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Review

## Formulation and Evaluation of Immediate-Release Tablets of Cenobamate

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Check for updates	Abstract
Published on: 24 Oct 2025	The objective of this study was to formulate and evaluate immediate- release (IR) tablets of Cenobamate, an anticonvulsant drug, to enhance its bioavailability and therapeutic efficacy. Cenobamate, being poorly soluble in
Published by: Futuristic Publications	water, poses formulation challenges. Various excipients and approaches were employed to improve the drug's solubility and facilitate its rapid release. Immediate-release tablet formulations were prepared using direct compression, incorporating different concentrations of superdisintegrants Crospovidine (CP),
2025 All rights reserved.  Creative Commons Attribution 4.0 International License.	Croscarmellose sodium (CCS) and Sodium starch glycolate (SSG)) and fillers microcrystalline cellulose to optimize disintegration time, dissolution rate, and drug release profile. The tablets were characterized by physical parameters such as hardness, friability, weight variation, and content uniformity. In vitro dissolution studies were conducted to assess the release characteristics of cenobamate tablets, aiming for a rapid release in the first 30 minutes. The formulated tablets met pharmacopoeial standards for uniformity of weight, content, and dissolution, with a marked improvement in drug release compared to conventional tablet forms. The results indicated that the immediate-release cenobamate tablets have the potential to provide rapid onset of action, contributing to more efficient management of seizure disorders. This formulation offers an effective approach to enhance the bioavailability and clinical performance of cenobamate for better therapeutic outcomes.
	Keywords: immediate-release Tablets of Cenobamate.

## 1. INTRODUCTION

The Oral route is one of the most sought after route for the systemic effect due to its ease of ingestion, simple, safest, convenient, non-invasive, versatility and most importantly, patient compliance. Solid oral delivery systems are cheaply manufactured because they don't require sterile conditions<sup>1</sup>. Although, increased focus and interest generated in the area of controlled release and targeted drug delivery system in recent years, tablet dosage forms that are intended to be swallowed whole, disintegrate, and release their medicaments fast and furiously in the gastrointestinal tract<sup>2</sup> An ideal dosage regimen of drug therapy is the one, which immediately nab the desired therapeutic concentration of drug in plasma (or at the site of action) and maintains it constantly for the entire duration treatment<sup>3</sup>. Of late, the scientists have focused their attention on the formulation immediately released tablet. The effort of developing a rapidly disintegrating tablet is accomplished by using suitable diluents and super disintegrants<sup>4</sup>

**Definition: Immediate Release Tablets:** Immediate release tablets are invented to disintegrate and release their dosage form with no special rate controlling features, such as special coatings and other techniques. Immediate release tablets are those which disintegrate swiftly and get dissolved to release the medicaments<sup>5</sup>. The oral bioavailability of drug dependent on disintegration, dissolution and various physiological factors<sup>6</sup> An immediate release dosage form helps a manufacturer to diversify market and simultaneously offering patients a convenient dosage form or dosage regimen.<sup>7</sup> The development of enhanced oral protein delivery technology by immediate release tablets which may release the drugs at an enhanced rate are very promising for the delivery of poorly soluble drugs high molecular weight protein and peptide. The oral route remains the perfect route for the administration of therapeutic agents because the low cost of therapy, manufacturing and ease of administration lead to high levels of patient compliance, <sup>8</sup>. Many patients require quick onset of action in particular therapeutic condition and consequently immediate release of medicament is required. It is estimated that 50% of the population is affected by this problem, which results in a high incidence of ineffective therapy.

## Advantages of Immediate Release Drug Delivery System:

- Improved compliance / added convenience, solubility, stability, bioavailability.
- Allows high drug loading, cost-effective.
- Ability to provide advantages of liquid medication in the form of solid preparation.
- Adaptable and amenable to existing processing and packaging machinery.
- Decreased dissolution and disintegration times for immediate release oral dosage forms.

## Disadvantage:

- Frequent dosing is necessary for a drug with a short half-life.
- Drug release at a time may produce high plasma concentration which may produce toxicity.
- Patient may suffer from tremors therefore they have difficulty to take tablet, powder and liquids. In dysphasia physical obstacles and adherence to an oesophagus may cause gastrointestinal ulceration.
- Swallowing of solid dosage forms like tablet and capsules and produce difficulty for young adult of incomplete development of muscular and nervous system and elderly patients suffer from dysphasia.

## Criteria for Immediate Release Drug Delivery System

Immediate release dosage form should in the case of solid dosage it should dissolve or disintegrate in the stomach within a short period.

- In the case of liquid dosage form it should be compatible with taste masking.
- Be portable without fragility concern.
- Have a pleasing mouth feel.
- It should not leave minimal or no residue in the mouth after oral administration.
- Exhibit low sensivity to environmental condition as humidity and temperature.
- Be manufactured using conventional processing and packaging equipment at low cost.
- Rapid dissolution and absorption of drug, which may produce rapid onset of action <sup>10</sup>

## **METHODOLOGY**

### **Buffer Preparation:**

**Preparation of 0.2M Potassium dihydrogen orthophosphate solution:** Accurately weighed 27.218 gm of monobasic potassium dihydrogen orthophosphate was dissolved in 1000mL of distilled water and mixed.

**Preparation of 0.2M sodium hydroxide solution:** Accurately weighed 8 gm sodium hydroxide pellets were dissolved 1000 ml of distilled water and mixed.

**Preparation of pH 6.8 Phosphate buffer:** Accurately measured 250 ml of 0.2M potassium Dihydrogen orthophosphate and 112.5 ml 0.2M NaOH was taken into the 1000ml volumetric flask. Volume was made up to 1000ml with distilled water.

## **Pre formulation Studies**

Pre formulation involves the application of biopharmaceutical principles to the physicochemical parameters of drug substance are characterized with the goal of designing optimum drug delivery system.

## **Analytical method development for CENOBAMATE:**

## a) Determination of absorption maxima

A spectrum of the working standards was obtained by scanning from 200-400 nm against the reagent blank to fix absorption maxima. The  $\lambda_{max}$  was found to be 270 nm. Hence all further investigation was carried out at the same wavelength.

## b) Preparation of Standard graph in pH 6.8 phosphate buffer

100 mg of Cenobamate was dissolved in 100 mL of pH 6.8 phosphate buffer to give a concentration in 1 mg/mL (1000 μg/mL) 1 ml was taken and diluted to 100 ml with pH 6.8 phosphate buffer to give a concentration of 0.01 mg/ml (10ug/ml). From this stock solution aliquots of 1.0 ml, 2.0 ml, 3.0 ml, 4.0ml, 5.0 ml, were pipette out in 10 ml volumetric flask and volume was made up to the mark with pH 6.8 phosphate buffer to produce concentration of 10, 20, 30, 40 and 50 ug/ml respectively. The absorbance of each concentration was measured at respective ( $\lambda_{max}$ ) i.e., 270 nm.

## **Formulation Development:**

- Drug and different concentrations for super Disintegrates and required ingredients were accurately weighed and passed through a 40-mesh screen to get uniform size particles and mixed in a glass mortar for 15 minutes.
- The obtained blend was lubricated with Magnesium stearate and glidant (Talc) was added and mixing was continued for further 5 minutes.
- The resultant mixture was directly compressed into tablets by using punch of rotary tablet compression machine. Compression force was kept constant for all formulations.

**INGREDIENTS FORMULATIONS** (MG) C1 **C2 C3 C4 C5 C6 C7 C8 C9** 25 25 25 25 25 25 25 25 25 Cenobamate 25 Crospovidine (CP) 50 75 Croscarmellose sodium (CCS) 25 50 75 Sodium starch glycolate (SSG) 25 50 75 20 Mannitol 20 20 20 20 20 20 20 20 Aspartane 15 15 15 15 15 15 15 15 15 Magnesium stearate 10 10 10 10 10 10 10 10 10 10 10 10 10 Talc 10 10 10 10 10 MCC 105 55 105 55 55 80 80 105 80 200 200 200 200 200 200 200 200 200 **Total weight** 

Table 7.1: Formulation of Immediate Release tablets

Total weight of tablets = 200mg

### 8. RESULTS AND DISCUSSION

### Determination of $\lambda_{max}$ :

The prepared stock solution was scanned between 200-400 nm to determine the absorption maxima. It was found to be 270 nm.

## Calibration curve of Cenobamate

The standard curve of Cenobamate was obtained and good correlation was obtained with R<sup>2</sup> value of 0.999 the medium selected was pH 6.8 phosphate buffer.

Table 8.1: Standard graph values of Cenobamate at 270 nm in pH 6.8 phosphate buffer

Concentration (µg/ml)	Absorbance
0	0
10	0.105
20	0.214
30	0.318
40	0.421
50	0.536

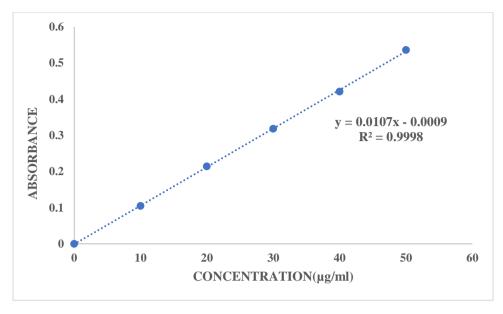


Fig 8.1: Standard curve of Cenobamat

## **Evaluation:**

## **Characterization of precompression blend:**

The pre-compression blend of Cenobamate was characterized with respect to angle of repose, bulk density, tapped density, Carr's index and Hausner's ratio. Angle of repose was less than 29.9°, Carr's index values were less than 27.75 for the precompression blend of all the batches indicating good to fair flowability and compressibility. Hausner's ratio was less than 1.43 for all batches indicating good flow properties.

**Formulation** Angle of **Bulk density Tapped** Carr's index Hausner's code repose (Θ)  $(gm/cm^3)$ density(gm/cm<sup>3</sup>) (%)ratio 28.56+0.27  $0.479 \pm 0.06$  $0.658 \pm 0.54$ 17.29+0.36 1.22±0.35 **C1 C2** 26.76±0.42  $0.515\pm0.24$  $0.680\pm0.23$  $18.34 \pm 0.23$  $1.24\pm0.44$ **C3** 29.17±0.56  $0.502\pm0.23$  $0.674 \pm 0.42$ 15.06±0.75  $1.21\pm0.23$ **C4** 23.96±0.88  $0.485 \pm 0.74$ 0.712±0.26 15.15±0.34 1.22±0.37 **C5** 30.62±0.78 0.494±0.30 0.697±0.35 14.72±0.46 1.29±0.42 **C6** 26.07±0.60  $0.481 \pm 0.64$  $0.652\pm0.60$  $17.87 \pm 0.84$  $1.25\pm0.45$ **C7** 30.45±0.42 0.478±0.34 0.549±0.20 18.25±0.54 1.23±0.06 **C8** 27.20±0.75 0.491±0.92 0.657±0.60 15.84±0.76 1.26±0.72 **C9** 23.24±0.23  $0.66\pm0.42$  $0.523\pm0.30$  $16.80\pm0.98$  $1.30\pm0.32$ 

Table 8.2: Physical properties of precompression blend

All the values represent n=3

### **Evaluation of tablets:**

## Physical evaluation of Cenobamate Immediate release tablets:

The results of the weight variation, Hardness, Thickness, Friability, and Drug content of tablets are given in table 8.3. All the tablets of different batches complied with the official requirement of weight variation as their weight variation passes the limit. The hardness of the tablets ranged from  $2.67 - 3.18 \text{ kg/cm}^2$  and the friability values were < than 0.69 % indicating that the tablets were compact and hard. The thickness of the tablets ranged from 1.83 - 2.21. All the formulations satisfied the content of the drug as they contained 96.12-99.35 % of Cenobamate and good uniformity in drug content was observed. Thus all physical attributes of the prepared tablets were found to be practically within control limits.

Table 8.3: Evaluation of Cenobamate Immediate release tablets

Formulation code	Weight variation (mg)	Thickness (mm)	Hardness (Kg/cm <sup>2</sup> )	Friability (%)	Content uniformity (%)	In Vitro Disintegration time (seconds)
C1	198	1.87	3.18	0.57	98.12	26
C2	196	1.99	2.95	0.69	99.08	45
С3	199	2.21	2.67	0.83	97.64	55
C4	201	1.83	2.83	0.77	99.38	34
C5	197	2.05	3.01	0.81	97.44	41
C6	200	2.22	2.88	0.45	99.29	21
C7	204	1.95	2.97	0.62	98.76	39
C8	195	2.11	3.05	0.59	99.89	53
С9	199	1.96	2.75	0.88	97.37	31

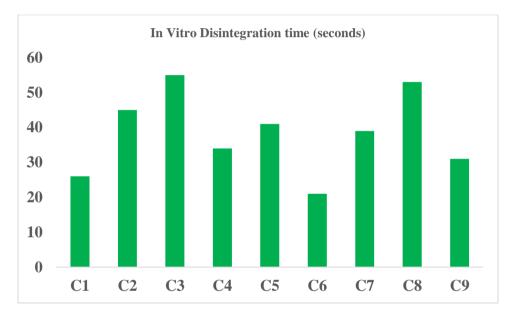


Figure 8.2: In vitro disintegration time graph

*In vitro* **Dissolution:** The drug release rate from tablets was studied using the USP type II dissolution test apparatus. The dissolution medium was 500 ml of pH 6.8 phosphate buffer at 50 rpm at a temperature of  $37 \pm 0.5$  °C. Samples of 5 ml were collected at different time intervals up to 30 min and has analyzed after appropriate dilution by using UV spectrophotometer at 270 nm

Table 8.4: In vitro data for formulation C1-C9

TIME (Minutes)	IN VITRO DRUG RELEASE								
	C1	C2	C3	C4	C5	<b>C6</b>	C7	C8	С9
0	0	0	0	0	0	0	0	0	0
5	58.99	65.41	68.37	56.57	61.02	64.69	53.24	59.17	62.85
10	61.75	73.16	78.29	63.81	74.17	78.41	61.59	63.69	66.47
15	66.25	77.93	83.07	71.26	78.71	82.27	68.51	71.53	75.39
20	72.87	83.72	89.12	87.01	89.29	92.85	74.05	79.28	88.64
25	77.44	88.89	92.46	91.37	93.08	96.61	83.98	86.69	92.22
30	91.21	93.17	96.38	94.41	95.24	99.11	87.23	93.82	95.29

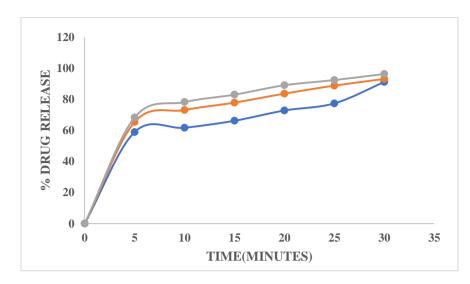


Fig 8.3: In vitro dissolution data for formulation C1-C3

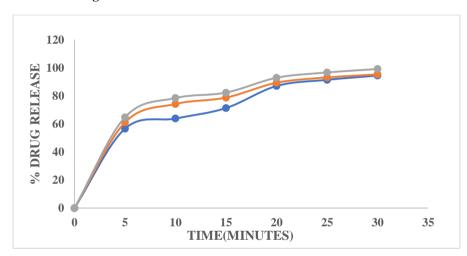


Fig 8.4: In vitro dissolution data for formulations C4-C6

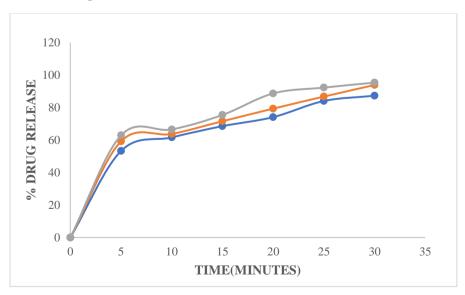


Figure 8.5: In vitro dissolution data for formulations C7 - C9

From the table it was evident that the formulation prepared with Crospovidine were showed good drug release i.e., C3 formulation (96.38%) in higher concentration of blend i.e 75 mg. Formulations prepared with Croscarmellose sodium showed good drug release i.e., 99.11 % (C6 formulation) in 75mg concentration. When increase in the concentration of Croscarmellose sodium drug able to retarded. Formulations prepared with Sodium starch glycolate showed maximum drug release i.e., 95.29 % (C8 formulation) at 30 min in 50 mg of blend. Among all formulations C6 considered as optimised formulation which showed maximum drug release at 30 min i.e., 99.11 %. Finally concluded that C3 formulation contains Croscarmellose sodium was optimized formulation.

### **Drug-Excipient compatibility studies by FTIR studies:**

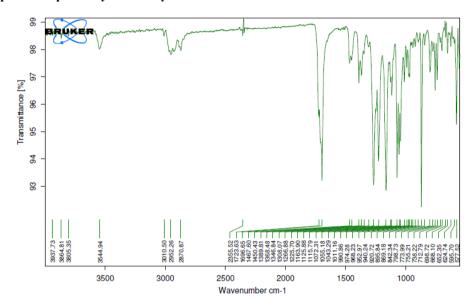


Fig 8.6: FTIR spectra of pure drug

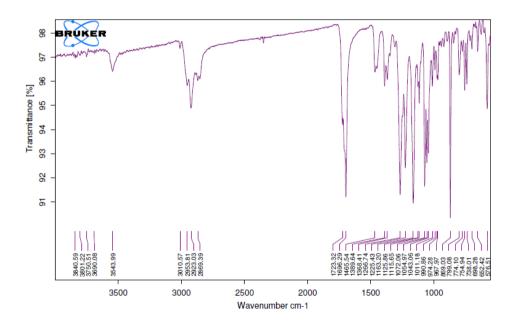


Fig 8.7: FTIR spectra of optimized formulation

Cenobamate was mixed with various proportions of excipients showed no colour change at the end of two months, providing no drug –excipient interactions.

## **CONCLUSION**

The formulation and evaluation of immediate-release tablets of Cenobamate have demonstrated promising results in terms of both physical characteristics and performance. The tablets were successfully

formulated with appropriate excipients, ensuring good flow properties, compressibility, and uniformity in weight and content. The in vitro dissolution studies indicated rapid and complete drug release, which is essential for achieving the desired therapeutic effect.

The results from the evaluation of Cenobamate immediate-release tablets confirm their potential for effective and rapid absorption in the body, making them a viable dosage form for patients requiring prompt therapeutic action. However, based on the formulation and evaluation, Cenobamate immediate-release tablets appear to be a promising candidate for the management of epilepsy and related conditions.

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