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Research Article

Formulation and evaluation of extended-release tablet Losartan potassium and Lisinopril

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Abstract

Background: The bilayer tablet concept has long been utilized to developed sustained release formulations. Bilayer tablet has a fast-releasing layer and contain second layer to sustain the drug release. A fast-releasing granules lead to sudden rise in the blood concentration. However, the blood level is maintained at steady state as the drug release from the sustaining granules.
Objective: Bilayer tablet consists of two layers of tablet in a single unit. This approach can be used for the treatment of various diseases which require not only single drug but also combination of drugs.
Method: Extended-release tablet prepared by the solvent casting method using HPMC microcrystalline cellulose ethyl cellulose prepared Bi-layer tablet is suitable for sequential release of two drugs in combination, separate two incompatible substances and also for sustained release tablet in which one layer is immediate release as initial dose and second layer is maintenance dose. The prepared films were evaluated for physical appearance, thickness, weight variation, folding endurance, surface pH, tensile strength, drug content, disintegration time, in vitro drug release, and accelerated stability according to ICH guidelines.
Result: All formulations produced smooth, flexible, and uniform films with satisfactory mechanical properties. Among the prepared formulations, F5 exhibited the most desirable characteristics, including uniform drug content, excellent folding endurance, rapid disintegration, and the highest cumulative drug release. Accelerated stability studies conducted at 600±5% RH for 90 days showed no significant changes in physicochemical properties, indicating good stability of the optimized formulation.
Conclusion: The developed Loratadine extended release demonstrated rapid disintegration, efficient drug release, satisfactory mechanical strength, and excellent stability. These findings suggest that the optimized formulation represents a promising alternative to conventional oral dosage forms, with the potential to improve patient compliance and provide rapid therapeutic action in the management of allergic disorders.
Keywords: Extended Release, Bilayer Tablet, Renin, Tablets.

1. Introduction

The oral route of drug delivery is considered as the preferred and most patient convenience means of drug administration. Consequently, much effort is directed during drug discovery to identify orally active candidates that will provide reproducible and effective plasma concentration in vivo [1]. The reality is that many compounds are either incompatibility or ineffectively absorbed after oral administration (bioavailability is an issue), or that the required during frequency is too short to enable once or twice daily administration (pharmacokinetic half- life in an issue) [2]. Conventional drug delivery systems have little or no control over drug release. This may result from constantly changing, unpredictable plasma concentrations [3]. The rate and extent of drug absorption from conventional drugs may vary greatly depending on factors such as the pysico-presence or absence of food, pH of the gastro-intestinal tract, and so on [4]. The design of modified release drug product is usually intended to optimize a therapeutic regimen by providing slow and continuous delivery of drug over the entire dosing interval whilst also providing greater patient compliance and convenience. Modified release formulation technologies offer an effective means to optimize the bio-availability and resulting blood concentration time profiles of drug [5]. Modified release refers to both delayed and extended-release systems [6]. For oral administration as well as oral delivery systems designed specially to modify the release of poorly water-soluble drugs [7]. Recent developments in the technology have prompted scientists to develop bilayer tablets with improved patient compliance and convenience [8]. The objective of the design and manufacture of the compressed tablet is to deliver orally

the correct amount of drug in the proper form, at or over the proper time and in the desired location and to have its chemical integrity protected to that point [9].

Harris interactive survey for hypertension, in the United States revealed that out of 90 % patients taking medication only 50% to 60% were involved in some form of lifestyle change to control BP [10]. Thus, majority of patients with hypertension rely on medication for the control of their BP [11]. More recent clinical trials suggest that the approach of using mono therapy for the control of hypertension is not likely to be successful in most patients and especially in those with some comorbidity (e.g. DM, heart failure) [12]. The achievement of BP goal typically requires 2 or more medications in various settings [13].

Highest dose combination (telmisartan 80mgplus amlodipine 10 mg) had the greatest least square mean systolic/diastolic BP reductions (26.4/20.1 mm Hg; $P < 0.05$ compared with both mono therapies) with over 90%BP response rates [14]. Peripheral edema was most common in the amlodipine 10-mg group (17.8%) but the rate had not ably lowered when amlodipine was used in combination with telmisartan [15]. Similar results were observed with other trial of olmesartan medoxomil / amlodipine combination the rapy vs. respective mono therapies where more effective BP reduction and BP goals (44.5-54% vs 28.5-30%) were achieved with combination therapy than with either of mono therapies. Over 70% of patients on combination therapy achieved BP goals [16].

Another double blind, parallel group randomized study for 12 weeks comparing the combination therapy of felodipine and metoprolol (5/50 mg) with either mono therapy exhibited significantly greater antihypertensive response (98%) with combination compared to mono therapy (felodipine- 79% and metoprolol- 82%). A significant greater reduction in mean systolic/diastolic BP (28/18 mmHg) with combination therapy was evinced compared to either felodipine (18/12 mm hg) or metoprolol (19/12 mm hg) [17].

Many panels including Hypertension in African Americans Working Group and European Society of Cardiology have strongly supported that treatment initiation with 2 or if needed 3 drugs are justified in many cases of hyper tension management. There are other various advantages with combination therapy [18]. Combining the drugs makes them available in a convenient dosing format, lowers the dose and can be given in once daily schedule thus improving compliance. There is an additive or synergistic antihypertensive effect at lower doses of individual components and at the same time the drugs in combination counteract the side effects of each other [19]. This helps more patients to achieve normal BP and even can be effective in hard-to-treat populations. Early normalization of BP may greatly motivate the patients to adhere to lifelong treatment [20].

2. Materials and Method

Losartan Potassium and Lisinopril were obtained as a gift sample from Lincoln Pharmaceutical Ahmedabad, India. Hydroxyl propyl methyl cellulose (HPMC K-4M), sodium carboxyl methylcellulose (Na CMC) was obtained from Sigma Chemicals, USA. Ethyl cellulose was obtained from Strides Arco Labs, Bangalore, India. Mannitol, magnesium stearate was supplied from Loba Chemie Mumbai, India. Hydrochloric acid GCC, U.K and ethanol BDH, England All other ingredients used were of analytical grade.

2.1 Pre formulation studies:

2.1.1 Preparation of standard graph for Enalapril and lactose using acidic buffer (pH 1.2): 100 mg of Enalapril and lactose sesqui hydrate was weighed accurately and dissolved in 100 mL of pH 1.2 acidic buffers in 100 mL volumetric flask (stock solution). 2 mL was taken from the stock solution and transferred into 100 mL volumetric flask and diluted up to 100 mL with pH 1.2 acidic buffers. The resulting solution was labeled as standard working Solution. 2 mL of the working solution was withdrawn and diluted up to 10 mL with pH 1.2 acidic buffer in 10 mL volumetric flask. The spectrum of this solution was run in 200 to 400 nm range in UV-visible spectrophotometer. The λ max of the Enalapril and lactose sesqui hydrate was found to be 283 nm.

2.1.2 Preparation of standard graph from above standard working solution, 1, 2, 3, 4, 5 and 7 mL was withdrawn and diluted up to 10 mL with pH 1.2 acidic buffer in 10 mL volumetric flask to get concentration of 2 µg, 4 µg, 7 µg, 8 µg, 10 µg and 12 µg respectively. The absorbance of each solution was measured by UV-visible spectrophotometer at 283 nm using the pH 1.2 acidic buffer as blank.

2.1.3 Formulation and Evaluation of extended-release tablets: Method selected for preparation of extended-release tablet is by wet granulation method

Rationale:

- Because of sticky /hygroscopic nature of polymer which is contributing to almost 20 to 50 % in total formulation, direct compression and dry granulation method may exhibit poor flow of material during compression which in turn may lead to weight variability / content uniformity problem.
- Drug compound and other materials in the formulation are thermally stable hence can be subjected to drying during processing.

Table No.1 Manufacturing steps and critical control points

Mfg Steps	Critical Quality Parameter
Sifting, Dry mixing Wet granulation [Using purified water-controlled spraying (qty/min) using peristaltic pump]. Drying Pre–blending & Final blending	Mesh size, Particle size, Addition seq., Mixing Time Binde radditionrate, Mixing time, granulation end point Inlet temperature. Drying time, Loss on drying, Particle size & physical properties of blend, blending time, material addition, blender RPM
Compression Physical evaluation of tablets Chemical Evaluation of tablets	Appearance, Weight, hardness, friability, thickness. Dissolution and Assay

Methods adopted for above tests are

• Appearance: Take 2 g of sample in a clean, dry Petri dish and observe, visual against black background and observations were recorded.
• Solubility: Solubility was determined in different solvents and solubility characteristics were reported.

2.2 Identification test

Firstly, clean the sample holder by acetone. Then Switch on the Instrument and take the sample in sample holder, and the results are observed. Fourier transform IR spectra were recorded on FT/IR- affinity type A. The scanning range was 400-4000 cm-1, resolution was 2 cm-1. Initially, a FTIR transmittance spectrum of was obtained from a KBr pellet and interpreted following the characteristic IR absorption bands.

2.2.1 Organoleptic Property:

Organoleptic properties are the aspects of food or other substances as experienced by the senses, including taste, sight, smell, and touch, in cases where dryness, moisture, and stale-fresh factors are to be considered

Table No. 2 Organoleptic Property of Drug

Sr. No.	Property	Lisinopril	Losartan Potassium
1	State	Solid, Powder	Solid, Powder
2	Appearance and Color	A white or almost white powder	A white or almost white powder
3	Odour	odorless	odorless
4	Appearance of the solution	Clear solution in Water (1%)	Clear solution in Water (1%)

2.2.2 Solubility Analysis

Pre-formulation solubility analysis was done to select a suitable solvent system to dissolve the drug and also to test its solubility in the dissolution medium which was to be used

2.2.3 Melting point determination

Melting point determination of the obtained drug sample was done because it is a good first indication of purity of the sample since the presence of relatively small amount of impurity can be detected by a lowering as well as widening in the melting point range.

2.2.4 Determination of pH of 5%

The pH is measured using a pH meter of a glass electrode in 5% w/v solution. pH fundamentally represents the value of hydrogen ion activity in solutions

2.3 Partition coefficient measurement

The partition coefficient (P) is defined as the ratio of the equilibrium concentrations (ci) of a dissolved substance in a two-phase system consisting of two largely immiscible solvents. In the case n-octanol and water

Po/w = cn octanol /c water

The partition coefficient (P) therefore is the quotient of two concentrations and is usually given in the form of its logarithm to base 10 (log P).

The partition coefficient is a ratio of concentrations of un-ionized compound between the two solutions. To measure the partition coefficient of ionizable solutes, the pH of the aqueous phase is adjusted such that the predominant form of the compound is un-ionized. The logarithm of the ratio of the concentrations of the un ionized solute in the solvents is called log P:

$$log\ P_{oct/wat} = log\left(\frac{[solute]_{octanol}}{[solute]^{un-ionized}_{water}}\right)$$

2.3.1 Shake flask method

The classical and most reliable method of log *P* determination is the shake-flask method**,** which consists of dissolving some of the solute in question in a volume of octanol and water, then measuring the concentration of the solute in each solvent. The most common method of measuring the distribution of the solute by UV spectrophotometer.

2.4 Determination of moisture content

The moisture is measured by LOD 60 ^{0}C for 3 hours

2.5 Physico-chemical characterization

2.5.1 Bulk density:

Weigh accurately 20 g of DRUG X, which was previously passed through #20 sieve and transferred in 100 ml graduated cylinder. Carefully level the powder without compacting, and read the unsettled apparent volume (V0). Calculate the apparent bulk density in gm/ml by the following formula

Bulk density = Weight of powder / Bulk volume

2.5.2 Tapped density:

Weigh accurately 25 g of drug, which was previously passed through #20 sieve and transfer in 100 ml graduated cylinder. Then mechanically tap the cylinder containing the sample by raising the cylinder and allowing it to drop under its own weight using mechanically tapped density tester that provides a fixed drop of 14± 2 mm at a nominal rate of 300 drops per minute. Tap the cylinder for 500 times initially and measure the tapped volume (V1) to the nearest graduated units, repeat the tapping an additional 750 times and measure the tapped volume (V2) to the nearest graduated units. If the difference between the two volumes is less than 2% then final the volume (V2). Calculate the tapped density in gm/ml by the following formula.

Tapped density = Weight of powder / Tapped volume

2.5.3 CARR'S Index:

The Compressibility Index of the powder blend was determined by Carr's compressibility index. It is a simple test to evaluate the BD and TD of a powder and the rate at which it packed down. The formula for Carr's Index is as below

Carr's Index= [(TD-BD)*100]/ TD

2.5.4 Hausner's ratio

The Hausner's ratio is a number that is correlated to the flow ability of a powder or granular material .

Hausner's ratio = TD/BD

2.5.5 Angle of repose:

The angle of repose of API powder was determined by the funnel method. The accurately weight powder blend were taken in the funnel. The height of the funnel was adjusted in such a way the tip of the funnel just touched the apex of the powder blend. The powder blend was allowed to flow through the funnel freely on to the surface. The diameter of the powder cone was measured and angle of repose was calculated using the following equation.

$$\tan \Theta = H/R$$

2.6 Evaluation of Bilayer Tablet:

2.6.1. Weight Variation Test:

Twenty tablets were randomly selected and weighed to determine the average weight and were compared with individual tablet weight. The percentage weight variation was calculated.

In all the formulations, the tablet weight was less than 324 mg hence a maximum deviation of ±7.5 % from the average tablet weight was allowed.

2.6.2. Friability Test:

Weighed amount of 20 de-dusted tablets were subjected to rotating drum of friability test apparatus. The drum rotated at a speed of 25 rpm. The apparatus was operated for 4 minutes and reweighed the tablets. Friability was calculated by the following formula.

F =100 (W0-W)/W0

F = Friability

W0 = Initial weight

W= Final weight

2.6.3. Hardness Test:

Hardness indicates the ability of a tablet to withstand mechanical shocks while handling. The hardness of the tablets was determined using Pfizer hardness tester. It was expressed in kg/cm2. Ten tablets were randomly selected from each formulation and hardness of the same was determined. The average value was also calculated.

2.6.4. Thickness Test:

Control of physical dimension of the tablets such as sizes and thickness is essential for consumer acceptance and to maintain tablet to tablet uniformity. The dimensional specifications were measured using screw gauge. Twenty tablets were randomly selected from formulations and thickness was measured individually. It was expressed in millimeter and average was calculated.

2.6.5. Wetting time:

A piece of tissue paper folded double was placed in a Petri dish containing 6 ml of water. The tablet was placed on the paper and the time for complete wetting of the tablet was measured in seconds. The method was slightly modified by maintaining water at 370C. Wetting time corresponding to the time taken for the tablet to disintegrate when kept motionless on the tongue was calculated.

2.6.6. Water absorption ratio:

A piece of tissue paper folded twice was placed in small petri dish (7.5cm) containing 7 ml water. A tablet was put on the tissue paper & allows wetting completely. The wetted tablet was then weighed. The water absorption ratio R was determined using following equation.

$$R = 100\times (Wa-Wb) / Wb$$

Where,

Wa = weight of a tablet after absorption

Wb =weight of a tablet before absorption

2.6.7. Disintegration Test:

The standard procedure of performing disintegration test for these dosage forms has several limitations and they do not suffice the measurement of very short disintegration times. The disintegration time for FDT needs to be modified as disintegration is required without

water thus the test should mimic disintegration in salivary contents. For this purpose, a Petri dish (10 cm diameter) was filled with 10 ml of water. The tablet was carefully put in the center of Petri dish and time for tablet to completely disintegrate into fine particle was noted.

2.6.8. In-vitro Dissolution studies:

In-vitro dissolution studies for all the fabricated tablets of Telmisartan were carried out using USP apparatus type II at 50 rpm. The dissolution medium used was 6.8 phosphate buffer (900 ml) maintained at 37 ±0. 5^0C.Aliquots of dissolution media were withdrawn (5ml) at different intervals and content of Telmisartan was measured by determining absorbance at 296 nm. 5ml aliquot was withdrawn at the 1min, 2min. .....to be continued at the 1 min. intervals and filtered by Whatman filter paper, suitably diluted and analyzed at 296 nm using UV - visible spectrophotometer. An equal volume of fresh medium, which was pre-warmed at 37^0C was replaced in to the dissolution medium after each sampling to maintain the constant volume throughout the test.

3. Result and Discussion

Firstly, clean the sample holder by acetone. Then Switch on the Instrument and take the sample in sample holder, and the results are observed. Fourier transform IR spectra were recorded on FT/IR- affinity type A. The scanning range was 400-4000 cm^{-1}, resolution was 2 cm^{-1}. Initially, a FTIR transmittance spectrum of was obtained from a KBr pellet and interpreted following the characteristic IR absorption bands.

Lisinopril IR curve:-

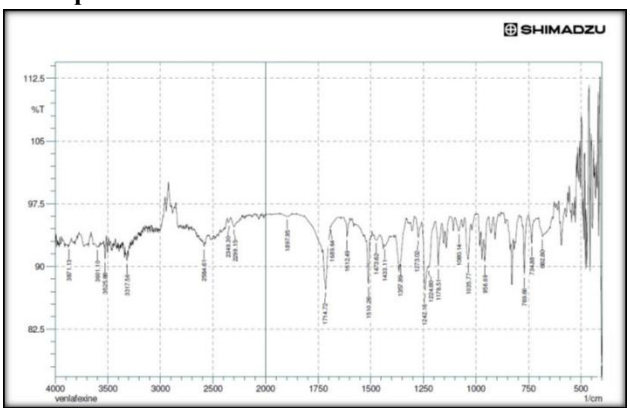

Figure No.1: Lisinopril IR curve

Losartan potassium IR curve

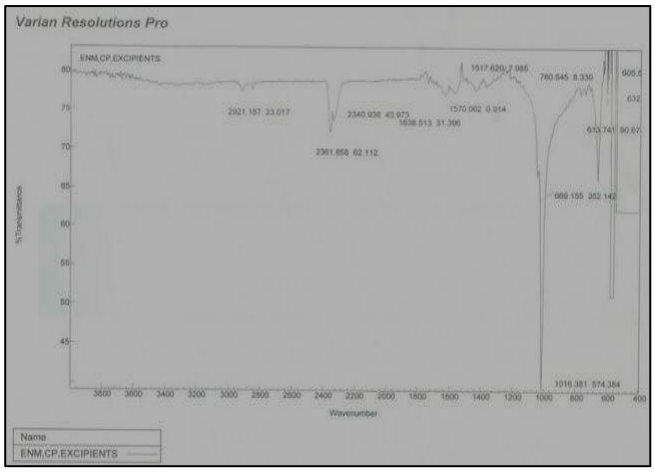

Figure No.2: Losartan potassium IR curve

Table-3 Absorption of drug at λ max of Lisinopril and Losartan potassium

S. No.	METO con. (g/ml)	Absorbance		TELMI con. (g/ml)	Absorbance	
		λ1(205nm)	λ2(247nm)		λ1(205nm)	λ2(247nm)
1	5	0.02	0.033	15	0.038	0.018
2	10	0.041	0.066	30	0.072	0.035
3	15	0.062	0.097	45	0.109	0.054
4	20	0.083	0.134	60	0.148	0.07
5	25	0.105	0.167	75	0.18	0.091

ax1= 0.0041 **ay1**=0.004583

ax2= 0.0066 **ay2**= 0.00223

Table No. 4: Pre-compression parameters of all formulations

For Sustain Release layer IPQC						
Sr. No.	Batch No.	Angle of repose in degrees	Bulk density (g/ml)	Tapped density (g/ml)	Compressibility Index (%)	Hausner ratio
1	B1	25.61	0.6681	0.6871	12.92%	1.028439
2	B2	25.07	0.6654	0.6954	10.77%	1.045086
3	B3	26.56	0.6645	0.6864	12.78%	1.032957
4	B4	26.70	0.6458	0.6874	10.87%	1.064416
5	B5	25.78	0.6445	0.6895	10.54%	1.069822
6	B6	24.89	0.6774	0.6875	11.7%	1.01491

3.1 In-vitro Dissolution studies:

In-vitro dissolution studies for all the fabricated tablets of Telmisartan were carried out using USP apparatus type II at 50 rpm. The dissolution medium used was 6.8 phosphate buffer (900 ml) maintained at 37 ±0.5^{0}C.Aliquots of dissolution media were withdrawn (5ml) at different intervals and content of Telmisartan was measured by determining absorbance at 296 nm. 5ml aliquot was withdrawn at the 1min, 2min. .....to be continued at the 1 min. intervals and filtered by Whatman filter paper, suitably diluted and analyzed at 296 nm using UV - visible spectrophotometer. An equal volume of fresh medium, which was pre-warmed at 37^{0}C was replaced in to the dissolution medium after each sampling to maintain the constant volume throughout the test.

Table No. 5: Evaluation results of tablets

Sr. N.	Batch No.	Thickness (mm)	Weight variation (mg)	Friability (%)	Hardness (kg/cm^2)
1	B1	2.32	600±5%	0.87	5.1
2	B2	2.43	605±5%	0.58	5.2
3	B3	2.37	603±5%	0.69	5.1
4	B4	2.34	599±5%	0.79	5.0
5	B5	2.40	600±5%	0.59	5.0
6	B6	2.36	600±5%	0.65	5.0

3.2 Stability Studies:

Stability studies of the selected formulated tablets were carried out by keeping the tablets at room temperature and at 40°C ± 2°C / 75 ± 5% RH (stability chamber) for 30days. The results are tabulated below.

Table No. 6: Stability study results

Parameter	Initial	At room temperature (After 30 days)	At40˚C±2˚C/ 75±5% RH (stability chamber) (After 30 days)
Hardness (kg/cm^2)	2.1	2.1	2.0
Friability (%)	0.66	0.72	0.72
Drug Release (%)	98.64	98.44	98.21
Drug content (%)	99.50	99.10	98.75

3.3 Evaluation Result

Table No. 7: Evaluation results of tablets

Sr. No.	Batch No.	Thickness (mm)	Weight variation (mg)	Friability (%)	Hardness (kg/cm^2)
1	B1	2.32	600±5%	0.87	5.1
2	B2	2.43	605±5%	0.58	5.2
3	B3	2.37	603±5%	0.69	5.1
4	B4	2.34	599±5%	0.79	5.0
5	**B5**	**2.40**	**600±5%**	**0.59**	**5.0**
6	B6	2.36	600±5%	0.65	5.0

4. Summary and Conclusion

The present investigation successfully designed, developed, and characterized extended release of Losartan Potassium and Lisinopril using the solvent casting method. Preformulation studies confirmed the identity, purity, and compatibility of Losartan Potassium and Lisinopril with the selected excipients, supporting their suitability for formulation development.

The prepared films exhibited satisfactory physicochemical characteristics, including uniform appearance, acceptable thickness and weight variation, near-neutral surface pH, excellent mechanical strength, high drug content uniformity, rapid disintegration, and efficient in vitro drug release. Among the five formulations, formulation F5 demonstrated the best overall performance, showing superior flexibility, highest drug content, shortest disintegration time, and nearly complete drug release within 10 minutes.

Accelerated stability studies conducted at 40 ± 2°C/75 ± 5% RH for 90 days confirmed that the optimized formulation remained physically and chemically stable, with no significant changes in its quality attributes. These findings indicate that the developed extended release provides a stable, effective, and patient-friendly dosage form for the rapid delivery of Losartan Potassium and Lisinopril.

Overall, the optimized formulation offers several advantages over conventional oral dosage forms, including ease of administration without water, rapid drug release, improved patient compliance, and the potential for faster therapeutic action. Future investigations should include taste-masking evaluation, ex vivo permeation studies, in vivo pharmacokinetic and pharmacodynamic assessment, long-term stability testing, and scale-up studies to establish the clinical applicability and commercial potential of the developed Losartan Potassium and Lisinopril extended-release tablet .

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