absorbance after the solution was filtered and appropriate dilutions were prepared.The experiment was carried out three times.

**Buoyancy study**[7,8]

The buoyancy lag time is the amount of time it takes for a pill to appear on the medium's surface, and the total floating time (TFT) is the amount of time the dosage form stays on the medium's surface continuously.The buoyancy of the tablets was investigated in a USP type II dissolution equipment at 37±0.5oC in 900ml of pH 1.2 simulated stomach juice. Visual observations were made on the duration of the floating.

**Swelling index**[1-3]

The prepared tablets were placed in a glass containing 200 mL of 0.1 N HCl at 37 ± 0.5°C. The percentage of swelling at different time interval was calculated by the following equation.

SI (%)= (Wt-Wo/Wo) * 100

Where, SI is swelling index, Wt is weight of tablet at time t, Wo is weight of the dry tablet before placing in the glass.

**In-vitro dissolution study**[7,8]

The USP paddle dissolving test apparatus was used to conduct in-vitro release investigations. 900 milliliters of 0.1 N HCl (pH1.2) were added to the dissolution vessel, and the medium's temperature was kept at 37±0.5oC. For 12 hours, 0.5 ml of sample was taken out at prearranged intervals, and the same volume of fresh medium was added while maintaining 100 rpm. A UV spectrophotometer was used to analyze the samples at 239 nm.

**Table 1.3:- Results of evaluation parameters for Nimodipine-B-CD (N-βCD inclusion complex) floating tablet**

| Para | NI | NE | NI | NB | NI | NI | NI | NE | NI |
|---|---|---|---|---|---|---|---|---|---|
| We vari | 59 | 60 | 60 | 60 | 60 | 60 | 60 | 60 | 59 |
| Thic | 4.( | 4.( | 4.( | 4.0 | 4.( | 4.( | 4.( | 4.1 | 4.( |
| Har | 3.2 | 3.1 | 3.3 | 3.3 | 3.2 | 3.1 | 3.1 | 3.2 | 3.2 |
| Fria | 0.8 | 0.8 | 0.9 | 0.7 | 0.1 | 0.1 | 0.8 | 0.8 | 0.1 |
| Drug | 84 2 | 84 2 | 74 4 | 78. 8 | 84 8 | 96 8 | 67 2 | 91 6 | 76 2 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **Buoya ti** | 25 2 | 28 | 35 | 27 | 27 | 28 | 31 | 28 | 30 |
| **Total t ti** | 11 5 | 12 2 | 11 6 | 11. | 11 8 | 11 6 | 11 8 | 11 5 | 11 9 |
| **Swe in** | 44 2 | 35 0.3 | 43 1 | 42. 0.2 | 42 9 | 38 6 | 39 3 | 38 +0 | 40 2 |

**In-vitro drug release**[32,33]

The data displayed the cumulative drug release over time for different formulations (NB1 to NB9). While there were variations in the rate and extent of release, all formulations showed an increase in drug release over time. Formulation NB6 showed the highest drug release, reaching nearly 99% by 12 hours, indicating a rapid release profile, while formulation NB7 showed the slowest release, releasing only 74.6% of the drug by the end of the 12-hour period.

Formulations NB1, NB2, and NB5 had intermediate release profiles, with the drug release increasing steadily but not as quickly as NB6. Notably, formulation NB3 showed a slightly delayed release pattern, with a steep increase in release from around 5 hours onward, reaching 75.11% at 12 hours. Formulations NB4 and NB8 showed moderate and consistent drug release over time, with NB8 achieving 92.65% release at a slightly slower rate than NB6.

The variation in release rates across the formulations might have been attributed to differences in the formulation components, such as the type of excipients used, the drug's solubility, or other factors influencing dissolution and absorption rates. These differences highlight the importance of formulation design in controlling the release profile of the drug.

**Table 1.4: Percentage Cumulative drug release of Nimodipine-B-CD (N-βCD inclusion complex) floating tablet.**

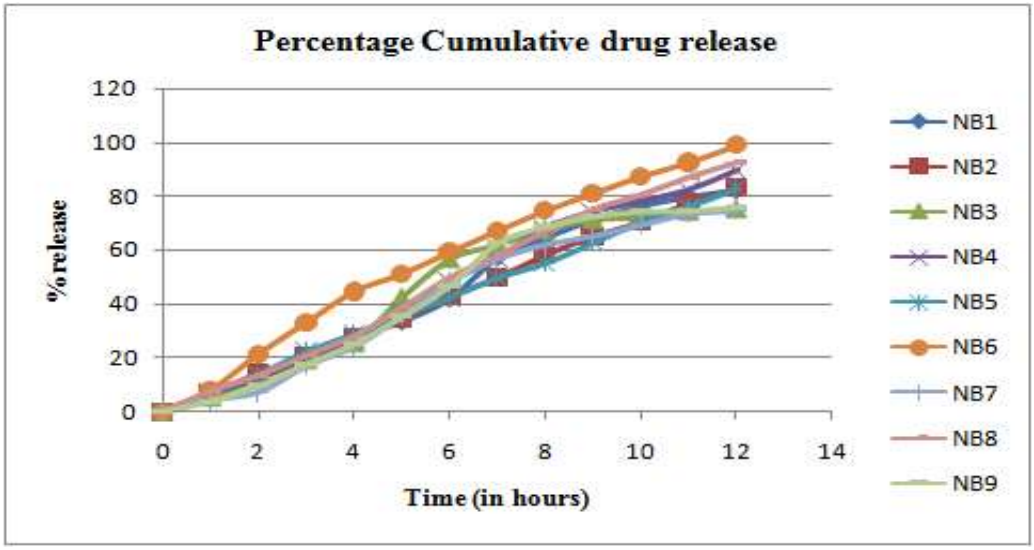



**Figure 1.1: Percentage Cumulative drug release of Nimodipine-B-CD (N-βCD inclusion complex) floating tablet**

**Result and Discussion**

**Preformulation Studies**

**Studies on solubility**[29]

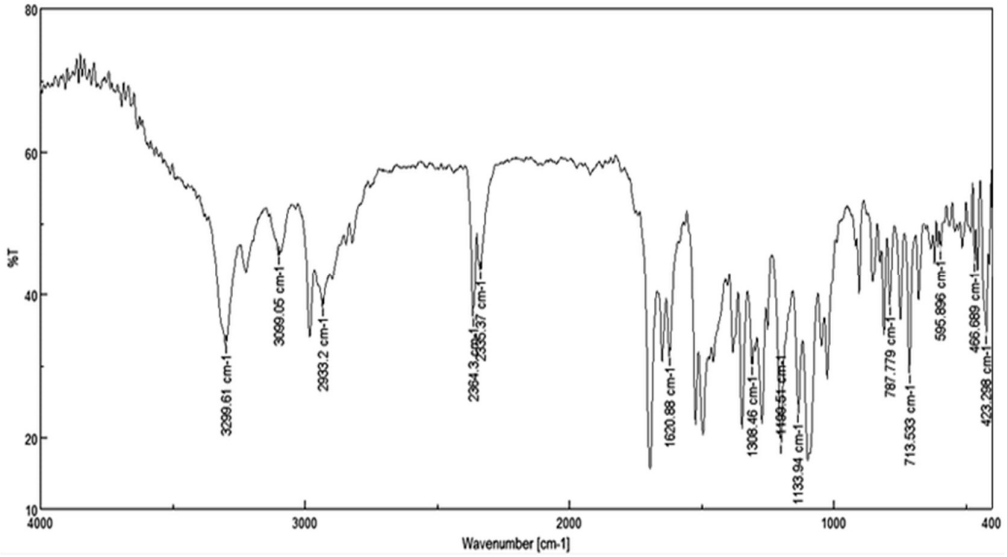
In water, nimodipine is essentially insoluble. It dissolves readily in ethyl acetate, is somewhat soluble in acetonitrile, sparingly soluble in ethanol, and soluble in acetate buffer pH 4.5. The solubility analysis carried out in various carriers.

**Drug carrier compatibility studies:-**

**Fourier Transform Infrared Spectroscopy (FTIR)**[22,29]

Figures 1.2-1.5 display the FTIR spectra of pure nimodipine and its mixture with various excipients. FTIR spectra analysis of drug-excipient compatibility showed that there was no interaction between the drug and excipients. As a result, the formulation's excipients and nimodipine worked well together.

**Figure 1.2: FTIR spectra of Nimodipine**



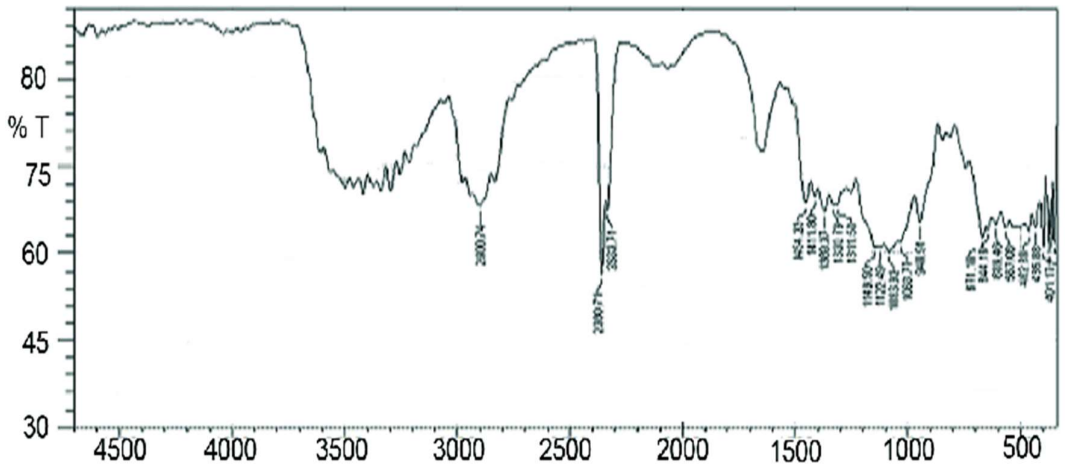




**Figure 1.3: FTIR spectra of HPMC k4m**

**Figure 1.4: FTIR spectra of HPMC k15m**

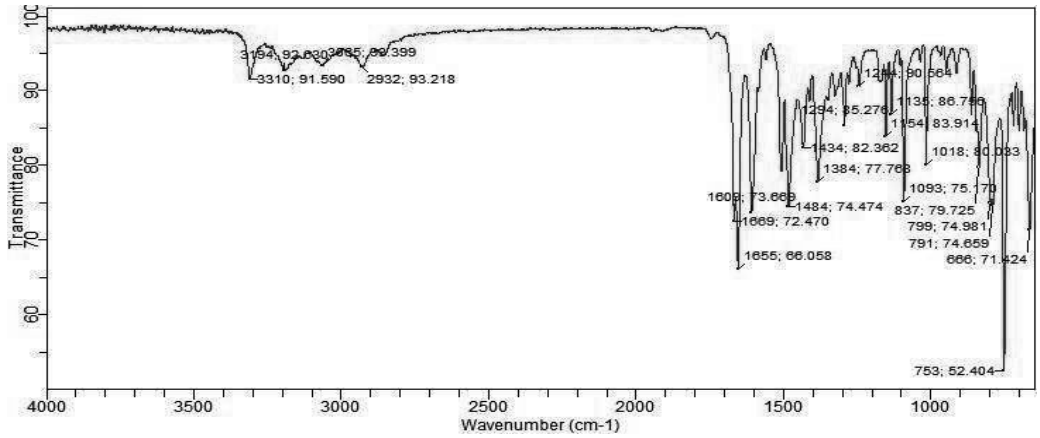
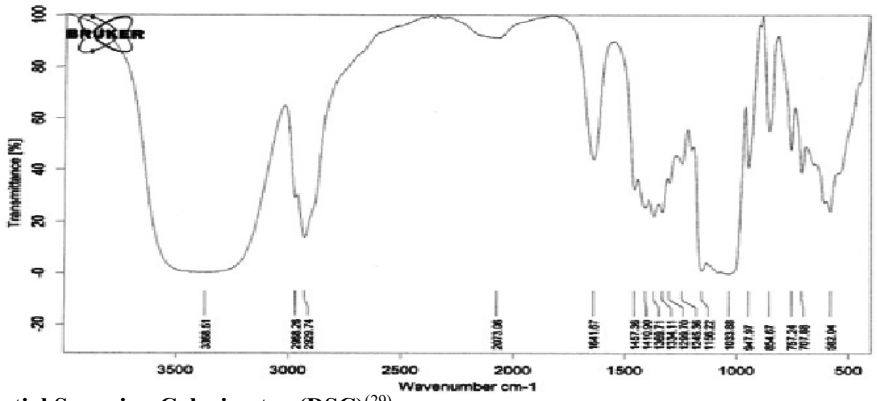


**Figure 1.5: FTIR spectra of B-cyclodextrin**

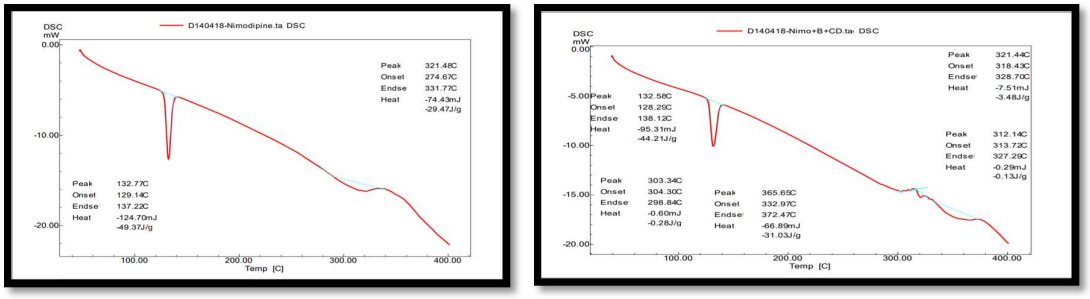



**Differential Scanning Calorimetry (DSC)**[29]

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]

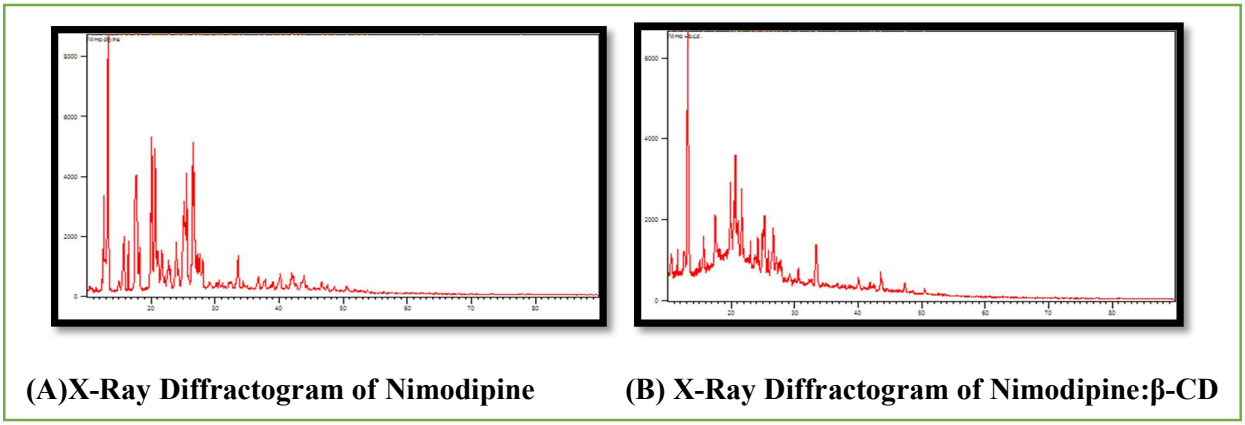
**Figure 1.6: DSC thermograms of nimodipine (A), nimodipine-βCD in 1:1M ratio (B).**

**Powder X-ray Diffractometry**[29,31]




**(A)DSC Thermogram of pure nimodipine** **(B) DSC Thermogram of pure nimodipine:β-cyclodextrin**

Because of its crystalline structure, nimodipine exhibits a variety of diffraction peaks. Nevertheless, there is a decrease in drug loading onto polymers in the solid dispersion. A few weaker and whiter nimodipine diffraction peaks are seen in solid dispersion; this could be explained by the adsorption process, where some of the amorphous drug may have crystallized as a result of the higher temperature.



**(A)X-Ray Diffractogram of Nimodipine** **(B) X-Ray Diffractogram of Nimodipine:β-CD**

**Figure 1.7: X-ray diffractograms of nimodipine (A), nimodipine-βCD in 1:1M ratio (B)**

**Dissolution study:-** [29,31]

For all formulations (NB1–NB9), the in vitro drug release investigation showed a steady rise in cumulative drug release over a 12-hour period. NB6 demonstrated the maximum drug release (≈99%) among the studied formulations, regulated and reliable, with NB8 achieving 92.65% drug release. While NB3 displayed a delayed release pattern with a noticeable rise after 5 hours, reaching 75.11% at 12 hours, formulations NB1, NB2, and NB5 displayed moderate release behavior.

variances in polymer content, excipient composition, and drug–polymer interactions could be the cause of the observed variances in drug release profiles. Overall, formulation NB6 showed the best release characteristics, indicating that it would be appropriate for applications involving sustained drug delivery.

**CONCLUSION**

By increasing blood flow to the brain, nimodipine, a calcium channel blocker, is mainly used to prevent and treat problems after subarachnoid hemorrhage. When taken orally, its limited water solubility may restrict its bioavailability. Several formulation techniques, including inclusion complexes with cyclodextrins dissolution properties. The NB6 formulation is the most promising option for controlled drug administration and sustained stomach retention since the addition of β-CD improved the floating tablets' overall performance by enhancing drug loading, release behavior, and prospective bioavailability.

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2. Ma L, Yao L, Zhang Z, Hao B. Nimodipine ameliorates subarachnoid hemorrhage-induced neuroinflammation and injury by protecting mitochondrial function and suggesting an effective and quick release profile. NB7, on the other hand, exhibited the slowest release, reaching just 74.6% drug release after 12 hours.

The release patterns of formulations NB4 and NB8 were (e.g., N-βCD) and microwave aided solid dispersion, were used to improve its solubility and therapeutic efficacy.

Nimodipine's solubility was generally improved by the inclusion complex creation with βCD rather than the solid dispersion method with PEG 6000, particularly in solvents like water, methanol, and PBS. Using a Central Composite Design with different concentrations of HPMC K4M and HPMC K15M, the floating tablets of nimodipine and nimodipine–β-Cyclodextrin (β-CD) inclusion complexes were successfully formed and improved. When compared to the pure Nimodipine formulations, the β-CD inclusion complex formulations showed improved drug release and better drug content uniformity. Due to complexation with β-CD, NB6 showed the highest drug content (96.34%) and cumulative drug release (99.11% after 12 hours) among all formulations, suggesting better solubility and regulating autophagy. Human Cell. 2025 Jan 20;38(2):46.

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