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Development and Characterization of Amlodipine Oral Disintegrating Films Incorporating Natural–Synthetic Polymer Blends for Enhanced Antihypertensive Therapy

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Futuristic Publications

Abstract This study aimed to create and characterise Amlodipine oral disintegrating films (ODFs) utilising mixes of natural and synthetic polymers to improve patient adherence and facilitate quick antihypertensive effects. ODFs were fabricated by the solvent casting technique, employing HPMC E15 as a synthetic film former and pectin as a natural biodegradable polymer. Six formulations (A1–A6) were developed by altering polymer ratios and assessed for physicomechanical properties, disintegration characteristics, drug content, in-vitro dissolution, release kinetics, and stability. All films exhibited a consistent look, appropriate thickness (152–175 μm), elevated folding endurance (182–230), near-neutral surface pH (6.57–6.71), and acceptable drug content (96.8–100.2%). All formulations exhibited rapid disintegration (18.7–29.6 s) and swift drug release (>80% within 6 min). Formulation A6 exhibited optimal performance, attaining 98.61% drug release at 6 minutes and total release within 8 minutes. The release kinetics adhered to Higuchi diffusion, exhibiting Fickian to anomalous transport characteristics. Stability investigations validated the robustness of the formulation. The optimised Amlodipine ODF provides a quick, user-friendly option for managing hypertension.

Keywords: Amlodipine; Oral disintegrating films; HPMC E15; Pectin; Hypertension; Fast dissolving films.

INTRODUCTION

Oral administration is the most favoured method for medication delivery due to its ease, non-invasiveness, and high patient adherence. Traditional solid-dose formulations, including tablets and capsules, provide obstacles such as dysphagia, delayed onset of action, and complications with first-pass metabolism.[1] These characteristics often undermine therapy efficacy and patient compliance, particularly in at-risk populations such as children, the elderly, and individuals with psychiatric conditions. Orodispersible films (ODFs) provide an effective solution by swiftly disintegrating in the oral cavity without requiring water, hence improving patient convenience and accelerating therapeutic onset.[2] Oral medicine distribution is thought to be the most practical, economical, and secure drug delivery route because it has the highest compliance rate, particularly among paediatric and elderly patients.

The successful delivery of the drug to the body is the ultimate goal of every medication delivery method. The oral disintegrating dose form is the most widely used commercial product among the various dosage forms[3].

These traditional fast-dispersing or dissolving tablets' main flaw is their solid physical structure. In certain populations, there is still a fear of swallowing, chewing, or choking on such solid-shaped items. Additionally, it is challenging to carry, store, handle, and administer wafer-like, porous, low-pressure molded tablets to patients especially the elderly and children due to their fragility/friability, which is caused by different manufacturing processes and necessitates the use of special, costly packaging to protect the dosage forms [4].

The development of Thin Oro Dissolving Film Technology has addressed the shortcomings of traditional fast dispersion or dissolving tablet formulations. The film has convenient packaging, is easy to create, handle, and administer, and it raises the danger of choking and the anxiety of choking. It also reduces the disagreeable flavour. Other names for these thin polymer films are mouth dissolving films (ODF), fast dissolving films (QDF), rapidly dissolving films (RDF), melt-in-mouth dosage forms (MDF), and oral dissolving films (ODF)[5].

ODFs consist of a polymeric film matrix (usually 10–150 μm thick at the product level), film-forming excipients, plasticisers, and functional additives such as sweeteners, flavours, surfactants, and taste-masking systems. Their intended function is fast wetting and breakdown in saliva (often aimed for within seconds to a minute, contingent on the design) coupled with sufficient mechanical strength for handling and packing.[6, 7] Due to geometric and handling limitations, ODFs have conventionally been optimal for low-to-moderate dosage pharmaceuticals.[8] The permissible drug load is significantly influenced by the polymer type, film area/thickness, and formulation procedures employed to enhance miscibility and content uniformity.[9]

Amlodipine is a long-acting, third-generation dihydropyridine calcium channel blocker commonly utilized for the treatment of hypertension, chronic stable angina, and vasospastic (Prinzmetal's) angina. The medication principally functions by obstructing the entry of calcium ions through L-type voltage-gated calcium channels in vascular smooth muscle and cardiac myocytes. This blockade results in peripheral arterial vasodilation, a subsequent decrease in total peripheral resistance, and a reduction in blood pressure.[10]

To our knowledge, no prior studies have documented the creation of Amlodipine oral disintegrating films utilising a blend of natural and synthetic polymers, specifically pectin and HPMC E15. This study introduces an innovative method to use the synergistic benefits of these polymers to improve film efficacy, patient adherence, and antihypertensive treatment.

MATERIAL AND METHODS

Chemicals

Amlodipine was obtained as Gift sample from UniChem laboratories Ltd., Mumbai. HPMC E15 purchased from Shilex Chemicals Pvt. Ltd., Delhi. Pectin, Sodium starch glycolate, Poly ethylene glycol 400 and Citric acid are purchased from S.D. Fine- Chemical Ltd, Mumbai. Sodium saccharine purchased from HI media Lab Pvt Ltd., Mumbai. Orange flavour purchased from Pentagon trading company, Mumbai. All the used reagents and chemicals were of analytical grade.

Calibration of AML

To a 100 millilitre volumetric flask, 100 milligrammes of carefully weighed AML are introduced. The volume was raised to 100 ml using a stock solution of 1 mg/ml of 6.8 pH phosphate buffer. The stock solution was diluted to obtain solutions with concentrations of 5-25 μg/ml using 6.8 pH phosphate buffer. A UV-VIS spectrophotometer (EI 1372, Electronics India, Pune, India) phosphate buffer blank 6.8 pH was used to quantify these solution's absorbance using a standard graph at wavelenth 238 nm.

Fourier Transform Infrared (FT-IR) Spectroscopy

Using a FTIR spectrophotometer (Shimadzu FTIR-8400S, Japan), the drug's FT-IR spectra were recorded. When using the diffuse reflectance technique, the mid-IR 4000-400 cm-1 spectral region was covered. The sample is first dispersed in KBr (100 mg) using a motor, and the materials are subsequently triturated into a fine powder bed inside the container using a compression gauge. Five tons of pressure was

applied for five minutes. Following the light route, the film was placed, the spectrum was recorded twice, and the characteristic peaks associated with the functional groups were determined.

Formulation Design:[11]

Amlodipine oral disintegrating films were formulated with a blend of natural and synthetic polymers to provide quick disintegration in the oral cavity while maintaining sufficient mechanical strength and homogeneous drug release. Hydroxypropyl methylcellulose (HPMC E15) was chosen as the principal film-forming synthetic polymer for its excellent clarity, flexibility, and safety, while pectin, a natural polysaccharide, was added to improve biodegradability, mucoadhesion, and disintegration properties. Six formulations (A1–A6) were created by altering the ratio of HPMC E15 to pectin to examine their synergistic impact on film characteristics. Sodium starch glycolate (SSG) served as a superdisintegrant to promote swift film disintegration in saliva. Glycerol functioned as a plasticiser to enhance flexibility and diminish brittleness, while citric acid and sodium saccharin improved taste and palatability, complemented by peppermint and lemon flavouring. Amlodipine besylate was uniformly integrated to guarantee precise dosage administration per 2 × 2 cm film.

The formulae of different formulations are as follows:

Table 1: Formulation of Amlodipine (AML) ODF

Ingredient (mg/film)	A1	A2	A3	A4	A5	A6
Amlodipine besylate (eq. 5 mg base)	5	5	5	5	5	5
HPMC E15	70	60	50	40	55	45
Pectin	30	40	50	60	45	55
Sodium starch glycolate (SSG)	2	3	4	5	4	5
Glycerol (plasticizer)	15	15	15	15	15	15
Citric acid	2	2	2	2	2	2
Sodium saccharin	2	2	2	2	2	2
Peppermint / lemon flavor	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Purified water (for casting)	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.

The above formulation was calculated for single film of 2x2 cm size. '' denoted as qs. to 4ml.

Preparation of ODF

We employed the solvent casting method to make Amlodipine ODF. Amlodipine oral disintegrating films were fabricated using the solvent casting method. The specified amount of HPMC E15 was dissolved in a predetermined volume of filtered water while being stirred continuously until a clear, homogeneous solution was achieved. Pectin was incrementally introduced to warm purified water in a separate beaker and permitted to fully hydrate with moderate agitation. The pectin solution was subsequently included into the HPMC solution to achieve a homogeneous polymer blend. Glycerol was incorporated as a plasticiser, succeeded by citric acid, sodium saccharin, and flavouring, and the amalgamation was agitated comprehensively. Amlodipine besylate was either dissolved or finely dispersed in a minimal volume of the polymer solution and integrated into the bulk through continuous stirring to guarantee uniform medication distribution. Sodium starch glycolate was thereafter uniformly disseminated into the drug–polymer solution. The resulting solution/suspension was degassed to eliminate entrapped air and subsequently poured onto a levelled glass or Teflon casting plate, then dried at 40–45 °C till a flexible film was created. The dried films were meticulously removed, examined for defects, and sectioned into 2 × 2 cm pieces, each holding the specified dosage of amlodipine. Films were preserved in hermetically sealed containers under regulated conditions until further assessment.

Evaluation of oral dissolving films formulations:

For ODF formulations, various quality control tests were carried out.

Different Performed in vitro examinations are:

Thickness measurement[12]:

A micrometer screw gauge was used to measure the thickness of the film five times, and an average of three readings was calculated. Maintaining uniformity in the film's thickness is essential because it has a direct impact on the dose's accuracy within the film. The thickness of the film should be less than 5%. Five points on the film should be measured: the center, the four corners, and the mean thickness. Six films of each formulation should be used for this test. The value was stated in millimeters.

Weight variation[13]

A weight was determined by selecting ten prepared films at random and averaging them. Weighing each film, we compared its weight to the deviation's average. Using an analytical balance, the average weight of the mouth dissolving oral films was calculated for each film. It is preferable if the weight of films is almost consistent. Making sure a film has the right amount of API and excipients is helpful.

Folding endurance[14]

To test folding endurance, a film is sliced and quickly folded in the same spot until it breaks. The number of times the film could be folded in the same way without breaking is what determines the folding endurance value. The topical folding endurance of the film was 100–150. The total number of folds the film can withstand without breaking is used to calculate the folding endurance value.

Drug content uniformity

Any standard assay procedure specified for the specific API in any standard pharmacopoeia will determine this. By evaluating the API content in each individual strip, content consistency is ascertained. 85–115% is the maximum content homogeneity[15].

$$\text{Drug content} = \frac{\text{sample absorbance}}{\text{standard absorbance}} \times \frac{\text{standard dilution}}{\text{sample dilution}} \times \frac{\%\text{purity of drug} \times \text{Avg.wt}}{100}$$

$$\%\ \text{Drug content} = \frac{\text{Drug content} \times 100}{\text{Label claim}}$$

Surface pH

The film that was going to be tested was put in a Petri dish, wet with 0.5 milliliters of distilled water, and left for thirty seconds. After allowing one minute for equilibration and contacting the formulation's surface with the pH meter's electrode, the pH was recorded. For every formulation, an average of three determinations was made.[16]

Assay of the Films:

The drug content of the prepared Oro dissolving films was tested. One film, chosen at random from the five, was weighed, then added to 100 milliliters of 6.8 pH buffer in a volumetric flask. For thirty minutes, a volumetric flask was submerged in a sonicator. The final solution's absorbance were measured at 238 nm wave length using a UV Visible spectrophotometer against a blank using 6.8 pH buffer. Using the standard graph, the concentrations were computed, and the formulation's total amount was determined.

***In vitro* disintegration studies:**

The test was performed using disintegration test apparatus. Disintegration time provides an indication of the disintegration characteristics and dissolution characteristics of the film. The required size of film (2×2 cm^2) is placed in a stainless steel wire mesh containing 25 ml of pH 6.8 simulated salivary fluids. Time taken by the film to break and dissolve is measured as disintegration time.[17]

***In vitro* Dissolution test[18]:**

The in-vitro dissolution study of the developed amlodipine oral disintegrating films (ODFs) was performed using a USP type II (paddle) dissolution apparatus (EI-1916, Electronics India, Pune, India). The films were placed in 500 mL of pH 6.8 phosphate buffer maintained at 37 ± 0.5 °C with a paddle rotation speed of 50 rpm. Samples (5 mL) were withdrawn at predetermined time intervals (2–20 minutes),

replaced with an equal volume of fresh dissolution medium, and analyzed using a UV–Visible spectrophotometer (EI-1372, Electronics India, Pune, India). The amount of drug released was calculated from the standard calibration curve and expressed as the percentage cumulative drug release. All dissolution studies were carried out in six replicates, and the mean values were reported.

Release Kinetics[19]

The findings from the in-vitro diffusion investigation were used to investigate the drug release kinetics of AML films, including their order and mechanism. The zero order, first order, and Higuchi equations were among the kinetic models that were plotted; the Korsmeyer-Peppas equations were used to determine the release.

Stability Studies

Drug stability refers to the ability of a formulation to retain its physical, chemical, and therapeutic properties within specified limits throughout its shelf life. Stability studies were conducted in accordance with ICH Q1A guidelines to ensure product quality and performance. Accelerated stability testing of the optimized formulations was carried out at 40 ± 2 °C / 75 ± 5% RH for three months**.** The samples were packed in aluminum foil strips and stored under controlled conditions. At predetermined intervals, formulations were evaluated for appearance, drug content, and in-vitro drug release**,** confirming their stability over the study period.[20]

RESULTS & DISCUSSION

Calibration of AML

Prepare the stock solution by combining 50 mg of AML with 100 ml of water. Ten millilitres of this stock solution were extracted and diluted with water to achieve a total volume of one hundred millilitres. A calibration curve was established utilising diverse concentrations (5–25 µg/ml) and the appropriate dilution of the stock solution. The absorbance was measured at 238 nm. Figure 1 illustrates the AML standard curve. The results were compiled in a table. The AML was calibrated using a pH 6.8 phosphate buffer; linearity was found with 0.9944=R^2 value.

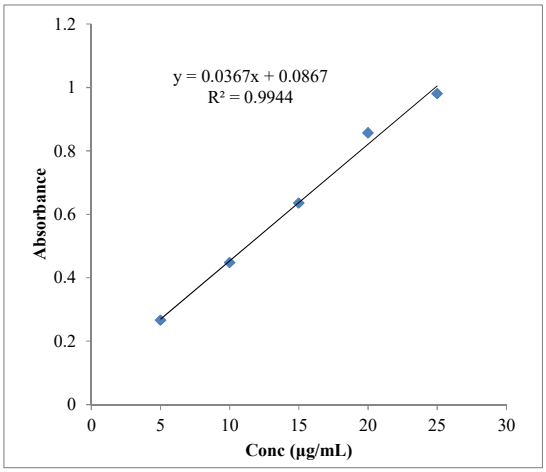

Fig 1: Standard Calibration Curve of AML in 6.8 pH phosphate buffer

Drug – excipient Compatibility Studies

FTIR spectrometer (Shimadzu FTIR-8400S, Japan) was used to determine the drug excipient compatibility, and the graphs from the figure were displayed. To find out if there was any interaction between the excipients and AML, the physical mixture was put through FTIR analysis. The lack of a drug-carrier chemical interaction is confirmed by the absence of any drug-characteristic peak appearance or disappearance. AML, HPMC E15, pectin and sodium starch glycolate physical mixtures examined for chemical interactions. Pure AML and optimised sample underwent FTIR analysis to determine the presence of the pure API in the mixtures and to describe it.

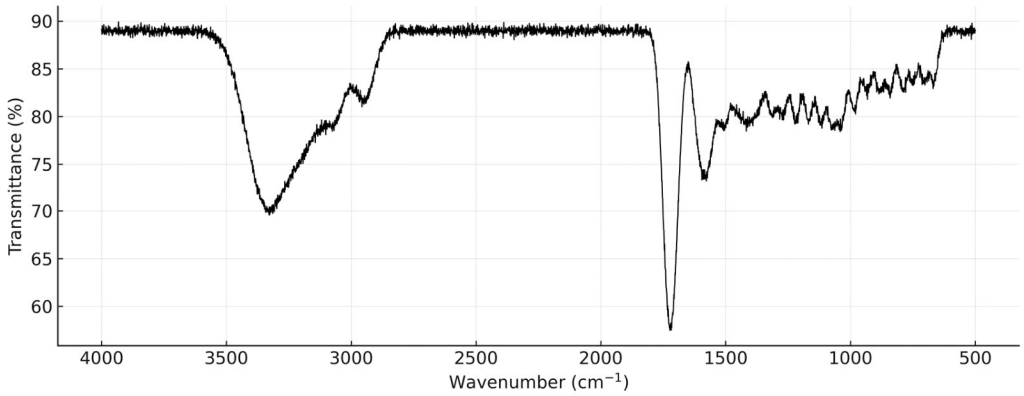

Fig 2: Pure AML FTIR Spectral Analysis

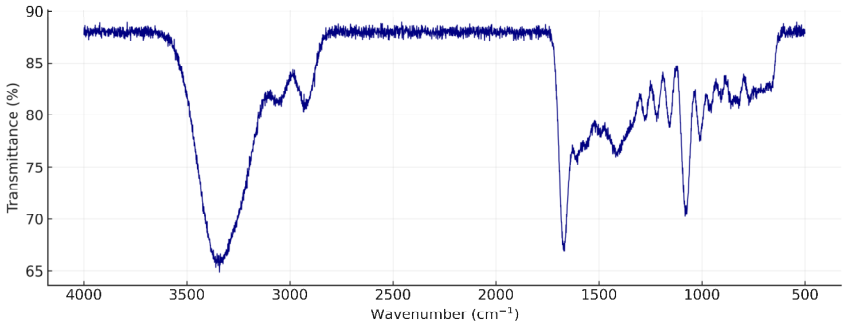

Fig 3: FTIR Spectral analysis of optimised formulation (A6)

The obtained FTIR spectra are superimposed in the Figure 2 and 3. The FTIR spectrum of pure Amlodipine exhibited distinctive peaks associated with its principal functional groups: a broad N–H and O–H stretching band at approximately 3350–3400 cm^{-1}, C–H stretching near 2900 cm^{-1}, a prominent C=O stretching peak around 1680–1700 cm^{-1}, and aromatic C–N and C–O vibrations within the range of 1200–1000 cm^{-1}. In the optimised ODF formulation, all principal drug peaks were preserved, exhibiting only moderate broadening and mild changes. No loss of distinctive peaks or emergence of new peaks was detected. The polymer-associated bands manifested as subtle overlapping shoulders without obscuring the drug's identification. The data show that no chemical contact or incompatibility existed between Amlodipine and the polymers. The observed alterations indicated only physical entrapment and hydrogen bonding, indicating that the medication maintained stability within the ODF matrix.

Evaluation of ODF:

Thickness

Thickness of all AML formulations showed in Table 2. The film thickness varied from 152 to 175 µm, with low standard deviations (4 to 6 µm), signifying exceptional consistency of solvent-cast films. The thickness marginally increased with the rising amount of pectin, attributable to the elevated solid polymer content.

Table 2: Determination of Thickness, folding endurance, surface pH and in-vitro disintegration time of all formulations

F. Code	Thickness (µm)± SD	Folding endurance (folds)	Surface pH	In-vitro disintegration Time (sec)
A 1	152.2 ± 4.3	182 ± 6	6.71 ± 0.08	29.6 ± 1.4
A 2	158.4 ± 4.9	195 ± 7	6.68 ± 0.07	26.4 ± 1.2
A 3	165.6 ± 5.0	208 ± 8	6.63 ± 0.06	22.8 ± 1.1
A 4	172.3 ± 6.1	214 ± 9	6.59 ± 0.08	19.5 ± 1.0

A 5	168.1 ± 4.2	221 ± 7	6.61 ± 0.07	21.2 ± 1.1
A 6	175.7 ± 5.9	230 ± 8	6.57 ± 0.06	18.7 ± 0.9

Folding Endurance:

Folding endurance findings were showed in Table 2. Folding endurance increased consistently from 182 ± 6 (A1) to 230 ± 8 (A6), indicating greater flexibility and mechanical strength with elevated polymer blend concentrations.

Surface pH of Films:

For each formulation, the mean of the three findings was determined, and the standard deviation was also computed. The surface pH of each film was found to be within 6-7.

In-vitro disintegration:

Disintegration times markedly diminished with increased concentrations of natural polymer (pectin) and SSG, varying from 29.6 ± 1.4 seconds (A1) to 18.7 ± 0.9 seconds (A6). The accelerated breakdown of A4–A6 indicates enhanced hydrophilicity and quick hydration properties.

Weight variation:

The weights of all films varied from 82.4 to 88.2 mg, with standard deviation values below 4%, signifying consistent casting and negligible fluctuation.

Drug Content Uniformity:

The drug content uniformity values ranged from 96.8% to 98.8%, indicating consistent drug distribution throughout the polymer matrix and effective mixing during formulation. The assay results, ranging from 98.4% to 100.2%, verify that all formulations comply with pharmacopeial standards for amlodipine content.

Assay:

The assay findings for each formulation are shown in Table 3. Among all batches, A4 and A6 had the greatest homogeneity of assay outcomes, indicating their appropriateness for subsequent in-vitro release assessment.

Table 3: Determination of Weight variation, Drug Content Uniformity and Assay

F. Code	Weight (mg)	Drug Content Uniformity (%)	Assay (%)
A1	82.4 ± 2.6	96.8 ± 2.1	98.4 ± 2.3
A2	84.1 ± 2.4	97.5 ± 1.9	98.9 ± 2.0
A3	86.3 ± 2.8	98.1 ± 2.2	99.3 ± 1.9
A4	87.5 ± 3.0	98.6 ± 2.0	99.8 ± 2.1
A5	85.9 ± 2.5	97.9 ± 1.8	99.1 ± 1.8
A6	88.2 ± 3.1	98.8 ± 2.3	100.2 ± 2.2

In-vitro dissolution

For A1 through A6, the percentage cumulative drug release is shown in Figure 4. Utilizing a Type II USP paddle apparatus, the in vitro dissolution investigations were conducted in phosphate buffer with a 6.8 pH. In 20 minutes, F5 with SSG released 100.02% of the drug and A6 with CCS released 99.47%. As a result, it has been determined to be the best formulation.

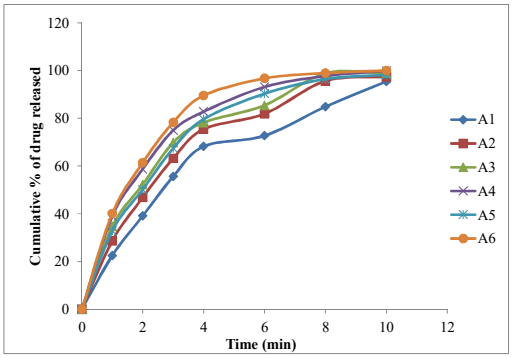

Fig 4: In vitro dissolution studies of Amlodipine formulations (A1-A6)

Release Rate Kinetics Application to Dissolution Data:

A variety of models were used to study drug release kinetics. A number of release models, including first-order, zero-order, Higuchi, and Korsmeyer-Peppas, were fitted to the acquired data in order to investigate the mechanism of the dosage form's drug release rate kinetics.

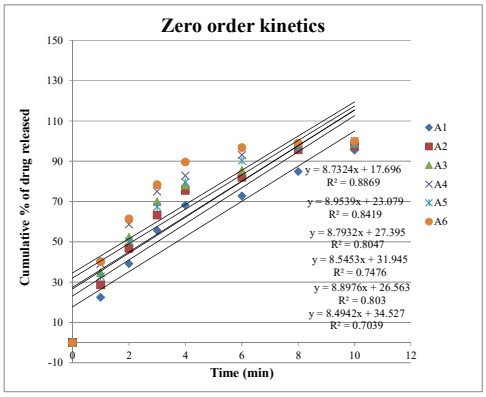

Fig 5: Zero order release kinetics graph of AML formulations (A1-A6)

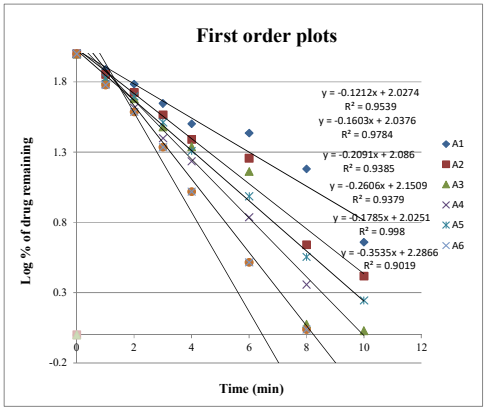

Fig 6: First order release kinetics graph of AML formulations (A1-A6)

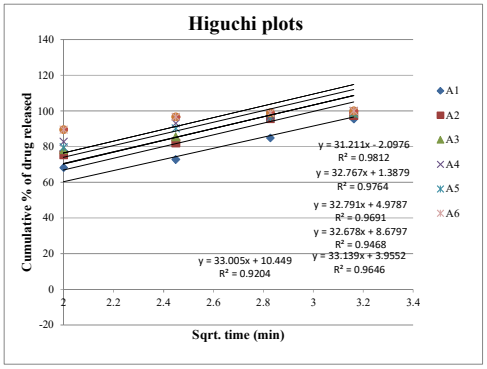

Fig 7: Higuchi release kinetics graph of AML formulations (A1-A6)

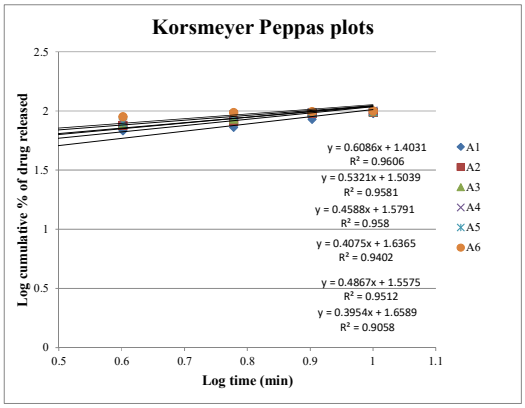

Fig 8: Korsmeyer-Peppas graph of AML formulations (A1-A6)

The drug release kinetics are summarized in Fig. 5 to 8. The release data of Amlodipine ODFs (A1–A6) were analysed using several kinetic models. All formulations demonstrated that the Higuchi model (R^2 = 0.92–0.98) provided the optimal fit, signifying that drug release is mostly governed by diffusion from the hydrated polymer matrix. First-order kinetics exhibited satisfactory results, particularly for A2 (R^2 = 0.9784) and A5 (R^2 = 0.998), indicating a concentration-dependent release mechanism. The Korsmeyer–Peppas n values varied from 0.39 to 0.61, signifying a transition from Fickian to anomalous diffusion. A1 (n = 0.6086) exhibited a mixed diffusion-relaxation mechanism, while films with higher pectin content (A4, A6) had mostly Fickian behaviour (n ≈ 0.40–0.41). These findings affirm that diffusion is the predominant release mechanism, influenced by the ratio of natural to synthetic polymer blends.

Selection of best formulation:

Formulation A6 was chosen as the optimised batch based on a comprehensive assessment of thickness, mechanical strength, surface pH, quick disintegration, drug content, assay, and dissolving profile. A6 exhibited satisfactory thickness (175 ± 6 µm), superior folding endurance (230 ± 8 folds), near-neutral surface pH (6.57 ± 0.06), and the quickest disintegration time (18.7 ± 0.9 s). It demonstrated exceptional weight consistency, elevated drug content (98.8 ± 2.3%), and assay (100.2 ± 2.2%). In-vitro disintegration trials demonstrated nearly whole drug release within 6–8 minutes (98.61% at 6 minutes; 99.91% at 8 minutes), which is optimal for a quickly acting oral disintegrating film for antihypertensive treatment. Consequently, A6 was deemed the optimal formulation.

Stability Studies:

According to ICH recommendations, stability studies were carried out to assess the drug formulation's stability. The optimised film A6 exhibited physical and chemical stability under accelerated conditions for a duration of three months. No discernible alterations in appearance, flexibility, or integrity were noted. The thickness and folding endurance exhibited negligible, non-significant fluctuations, suggesting that the film structure remained unaltered. The drug content and assay readings exceeded 97%, indicating negligible degradation, suggesting that the rapid-release profile was preserved. The stability research verifies that A6 is a resilient and stable optimised formulation appropriate for subsequent development.

CONCLUSION

Amlodipine oral disintegrating films were effectively developed with mixes of natural and synthetic polymers by the solvent casting

technique. All formulations demonstrated adequate mechanical strength, swift disintegration, consistent drug content, and rapid drug release. Formulation A6 was identified as the optimised batch, exhibiting the quickest disintegration time, maximum dissolving rate, and superior stability. The research validates that pectin–HPMC composites are appropriate for creating fast-dissolving, patient-oriented Amlodipine films, especially advantageous for paediatric, geriatric, and dysphagic patients necessitating swift antihypertensive treatment.

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