CODEN [USA]: IAJPBB ISSN : 2349-7750

INDO AMERICAN JOURNAL OF
PHARMACEUTICAL SCIENCES
SJIF Impact Factor: 7.187

Available online at: http://www.iajps.com Research Article

FORMULATION AND EVALUATION OF IMMEDIATE-RELEASE TABLETS OF CENOBAMATE

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Abstract:
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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Please cite this article in press ***Boda Roshini*** *et al.,* ***Formulation And Evaluation Of Immediate-Release Tablets Of Cenobamate****, Indo Am. J. P. Sci, 2025; 12(10).*

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 [1] . 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 [2]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 [3] . 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 [4]

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. [5] The oral bioavailability of drug dependent on disintegration, dissolution and various physiological factors. [6] An immediate release dosage form helps amanufacturer to diversify market and simultaneously offering patients a convenient dosage form or dosage regimen. [7] 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, [8]. Many patients require quick onset of action in particular therapeutic condition and consequently immediate release of medicament is required. It is estimated that50% of the population is affected by this problem, which results in a high incidence of ineffective therapy.

CRITERIA FOR IMMEDIATE RELEASE DRUG DELIVERY SYSTEM

Immediate release dosage form shouldIn 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.[10]

Mass-Extrusion: In this technology softening the blend of active drug with water-soluble solvent methanol, polyethylene glycol and softened mass put into the extruder to form a cylinder shape of the product and segmented with using the heated blade to formulate a dosage form as tablets .[15]

Solid Dispersions:

Solid products containing at least two different components, mainly hydrophilic matrix and a hydrophobic drug. The matrix can be either crystalline or amorphous. This method deal with the challenge of mixing a matrix and drug, preferably on a molecular level, while matrix and drug are generally poorly miscible 19. When formulating immediate release solid dosage forms from solid amorphous dispersion for oral administration to effective use in an environment such as the GI tract of a human, it is often desirable to increase the amount of dispersion occurs in the dosage form.[16]

(B) Dry Granulation: In dry granulation process the powder mixture is compressed without the use of heat and solvent. The two basic procedures are to form a compact of material by compression and then to mill the compact to obtain granules. Below two methods are used for dry granulation . [17]

Lyophilization: It depends on simple principle i.e. sublimation. The sublimation is processed in which conversion of a substance from a solid state to vapor state, without changing in the liquid phase. Lyophilisation is performed at temperature and pressure conditions below the triple point. The whole process is performed at low temperature and pressure by applying vacuum; hence it is suitable for drying of thermolabile compounds. [18]

Novel Granulation Technologies:

(a) **Pneumatic Dry Granulation (PDG)**: It is a novel technique of dry method in which the formulation of granules is carried out by automatically or semi-automatically. This techniques granule has excellent properties as compared to dry granulation, direct compression, wet granulation and granules are showing high compressibility and flowability The outcome can be attained without utilizing exotic and high-cost excipients. [19]

(b) Freeze Granulation Technology (FGT): Integrated Biosystems, Inc. (California, USA)

had patented freeze GT that results in spherical and free flowing granules with ideal homogeneity. Its require spraying of a suspension containing powder into liquid nitrogen where the drops were swiftly frozen to form granules which upon subsequent freeze-drying yields dry granules. [20]

(c) **Spray Drying Granulation:** This technology facilitated to improved flow, homogeneous distribution of colors, drug and required less lubricant as compared to wet massed products. It can be co-precipitate an active pharmaceutical ingredient with a suitable polymer to form a stable amorphous solid dispersion and promote improved bioavailability and dissolution rate of many drug products.[21]

TOPO (TOPO Granulator) Technology: Hermes Pharma has developed a unique technology

MATERIALS AND METHODS:

Cenobamate Procured From Hetero labs Hyderabad, India Provided by SURA LABS, Dilsukhnagar, Hyderabad.
Crospovidone (CP) S.D. Fine Chemicals. Pvt Ltd, Mumbai, India
Croscarmellose sodium (CCS) S.D. Fine Chemicals. Pvt Ltd
Sodium starch glycolate (SSG) S.D. Fine Chemicals. Pvt Ltd
Mannitol S.D. Fine Chemicals. Pvt Ltd
Aspartane S.D. Fine Chemicals. Pvt Ltd
Magnesium stearate S.D. Fine Chemicals. Pvt Ltd
Talc S.D. Fine Chemicals. Pvt Ltd
MCC S.D. Fine Chemicals. Pvt Ltd

Equipment's used

Name of the Equipment	Manufacturer
Weighing Balance	Sartourius
Tablet Compression Machine (Multistation)	Lab Press Limited, India.
Hardness tester	Monsanto, Mumbai, India.
Vernier callipers	Mitutoyo, Japan.
Roche Friabilator	Labindia, Mumbai, India
DissolutionApparatus	Labindia, Mumbai, India
UV-Visible Spectrophotometer	Labindia, Mumbai, India
pH meter	Labindia, Mumbai, India
FT-IR Spectrophotometer	Bruker

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 1000ml of distilled water and mixed.

Preparation of pH 6.8 Phosphate buffer: Accurately measured 250ml 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 200-400nm against the reagent blank to fix absorption maxima. The λ_{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 1mg/mL (1000µg/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 (10µg/ml). From this stock solution aliquots of 1.0 ml, 2.0ml, 3.0 ml, 4.0ml, 5.0ml, 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 50µg/ml respectively. The absorbance of each concentration was measured at respective (λmax) 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.

Table 7.1: Formulation of Immediate Release tablets

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

Total weight of tablets = 200mg

8. RESULTS AND DISCUSSION:

Determination of λ_{max} :

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

Calibration curve of Cenobamate

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

Table 8.1: Standard graph values of Cenobamate at 270nm 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

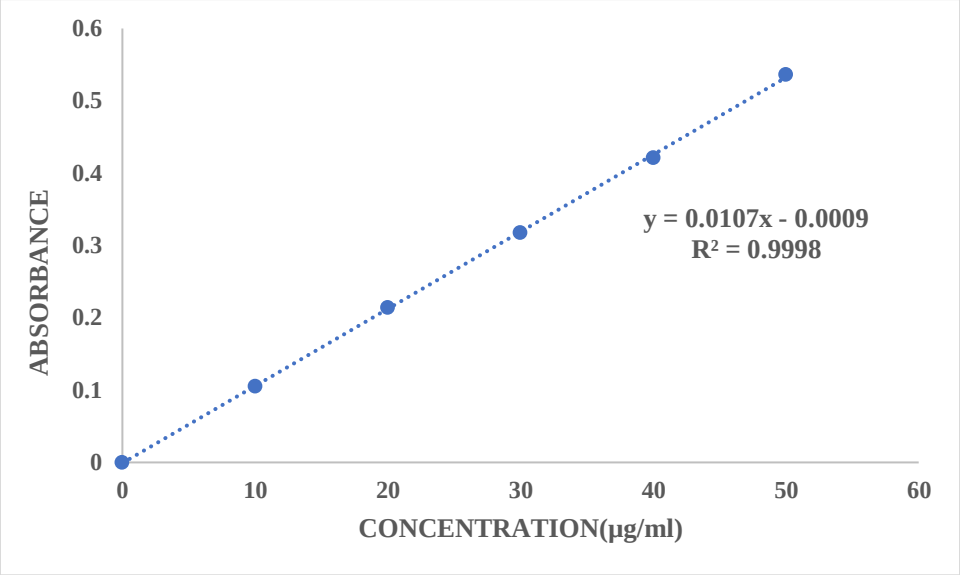

Fig 8.1: Standard curve of Cenobamat

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.

Table 8.2 : Physical properties of precompression blend

Formulation code	Angle of repose (Θ)	Bulk density (gm/cm^3)	Tapped density(gm/cm^3)	Carr's index (%)	Hausner's ratio
C1	28.56±0.27	0.479±0.06	0.658±0.54	17.29±0.36	1.22±0.35
C2	26.76±0.42	0.515±0.24	0.680±0.23	18.34±0.23	1.24±0.44
C3	29.17±0.56	0.502±0.23	0.674±0.42	15.06±0.75	1.21±0.23
C4	23.96±0.88	0.485±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±0.64	0.652±0.60	17.87±0.84	1.25±0.45
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	0.523±0.30	0.66±0.42	16.80±0.98	1.30±0.32

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 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^2)	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
C3	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
C9	199	1.96	2.75	0.88	97.37	31

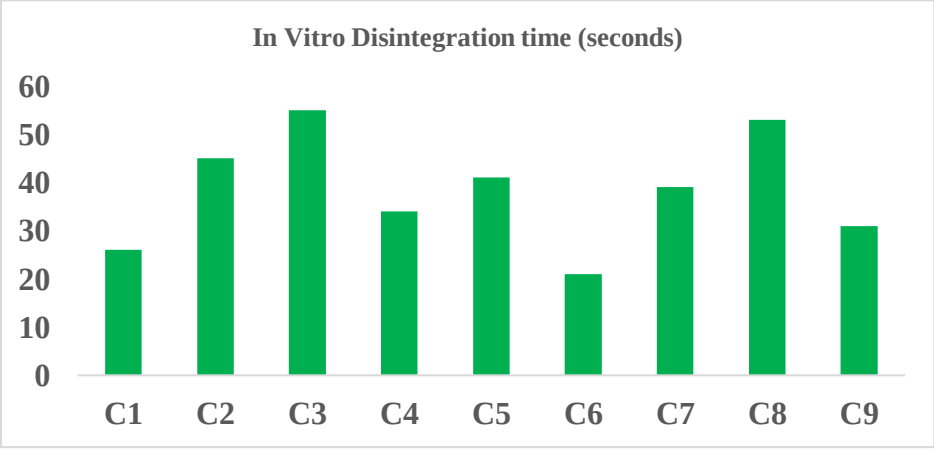

Figure 8.2: *In vitro* disintegration time graph

***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±0.5 ˚C. Samples of 5 ml were collected at different time intervals up to 30min and has analyzed after appropriate dilution by using UV spectrophotometer at 270nm

Table 8.4: *In vitro* data for formulation C1- C9

TIME (Minutes)	*IN VITRO* DRUG RELEASE								
	C1	C2	C3	C4	C5	C6	C7	C8	C9
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

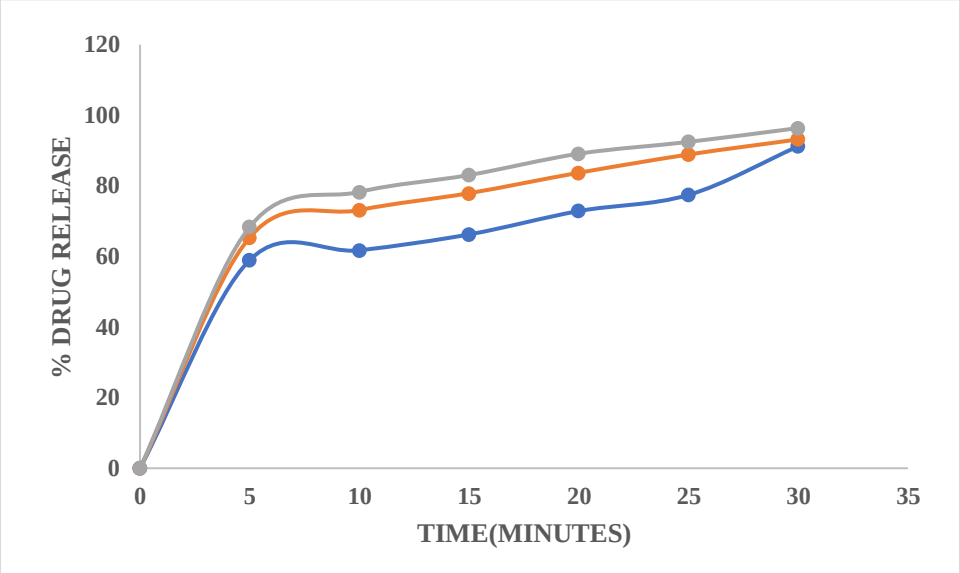

Fig 8.3*: In vitro* dissolution data for formulation C1-C3

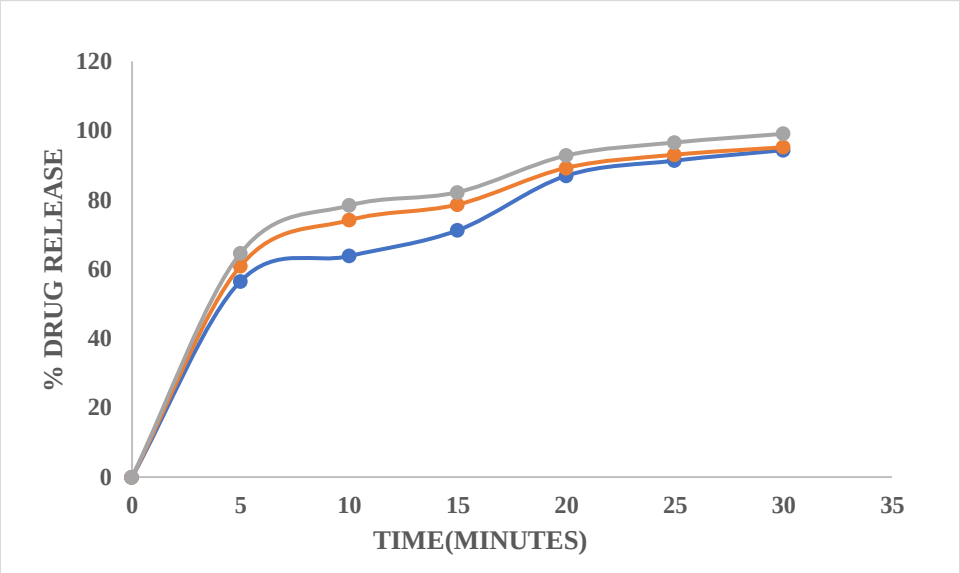

Fig 8.4: *In vitro* dissolution data for formulations C4 - C6

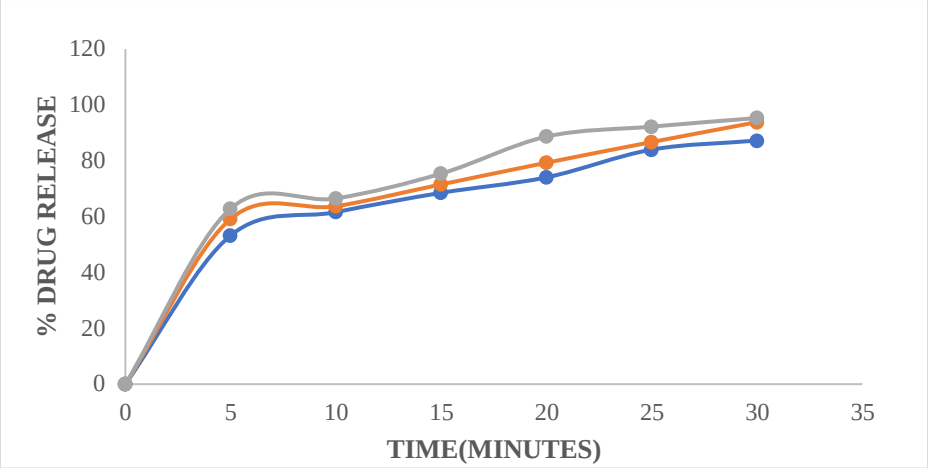

Figure 8.5: *In vitro* dissolution data for formulations C7 - C9

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:

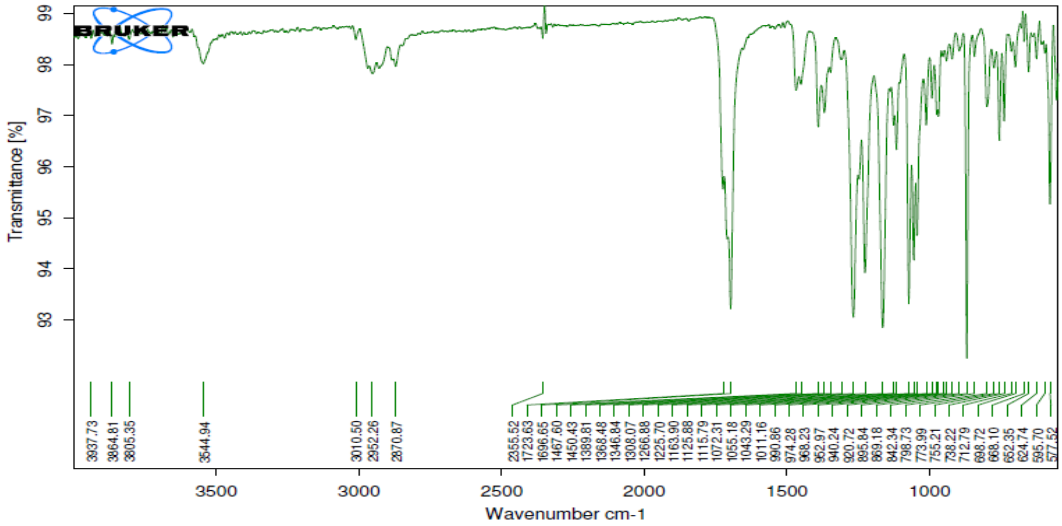

Fig 8.6: FTIR spectra of pure drug

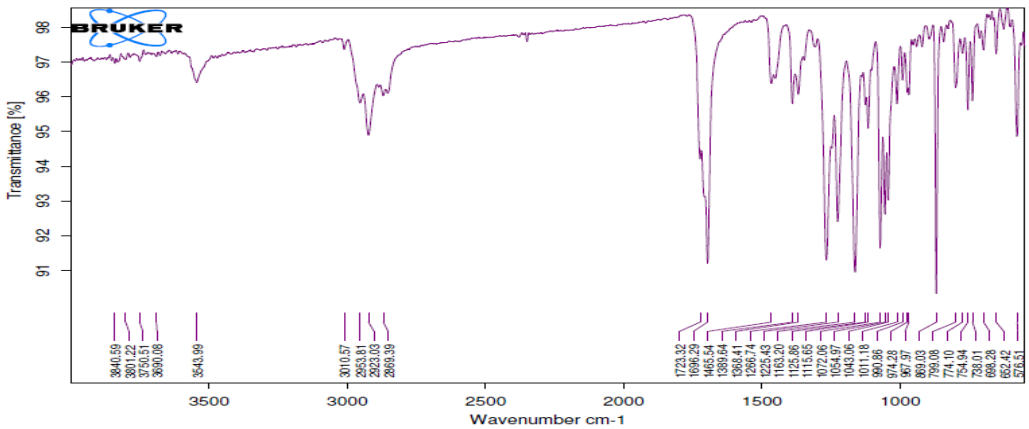

Fig 8.7: FTIR spectra of optimized formulation

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

9. 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.

ACKNOWLEDGEMENT

The Authors are thankful to the Management and Principal, Holy Mary Institute of Technology and Science (College of Pharmacy), Keesara - Bogaram - Ghatkesar, Telangana, Telangana, for extending support to carry out the research work. Finally, the authors express their gratitude to the Sura Pharma Labs, Dilsukhnagar, Hyderabad, for providing research equipment and facilities

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