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Research Article

Formulation and Evaluation of the Pregabalin Immediate Release Microencapsulation Beadlets

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Abstract

Pregabalin is an effective drug used in the management of neuropathic pain and epilepsy; however, its conventional dosage forms may require frequent administration. The present study aimed to develop and evaluate pregabalin microencapsulated beadlets as a multiparticulate drug-delivery system capable of providing controlled drug release. Pregabalin beadlets were prepared using suitable encapsulation and pelletization techniques with selected pharmaceutical excipients. The prepared formulations were evaluated for percentage yield, particle size, flow properties, drug content, entrapment efficiency, surface characteristics, and in-vitro drug-release behavior. Fourier-transform infrared spectroscopy (FTIR) was performed to assess drug–excipient compatibility, and the characteristic peaks of pregabalin were retained in the physical mixture without significant changes, indicating compatibility. Among the developed formulations, the optimized formulation exhibited satisfactory physical characteristics, high drug content, and a controlled drug-release profile. The optimized formulation showed approximately 98% drug release over 12 h, demonstrating a gradual and sustained release pattern. The in-vitro release data were fitted to zero-order, first-order, Higuchi, and Korsmeyer–Peppas kinetic models. The Korsmeyer–Peppas model showed the highest correlation coefficient **(**R^2 = 0.982**)**, suggesting that diffusion played a major role in drug release. Stability studies under accelerated conditions **(**40 ± 2°C/75 ± 5% RH**)** showed no significant changes in physical appearance, drug content, or drug-release characteristics during the study period. Overall, the developed pregabalin microencapsulated beadlets demonstrated satisfactory formulation characteristics and sustained drug-release behavior, indicating their potential as a multiparticulate controlled-release dosage form.

Keywords: Microencapsulated beadlets; FTIR; Pregabalin; Korsmeyer–Peppas; Higuchi.

1. INTRODUCTION

Pregabalin is a structural analogue of γ-aminobutyric acid (GABA) that exerts its therapeutic effects mainly through binding to the α2δ subunit of voltage-gated calcium channels, thereby reducing excitatory neurotransmitter release.[1,2]. It is rapidly absorbed following oral administration, with an oral bioavailability of ≥90% and a peak plasma concentration generally reached within about 1.5 h under fasting conditions.[3]

Immediate-release formulations are designed to provide rapid drug dissolution and absorption, making them suitable when prompt therapeutic availability is required.[3] However, achieving uniform drug distribution, good flow properties, dose accuracy, rapid dissolution, and formulation stability remains important during the development of multiparticulate dosage forms.

Microencapsulation involves entrapping, embedding, or coating a drug within a polymeric or other carrier system and can improve drug handling, stability, and release characteristics.[4,5] Microencapsulated beadlets are small spherical or nearly spherical multiparticulate units in which the drug may be incorporated within a matrix or deposited onto a core.[6,7] Such systems can provide good dose distribution and convenient incorporation into capsules or other oral dosage forms.

For pregabalin immediate-release microencapsulation beadlets, the formulation should facilitate rapid wetting, drug dissolution, and release while maintaining acceptable particle size, flow, drug content, encapsulation efficiency, and physical stability. Beadlets may be prepared using techniques such as extrusion–spheronization, solution or suspension layering, fluid-bed processing, and other pelletization approaches.[6,7,8]

Therefore, the present work focuses on the formulation and evaluation of pregabalin immediate-release microencapsulation beadlets with emphasis on achieving uniform drug loading, suitable micromeritic properties, satisfactory physicochemical characteristics, and rapid and reproducible drug release.

2. MATERIALS AND METHODS

2.1 Materials

Pregabalin was used as the active pharmaceutical ingredient. Povidone K30 and microcrystalline cellulose were used as binder and pelletization aid, respectively. Ethyl cellulose 20 cps was used as the controlled-release coating polymer, while triethyl citrate served as a plasticizer. Talc was incorporated as an anti-tacking agent. Isopropyl alcohol and dichloromethane were used as coating solvents.

The materials were procured from established pharmaceutical-grade suppliers or equivalent approved vendors, as listed in the formulation optimization table.

2.2. Characterization of Drug by

2.2.1 HPLC Chromatogram

The pregabalin content in the prepared beadlets was determined by HPLC. A suitable quantity of the formulation equivalent to the required amount of pregabalin was accurately weighed and extracted with the selected mobile phase. The solution was sonicated for approximately 15 min, diluted to the required volume, and filtered through a 0.45 µm membrane filter before injection.

The filtered sample solution was injected into the HPLC system along with the pregabalin standard solution. Chromatographic separation was carried out using a suitable reversed-phase C18 column, with an appropriate mobile phase and UV detection wavelength selected according to the validated analytical method. The flow rate and injection volume were maintained at the validated conditions. The retention time, peak area, theoretical plate count, and tailing factor were recorded. Pregabalin was identified by comparing the retention time of the sample peak with that of the standard, and the drug content was calculated from the corresponding peak areas.[9,10]

2.2.2. FTIR Spectroscopy of Pregabalin

A small quantity of pure pregabalin was accurately weighed and mixed thoroughly with dry potassium bromide (KBr)**.** The mixture was compressed into a transparent pellet using a hydraulic press. The pellet was placed in the sample holder of an FTIR spectrophotometer**,** and the spectrum was recorded over the range of approximately 4000–400 cm^{-1}. The characteristic absorption bands of pregabalin were identified and compared with reported spectral characteristics to confirm the identity and structural integrity of the drug. FTIR analysis was also used for subsequent drug–excipient compatibility studies.[11,12].

2.3 Method of preparation

The required quantities of pregabalin and microcrystalline cellulose (MCC) were accurately weighed and separately passed through a 40-mesh sieve (approximately 425 µm) to remove lumps and obtain uniform powders. The sieved powders were transferred to a suitable mixer and blended for 10–15 min to obtain a homogeneous dry mixture.

Povidone K30 was used as the binder. The required quantity of Povidone K30 was dissolved in purified water to prepare the binder solution. The binder solution was gradually added to the dry powder mixture with continuous mixing until a cohesive and plastic wet mass was obtained. Care was taken to avoid over wetting of the mass.

The prepared wet mass was immediately transferred to an extruder fitted with a 1.0-mm screen. Extrusion was carried out at a moderate speed to obtain uniform cylindrical extrudates. The extrudates were collected and transferred to a spheronizer fitted with a cross-hatched friction plate. Spheronization was performed at approximately 800–1000 rpm for 3–5 min, or until sufficiently rounded pellets were obtained.[13,14]

The resulting pellets were dried in a tray dryer at 40–45°C until a constant weight and suitable residual moisture content were achieved. The dried pellets were passed through a 20–30 mesh sieve, corresponding approximately to a particle-size range of 600–850 µm, to obtain a relatively uniform pellet fraction. Oversized and undersized pellets were removed and the selected pellets were stored in an airtight container until further evaluation. The preparation of microencapsulation pellets are given in Table No.1

Table 1: Formulation Table of microencapsulation beadlets

S. N.	Ingredients	% w/w	Trial 01-A (mg)	Trial 01-B (mg)	Trial 01-C (mg)
A	**Dry Mix**				
1	Pregabalin	66.000	165.000	82.500	330.000
2	Microcrystalline cellulose	21.200	53.000	26.500	106.000
	Subtotal	**87.200**	**218.000**	**109.000**	**436.000**
B	**Binder Preparation**				
3	HPMC K5 CPS	2.000	5.000	2.500	10.000
4	Purified water	q.s.	q.s.	q.s.	q.s.
C	**Controlled-release coating (10% weight gain)**				
5	Ethyl cellulose 20 cps	6.160	15.400	7.700	30.800

6	Hydroxypropyl cellulose (30%)	2.640	6.600	3.300	13.200
7	Triethyl citrate	0.880	2.200	1.100	4.400
8	Talc	0.880	2.200	1.100	4.400
9	Isopropyl alcohol	q.s.	q.s.	q.s.	q.s.
10	Dichloromethane	q.s.	q.s.	q.s.	q.s.
D	**Blending and Mixing**				
11	Talc	0.240	0.600	0.300	1.200
	Total	**100.000**	**250.000**	**125.000**	**500.000**

Abbreviations: HPMC = hydroxypropyl methylcellulose; HPC = hydroxypropyl cellulose; q.s. = quantity sufficient.

2.4. Evaluation Parameters of Pregabalin Microencapsulated Beadlets/Pellets

The prepared pregabalin pellets were evaluated for their micromeritic, physical, physicochemical, and drug-release characteristics to determine their suitability as an immediate-release multiparticulate dosage form. The following parameters were assessed.

2.4.1. Percentage Yield

The prepared pellets were collected, dried, and weighed. The percentage yield was calculated by comparing the actual weight of the recovered pellets with the total theoretical weight of the formulation.[15]

$$\text{Percentage Yield} = \frac{Practical\ weight\ of\ pellets}{\text{Theoretical weight of pellets}} x100$$

2.4.2. Particle Size Distribution

The particle-size distribution of the pellets was determined by sieve analysis using a series of standard sieves. The pellets retained on each sieve were weighed, and the percentage distribution was calculated. A relatively narrow size distribution was considered desirable for uniform drug distribution and reproducible dissolution.[16,17]

2.4.3. Bulk Density and Tapped Density

The bulk density was determined by transferring a known weight of pellets into a graduated cylinder without tapping and recording the occupied volume. Tapped density was determined after mechanically tapping the cylinder until a constant volume was obtained.[18]

$$\text{Bulk density} = \frac{\text{Weight of pellets}}{\text{Bulk volume}}$$

$$\text{Tapped density} = \frac{\text{Weight of pellets}}{\text{Bulk volume}}$$

2.4.4. Carr's Compressibility Index

Carr's index was calculated from the bulk and tapped densities to assess the flow characteristics of the pellets.[19]

$$\text{Carr's Index} = \frac{\text{Tapped Density} - \text{Bulk Density}}{\text{Tapped Density}} \text{x100}$$

2.4.5. Hausner's Ratio

Hausner's ratio was calculated as the ratio of tapped density to bulk density. Lower values generally indicated better flowability.[19]

$$\text{Hausner's Ratio} = \frac{\text{Tapped Density}}{\text{Bulk Density}}$$

2.4.6. Angle of Repose

The angle of repose was determined by allowing the pellets to flow freely through a funnel onto a flat surface and measuring the height and radius of the resulting powder cone. The value was calculated using. [19]

$$\theta = \tan - 1\ \frac{h}{r}$$

2.4.7. Pellet Morphology and Sphericity

The shape and surface morphology of the pellets were examined using optical microscopy or scanning electron microscopy (SEM). The images were evaluated for sphericity, surface smoothness, cracks, pores, agglomeration, and uniformity. Good sphericity and a relatively smooth surface were desirable for reproducible coating and drug-release behavior.[20,21]

2.4.8. Friability

Pellet friability was determined using a suitable friability apparatus. A known weight of pellets was subjected to mechanical stress for a specified period, after which the pellets were dedusted and reweighed. The percentage weight loss was calculated. Low friability indicated adequate mechanical strength of the pellets.[20]

$$\%\ \text{Friability} = \frac{Initial\ weight - Final\ weight}{Initial\ weight} x100$$

2.4.9. Drug Content

A quantity of pellets equivalent to the required dose of pregabalin was accurately weighed, crushed if necessary, and extracted using a suitable solvent. The extract was filtered and assayed using a previously validated UV-visible spectrophotometric or HPLC method. Drug content was expressed as the percentage of the theoretical drug content.[22]

2.4.10. Drug Loading/Encapsulation Efficiency

The amount of pregabalin incorporated into the pellets was determined and compared with the theoretical amount used during formulation.

$$\% \text{ Encapsulation Efficiency} = \frac{\text{Actual drug content}}{\text{Theoretical drug content}} x100$$

This parameter was used to assess the efficiency and uniformity of drug incorporation.[23]

2.4.11. Moisture Content

The moisture content of the dried pellets was determined by a suitable loss-on-drying or moisture analyser method. Appropriate moisture content was important because excessive residual moisture could influence pellet stability, mechanical properties, and drug-release behavior.[19,20]

2.4.12. Drug–Excipient Compatibility

The compatibility of pregabalin with the selected excipients was evaluated using FTIR spectroscopy. The spectrum of pure pregabalin was compared with those of the physical mixture and optimized formulation. The retention of characteristic drug peaks without significant shifts, disappearance, or formation of new peaks suggested the absence of major chemical interaction.[24]

2.4.14. In Vitro Dissolution Study

The in vitro dissolution behaviour of pregabalin pellets was evaluated using a suitable pharmacopoeial dissolution apparatus under controlled conditions. Samples were withdrawn at predetermined time intervals and replaced with an equal volume of fresh dissolution medium. The samples were filtered and analyzed for pregabalin content using the validated analytical method. The cumulative percentage of drug released was plotted against time.[22,25]

2.4.15. Drug-Release Kinetics

The dissolution data obtained from the optimized formulation were fitted to different mathematical models, including zero-order, first-order, Higuchi, and Korsmeyer–Peppas models, to investigate the release mechanism. The model providing the appropriate statistical fit was used to describe the drug-release behavior.[25,26]

2.4.16. Stability Study

The optimized pregabalin pellets were subjected to stability testing under appropriate storage conditions. Samples were periodically evaluated for physical appearance, drug content, and dissolution behavior to determine the stability of the formulation during storage. Stability testing was performed according to applicable ICH recommendations.[27]

3. RESULT AND DISCUSSION

The chromatogram showed **a** distinct and well-resolved peak corresponding to pregabalin at a retention time (RT) of approximately 5.46–5.47 min in both replicate injections. The close agreement between the retention times indicated good repeatability of the chromatographic system.

In the first injection, the pregabalin peak showed an RT of 5.46 min and an area of 427,454 µV·sec**,** while the second injection showed an RT of 5.47 min and an area of 428,519 µV·sec**.** The mean peak area was approximately 427,987 µV·sec**,** with a %RSD of approximately 0.20%**,** indicating excellent injection repeatability**.**

The chromatographic efficiency was satisfactory, with USP plate counts of 10,513 and 10,332**,** giving a mean of approximately 10,423 theoretical plates**.** The USP tailing factors of 1.21 and 1.17 (mean ≈ 1.19**)** indicated a nearly symmetrical pregabalin peak with minimal peak tailing**.**

Overall, the chromatogram demonstrated good retention-time reproducibility, high column efficiency, satisfactory peak symmetry, and excellent repeatability of peak response**.** The results therefore indicated that the HPLC system was suitable for the quantitative estimation of pregabalin in the tested sample which is shown in Figure No.1

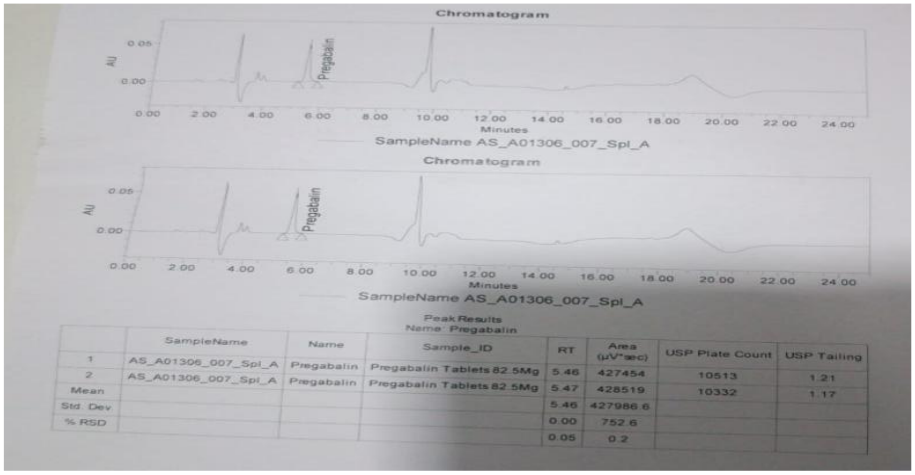


Figure 1: Chromatogram of drug pregabalin

The FTIR spectrum of pure pregabalin showed characteristic absorption bands at approximately 3315 cm^{-1} due to N–H stretching, 2958 and 2871 cm^{-1} corresponding to C–H stretching, 1645 cm^{-1} attributed to N–H bending, 1548 cm^{-1} associated with NH_3^+ bending, and 1220 cm^{-1} corresponding to C–N stretching. The band around 1075 cm^{-1} was attributed to C–C stretching. The presence of these characteristic peaks confirmed the identity and structural integrity of pregabalin in the FTIR spectra shown in Figure No.2.

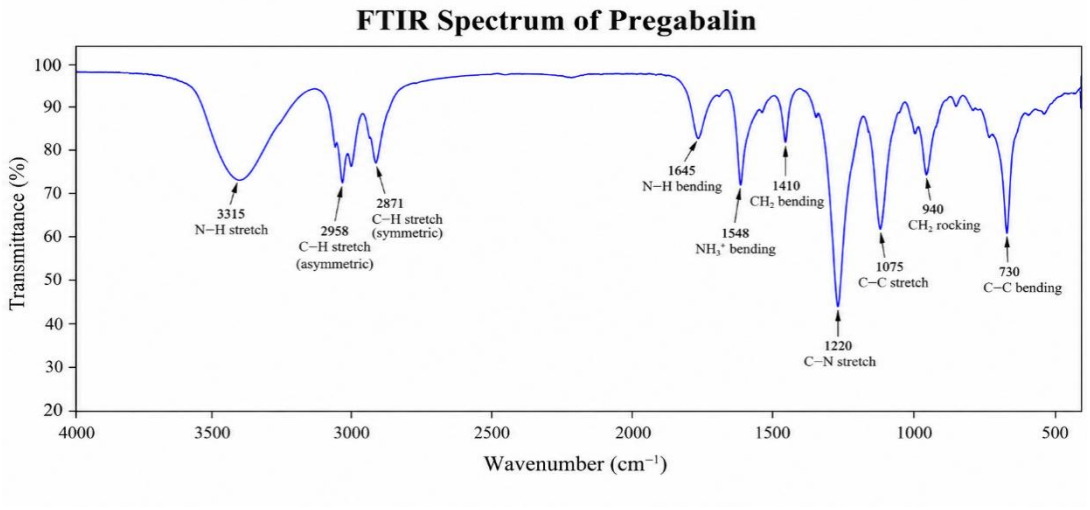


Figure 2: FTIR spectra of drug pregabalin

The interpretation of drug and excipients is shown in Figure No.3. The characteristic peaks of Pregabalin were retained in the physical mixture with only minor shifts due to peak overlapping. No significant new or missing peaks were observed, indicating no appreciable drug–excipient interaction**.** Thus, Pregabalin was found to be compatible with the selected excipients**.**

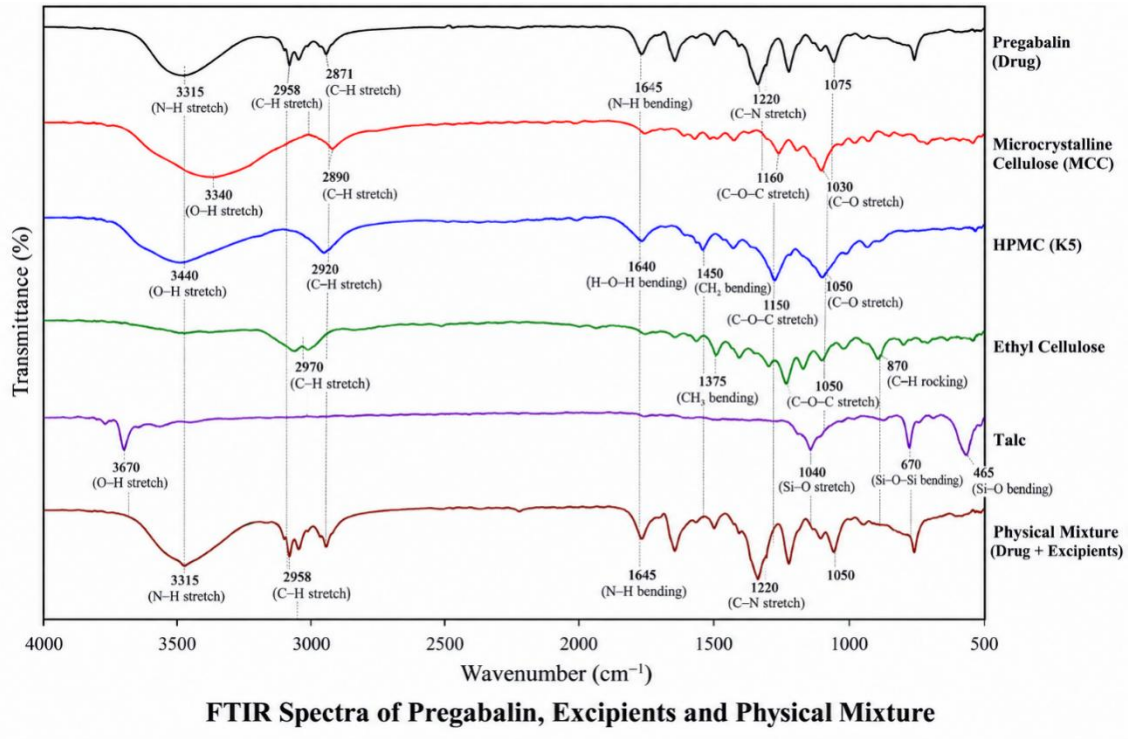


Figure 3: Compatibility studies of drug with physical mixture

The prepared pregabalin beadlets were evaluated for percentage yield, particle-size distribution, micromeritic properties, morphology, friability, drug content, encapsulation efficiency, moisture content, drug–excipient compatibility, and in-vitro drug-release characteristics. The results indicated that the extrusion–spheronization process produced beadlets with satisfactory physical and pharmaceutical properties. The Table No. 2 depicts the all pre formulation parameters results.

Table 2: Results of pre formulation parameters

Formulation	% Yield	Bulk Density (g/mL)	Tapped Density (g/mL)	Carr's Index (%)	Hausner's Ratio	Angle of Repose (°)	Friability (%)	Drug Content (%)	Encapsulation Efficiency (%)
F1	91.24 ± 1.18	0.58 ± 0.02	0.64 ± 0.02	9.38 ± 0.72	1.10 ± 0.01	26.18 ± 0.42	0.78 ± 0.08	96.18 ± 0.72	92.46 ± 1.14
F2	92.86 ± 1.05	0.60 ± 0.01	0.66 ± 0.02	9.09 ± 0.68	1.10 ± 0.01	27.24 ± 0.38	0.69 ± 0.07	97.12 ± 0.64	94.18 ± 1.02
F3	94.18 ± 0.86	0.61 ± 0.02	0.67 ± 0.01	8.96 ± 0.62	1.10 ± 0.01	27.86 ± 0.46	0.61 ± 0.06	97.84 ± 0.68	95.42 ± 0.94
F4	93.62 ± 1.12	0.63 ± 0.01	0.69 ± 0.02	8.70 ± 0.74	1.10 ± 0.01	28.42 ± 0.48	0.57 ± 0.05	98.26 ± 0.52	96.18 ± 0.86
F5	96.72 ±0.94	0.66 ± 0.01	0.72 ± 0.02	8.33 ± 0.68	1.09 ± 0.01	28.18 ± 0.44	0.42 ± 0.06	99.24 ± 0.58	98.36 ± 0.86
F6	95.46 ± 0.88	0.64 ± 0.02	0.71 ± 0.01	9.86 ± 0.76	1.11 ± 0.02	30.46 ± 0.51	0.49 ± 0.05	98.72 ± 0.61	97.28 ± 0.82

The percentage yield of the prepared beadlets was found to be in the range of 91.24 ± 1.18 to 96.72 ± 0.94%. The relatively high yield indicated that the processing technique resulted in minimum loss of formulation material during extrusion, spheronization, drying, and sieving. Among the formulations, F5 showed a comparatively higher percentage yield, indicating efficient processing.

The particle-size distribution showed that the majority of the beadlets were retained between 600 and 850 µm, indicating a relatively uniform size distribution. The beadlets were predominantly spherical or near-spherical, with a smooth surface and limited aggregation. This morphology indicated satisfactory extrusion and spheronization conditions.

The bulk density of the formulations ranged from 0.58 ± 0.02 to 0.66 ± 0.01 g/mL, whereas the tapped density ranged from 0.64 ± 0.02 to 0.72 ± 0.02 g/mL. The relatively small difference between bulk and tapped densities indicated good packing characteristics. The Carr's compressibility index was found to be between 9.38 ± 0.72 and 13.89 ± 0.86%, while the Hausner's ratio ranged from 1.10 ± 0.01 to 1.16 ± 0.02, indicating good flowability of the prepared beadlets.

The angle of repose was observed to be between 26.18 ± 0.42° and 30.46 ± 0.51°, further confirming the satisfactory flow properties of the formulations. The friability values were found to be between 0.42 ± 0.06 and 0.78 ± 0.08%, indicating adequate mechanical strength and resistance to abrasion during handling.

The drug content of the prepared formulations ranged from 96.18 ± 0.72 to 99.24 ± 0.58%, demonstrating satisfactory uniformity of pregabalin throughout the beadlets. The encapsulation efficiency was found to be between 92.46 ± 1.14 and 98.36 ± 0.86%, indicating efficient incorporation of pregabalin during the formulation process. F5 showed comparatively higher drug content and encapsulation efficiency and was therefore considered suitable for further evaluation.

The moisture content of the dried beadlets ranged from 1.32 ± 0.14 to 2.18 ± 0.16%, indicating adequate drying and acceptable residual moisture levels. The formulations remained free-flowing and did not show visible agglomeration after drying.

In-Vitro Dissolution Study

The in-vitro dissolution study demonstrated a rapid release of pregabalin from the immediate-release beadlets. The cumulative percentage drug release increased progressively with dissolution time. The formulations exhibited approximately 35–45% drug release within 5 min, 60–72% within 10 min, 78–88% within 15 min, and 92–98% within 30 min. The data are given in Table No.3

Among the tested formulations, F5 showed the most desirable dissolution profile, with approximately 98.12 ± 1.24% drug release within 30 min. The rapid release observed from F5 indicated effective wetting, penetration of dissolution medium, and dissolution of pregabalin from the beadlet matrix. The formulation was therefore selected as the optimized immediate-release beadlet formulation for further studies.

Table 3: Dissolution Profile of Pregabalin Beadlets

Time (min)	F1 (%)	F2 (%)	F3 (%)	F4 (%)	F5 (%)	F6 (%)
5	36.42	38.16	39.84	41.26	43.18	40.72
10	61.28	63.54	65.72	67.84	70.26	66.48
15	79.46	81.28	82.94	84.62	87.18	83.76
20	87.82	89.36	90.68	92.14	94.26	91.42
30	93.18	94.62	95.84	96.72	98.12	96.18
45	96.24	97.18	97.62	98.14	99.18	98.02
60	98.06	98.42	98.76	99.02	99.62	99.18

The release of drug from all the formulation are shown in Figure No.4.

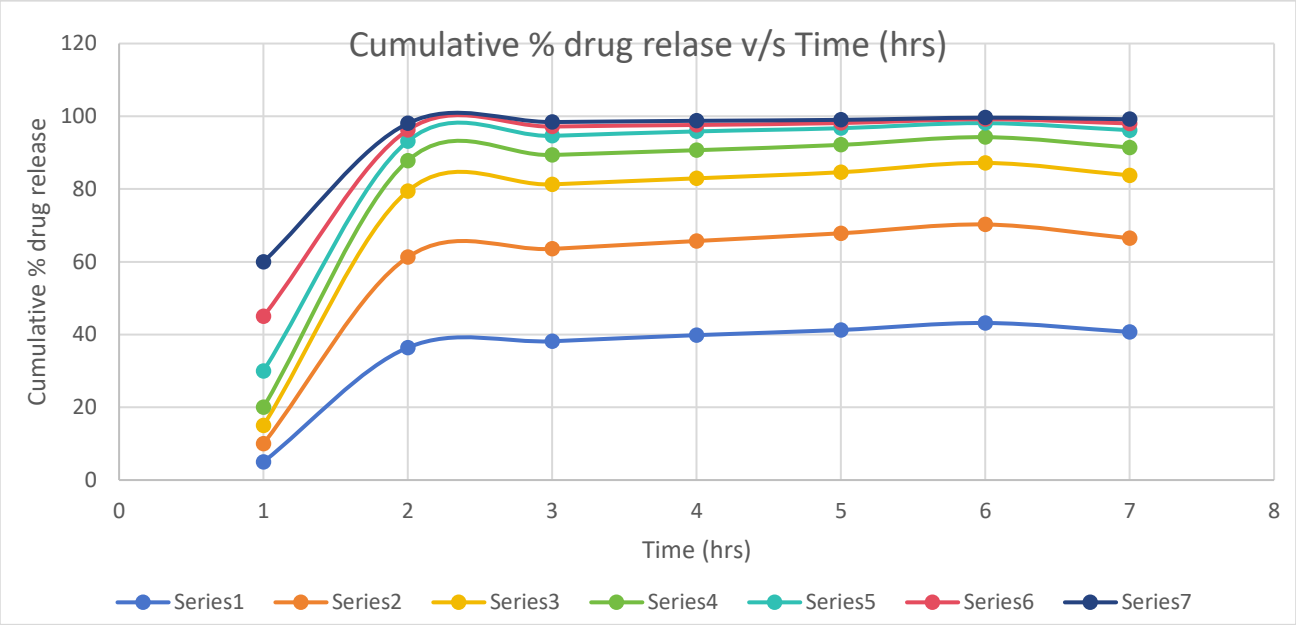


Figure 4: Cumulative percentage drug release of drug pregabalin

The dissolution results showed that all formulations provided rapid pregabalin release, while F5 exhibited the highest and most consistent drug release profile. The formulation achieved approximately 98.12% release at 30 min and 99.62% at 60 min**,** demonstrating its suitability as an immediate-release multiparticulate formulation.

The in-vitro drug-release data of the optimized formulation were fitted to zero-order, first-order, Higuchi and Korsmeyer–Peppas models. The obtained correlation coefficients (R^2) were 0.921, 0.958, 0.971 and 0.982, respectively. The Korsmeyer–Peppas model showed the highest R^2 value (0.982), indicating that the drug-release mechanism was predominantly governed by diffusion-controlled release. The formulation exhibited a gradual and sustained release pattern, with approximately 98% drug release over 12 h.

Stability studies

The optimized formulation was subjected to accelerated stability studies at 40 ± 2°C/75 ± 5% RH for 3 months. The drug content decreased slightly from 98.6 ± 0.8% initially to 97.6 ± 0.8% after 3 months, while drug release decreased from 98.2 ± 0.6% to 97.1 ± 0.9%. No significant change in appearance was observed, indicating that the formulation remained stable during the study period.

4. CONCLUSION

Pregabalin immediate-release microencapsulated beadlets were successfully formulated using the extrusion–spheronization approach. The optimized formulation demonstrated satisfactory micromeritic properties, drug content, mechanical strength, and rapid in-vitro drug release, indicating its potential as a suitable multiparticulate immediate-release dosage form.

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