Journal of Pharma Research
Available online through
www.jprinfo.com

Research Article
ISSN: 2319-5622

Formulation and Evaluation of Immediate release Amlodipine Besylate and Losartan Potassium Film coated Tablets

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Received on: 11-12-2015; Revised and Accepted on: 21-12-2015

ABSTRACT

Attempts were made in the present investigation to develop a pharmaceutically stable formulation of Amlodipine besylate and Losartan potassium immediate release tablets. Amlodipine and Losartan potassium were indicated for the treatment of hypertension. All formualtions were prepared by wet granulation method by using microcrystalline cellulose, povidone, Dicalcium phosphate dihydrate, mannitol, colloidal silicon dioxide, and magnesium stearate. On direct compression batch was taken and results were compared with wet granulated batch of same composition. Film coating was done by using Opadry white to protect Losartan potassium from moisture. The tablets prepared were found to be within the official limits with respect to weight variation, thickness, hardness, friability, disintegration and dissolution. Among the all formulations the release profile of trial F10 was found to be similar to the marketed product release profile. These results clearly reflect that the prepared formulation releasing the drug immediately within the specifications. The final formulation also shows good comparative dissolution profile with marketed preparation.

Key Words:*AmlodipineBesylate, Losartan potassium, Immediate Release Tablets, FT-IR, Stability Studies.*

INTRODUCTION

Drugs are rarely administered as pure chemical substances. They are most frequently given as formulated preparations or medicines, usually orally, the most popular dosage forms being tablets, capsules, suspensions, solutions and emulsion. Oral drug delivery is the simplest and easiest way of administering drugs. Because of the greater stability, smaller bulk, accurate dosage and easy production, solid oral dosages forms have many advantages over other types of oral dosage forms. Therefore, most of the new chemical entities (NCE) under development these days are intended to be used as a solid dosage form that originate an effective and reproducible in vivo plasma concentration after oral administration [1-3].

1. Immediate Release Tablets: [4, 5]

The term "immediate release" pharmaceutical formulation includes any formulation in which the rate of release of drug from the formulation and/or the absorption of drug, is neither appreciably, nor intentionally, retarded by galenic manipulations. Immediate release may be provided for by way of an appropriate pharmaceutically acceptable diluent or carrier, which diluent or carrier does not prolong, to an appreciable extent, the rate of drug release and/or absorption.

MATERIALS AND METHODS

1. Materials used:

Losartan potassium, Amlodipine Besilate, Mannitol, Microcrystalline cellulose, Dicalcium phosphate dehydrate, Povidone, Croscarmellose sodium, Colloidal silicone dioxide, Magnesium stearate.

2. Methods used:

2.1. Evaluation of powder flow properties:

Bulk density:

Bulk density of a powder is the ratio of mass of the powder to the Bulk volume. Bulk density was determined by pouring pre sieved (Sieve No. 18) powder into a graduated cylinder via a large funnel and volume and weight was measured [6-8]. Bulk density was measured by using formula,

$$P = m/V_o$$

Where,

P = Bulk density; m = Mass of the Powder;
V_o = Untapped Volume

Tapped Density:

The tapped density is measured for two primary purposes: [9]

a) The tapped value is more reproducibly measured than the bulk value and
b) The "flowability" of a powder is inferred from the ratio of these two measured densities.

Weighed quantity of sample was taken into graduated cylinder, volume occupied by sample was noted down. Then cylinder was subjected to 100 taps in tapped density tester (Electro Lab USP - II), the % Volume variation was calculated by following form.

$$P_t = m/V_i$$

Where,

P_t = Tapped density; m = Mass of the powder
V_i = Tapped volume

Carr's compressibility Index: [10]

Compressibility is the ability of powder to decrease in volume under pressure. Using untapped density and tapped density the percentage compressibility of powder was determined, which was given as Carr's compressibility index.

$$CI = V_i - V_0 / V_i \times 100$$

Where,

CI = Compressibility index; Vo = Bulk density
V_i = Tapped density

Hausner's Ratio: [11, 12]

It is the measurement of frictional resistance of the drug. It was determined by the ratio of tapped density and bulk density.

$$\text{Hausner's Ratio} = V_i / V_o$$

Where,

Vo = Bulk density; V_i = Tapped density

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Table No. 1: Flow Properties and Corresponding, Compressibility index, Hausner ratio

Flow property	C.I (%)	Hausner ratio
Excellent	≤10	1.00 – 1.11
Good	11 – 15	1.12 – 1.18
Fair	16 – 20	1.19 – 1.25
Passable	21 – 25	1.26 – 1.34
Poor	26 – 31	1.35 – 1.45
Very poor	32 – 37	1.46 – 1.59
Very, very poor	>38	>1.60

2.2. Evaluation Parameters of tablets:

Uniformity of weight: [13, 14]

Twenty tablets were randomly selected from each batch and individually weighed. The average weight and standard deviation of 20 tablets was calculated. The batch passes the test for weight variation, if not more than two of the individual weights deviates from the average weight by more than the percentage shown in the Table and none should deviate by more than twice the percentage shown. The average weight and standard deviation of the tablets of each batch were given in the table.

Table No. 2: Weight Variation Specification

IP/BP	Limit	USP
80 mg or less	10%	130mg or less
More than 80mg or Less than 250mg	7.5%	130mg to 324mg
250mg or more	5%	More than 324mg

Thickness: [15, 16]

The control of physical dimension of the tablet such as thickness is essential for consumer acceptance and to maintain uniformity of tablet weight. Six tablets were randomly selected from each batch and their thickness was measured by using verniercallipers. The average thickness with standard deviation of the tablets from each batch were measured and tabulated.

Hardness: [17, 18]

The tablet crushing load is the force required to break a tablet by compression. Hardness was measured by using hardness tester (Dr.Schleniger hardness tester). For each batch, six tablets were selected randomly and evaluated.

Friability: [19, 20]

Friability test is performed to assess the effect of friction and shocks, which may often cause tablet to chip, cap or break. Roche friabilator was used for this purpose. Pre weighed sample of twenty tablets were placed in the friabilator, which was then operated for 100 revolutions. After 100 revolutions the tablets were dusted and reweighed. Compressed tablets should not lose more than 1% of their weight.

$$\text{Percentage Friability} = \frac{(\text{Initial Weight} - \text{Final Weight})}{\text{Final Weight}} \times 100$$

Disintegration Time: [21, 22]

Randomly six tablets were selected from each batch for disintegration test. Disintegration test was performed without disc in water (37 ± 0.5 °C) using United States Pharmacopeia (USP) disintegration apparatus.

Table No. 3: Specifications for disintegration time of tablets

Uncoated Tablet	NMT 15 min, in water with Disc $37^0C \pm 2^0C$
Coated Tablet	NMT 30 min, In water with Disc for **Film Coated Tab**, and NMT 60 min Other than Film coated tablet
Enteric Coated Tab	Intact for 1 hr in 0.1 N HCl& disintegrate within 2 hr in Mixed 6.8 Phosphate buffer. According to USP 1 hr in Simulated gastric fluid, then in Simulated Intestinal Fluid.
Dispersible/Soluble	Within 3 min in water at $25^0C \pm 1^0C$ (**IP**) & 15 – 25^0C (**BP**)
Orodispersible	Within 1 min
Effervescent Tab	5 min in 250 ml water at 20 – 30^0C (**IP**) & 5 min in 200 ml water at 15-25^0C (**BP**)
Buccal& Sublingual	Not Applicable but dissolve within 15 – 30 min.

Dissolution Studies: [21, 22]

Dissolution is the process by which a solid solute enters a solution. In the pharmaceutical industry, it may be defined as the amount of drug substance that goes into solution per unit time under standardized conditions of liquid/solid interface, temperature and solvent composition [22-25].

Dissolution is considered one of the most important quality control tests performed on pharmaceutical dosage forms and is now developing into a tool for predicting bioavailability.

In-vitro drug release of the samples is carried out in **USP-Type II** Dissolution Apparatus (**Paddle type**) and Quantitative determination by **UV-Spectroscopic method**.

Stability Studies: [21, 22]

Stability is defined as the capacity of a drug substance or drug product to remain within the established specifications to maintain its identity, strength, quality and purity though out the retest or expiration date period.

The objective of stability study is to determine the shelf life, namely the time period of storage at a specified condition within which the drug product still meets its established specifications. Stability is an essential factor of quality, safety and efficacy of a drug product. A drug product, which is not of sufficient stability, can result in changes in physical (like hardness, dissolution rate, phase separation etc) as well as chemical characteristics (formation of high risk decomposition substances).

The Chemical stability of drug is of great importance since it becomes less effective as it undergoes degradation. Also drug decomposition may yield toxic byproducts that are harmful to the patient.

Stability testing provides evidence that the quality of drug substance or drug product changes with time under the influence of various environmental conditions such as temperature, relative humidity etc.

The stability study consists of a series of tests in order to obtain an assurance of stability of a drug product, namely maintenance of the drug product packed in specified packaging material and stored in the established storage condition within the determined time period.

The International Conference on Harmonization (ICH) Guidelines describes the following stability test storage conditions:

Long-term Testing : $25^oC \pm 2^oC/60\%$ RH ± 5% RH for 12 Months.
Intermediate Testing : $30^oC \pm 2^oC/65\%$ RH ± 5% RH for 12 months.
Accelerated Testing : $40^oC \pm 2^oC/75\%$ RH ± 5% RH for 6 Months.

Procedure:

Accelerated stability studies on promising tablets was carried out by storing 15 tablets rubber stopped vials at elevated temperature of 40 ± 2° C/ 75±5% RH (Stability chamber, Osworld) over a period of 30 days (1 month). After that , the tablets were visually examined for any physical changes, changes in drug content, disintegration time, hardness, friability and *invitro* dissolution profile.

RESULTS AND DISCUSSION

1. Results:

Table No. 4: Formula for All formulations

S. No.	*Ingredients*	*F1 A*	*F1 B*	*F2 A*	*F2 B*	*F3*	*F4*	*F5*	*F6*	*F7*	*F8*	*F9*	*F10*
1	Losartan Potassium	100	100	100	100	100	100	100	100	100	100	100	100
2	Amlodipine Besilate	6.93	6.93	6.93	6.93	6.93	6.93	6.93	6.93	6.93	6.93	6.93	6.93
3	Mannitol (pearlitol 25 C)	24	24	24	24	24	24	-	24	24	24	24	24
4	cellulose,Microcrystalline (Avicel PH101)	157.57	157.57	157.57	157.57	157.57	233.57	181.57	171.57	171.57	161.57	151.57	143.57
5	Dicalcium phosphate dehydrate (Calipharm D)	76	76	76	76	76	-	76	76	76	76	76	76
6	Povidone (plasdone K29/32)	9.5	9.5	9.5	9.5	9.5	9.5	9.5	9.5	9.5	9.5	9.5	9.5
7	cross carmellose sodium (Ac-di-sol)	12	12	12	12	12	12	12	6	0	8	14	14
8	Isopropyl alcohol	-	QS	QS	QS	-	Qs	QS	QS	QS	QS	QS	QS
9	Purified water	QS	-	-	-	-	-	-	-	-	-	-	-
	Extragranular												
10	cross carmellose sodium (Ac-di-sol)	8	8	8	8	8	8	8	0	6	8	12	20
11	Colloidal silicone dioxide	3.6	3.6	3.6	3.6	3.6	3.6	3.6	3.6	3.6	3.6	3.6	3.6
12	Magnesium stearate (Ferro-VG)	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4	2.4
	total core tablet weight	400	400	400	400	400	400	400	400	400	400	400	400
13	Coating compostion	-		12	12	12	12	12	12	12	12	12	12
14	IPA	-		Qs	-	-	-	-	-	-	-	-	-
15	water	-		-	QS	QS	QS	QS	QS	QS	QS	QS	QS
	Coated tablet weight	-		412	412	412	412	412	412	412	412	412	412

Note: All values in mg/tablet.

Table No. 5: Solubility studies

S. No.	Buffer	Solubility of Amlodipine Besylate (mg/ml)				Solubility of Losartan Potassium (mg/ml)			
		Trial 1	*Trial 2*	*Trial 3*	*Avg*	*Trial 1*	*Trial 2*	*Trial 3*	*Avg*
1	pH of 1.5 HCl	0.62	0.52	0.58	0.57	0.27	0.98	1.20	0.82
2	pH of 3.0 acetate buffer	0.92	1.03	0.93	0.96	66.14	73.82	71.36	70.44
3	pH of 4.5 acetate buffer	1.08	1.14	1.13	1.12	284.52	296.33	289.12	289.99
4	pH of 5.5 acetate buffer	1.26	1.19	1.28	1.24	327.21	330.45	325.41	327.69
5	pH of 6.8 phosphate Buffer	0.32	0.36	0.34	0.34	330.54	326.89	333.52	330.32
6	pH of 7.4 phosphate Buffer	0.29	0.31	0.32	0.31	389.32	396.43	388.67	391.47

Table No. 6: The Flow properties of API's

Property	Amlodipine besylate	Losartan potassium
Bulk density (g/ml)	0.480	0.40
Tapped density (g/ml)	0.680	0.67
Compressibility index(%)	29.41	28.64
Hausner's ratio	1.41	1.32

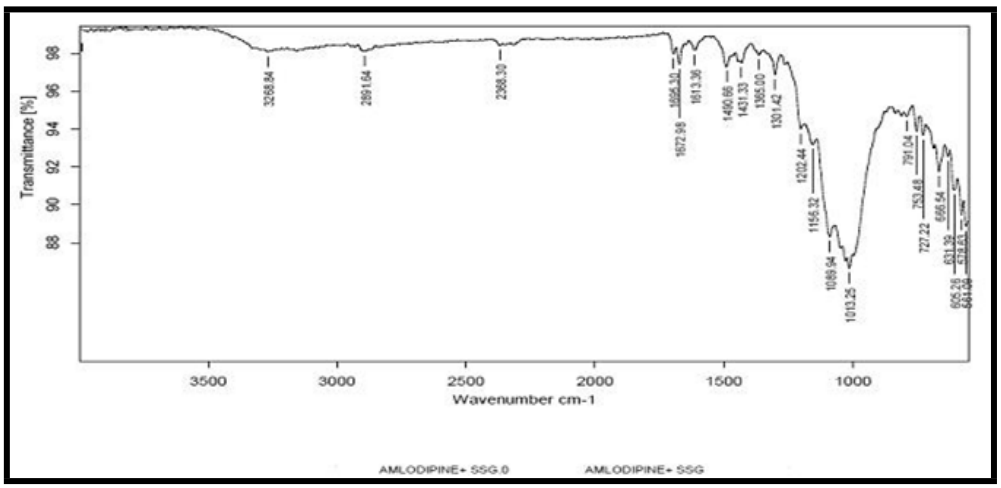

Fig. 1: FTIR studies of Amlodipine

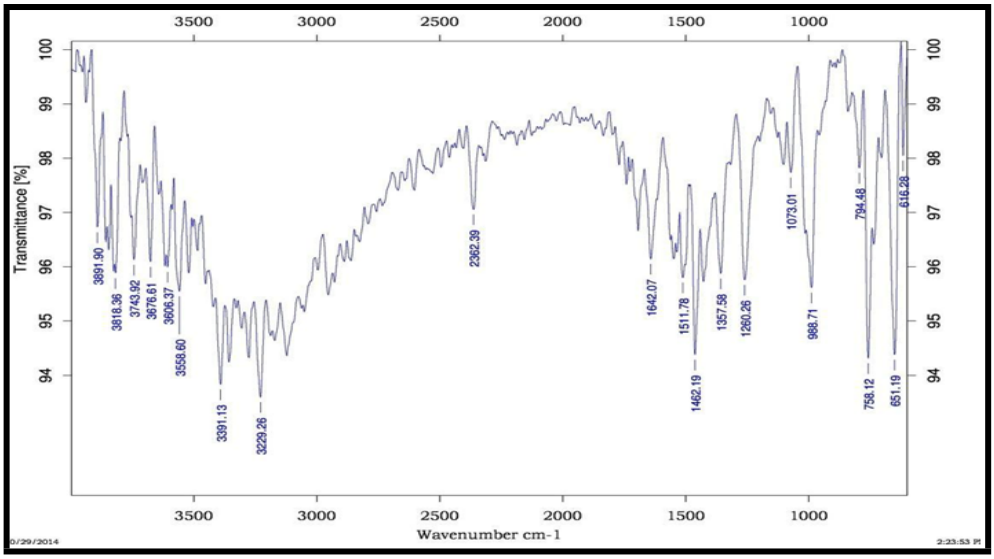

Fig. 2: FTIR spectrum of Losartan Potassium

Table No. 7 : Drug- Excipient compatibility studies at 40°C/75% RH

S. No	Name of the ingredient	A:L:E ratio	Initial		15 Days		1 Month		Compatibility
			A	B	A	B	A	B	
1	Amlodipine besilate	-	W	W	W	W	W	W	-
2	Losartan potassium	-	W	W	W	W	W	W	-
3	Amlodipine besilate + Losartan Potassium	1:10	W	W	W	W	W	W	Compatible
4	Microcrystalline cellulose	1:10:20	W	W	W	W	W	W	Compatible
5	Dibasic calcium phosphate	1:10:20	W	W	W	W	W	W	Compatible
6	Sodium starch glycolate	1:10:05	W	W	W	W	W	W	Compatible
7	Croscarmellose sodium	1:10:05	W	W	W	W	W	W	Compatible
8	Pregelatinized starch	1:10:10	W	W	W	W	W	W	Compatible
9	Povidone	1:10:05	W	W	W	W	W	W	Compatible
10	Magnesium stearate	1:0:0.5	W	W	W	W	W	W	Compatible
11	Sodium stearylfumarate	1:0:0.5	W	W	W	W	W	W	Compatible
12	Colloidal silicone dioxide	1:0:0.5	W	W	W	W	W	W	Compatible
13	Hydroxyl propyl cellulose	1:0:0.5	W	W	W	W	W	W	Compatible
14	Hydroxyl propyl methyl Cellulose	1:0:0.5	W	W	W	W	W	W	Compatible
15	Talc	1:0:0.5	W	W	W	W	W	W	Compatible
16	Titanium dioxide	1:0:0.5	W	W	W	W	W	W	Compatible
17	PEG 400	1:0:0.5	W	W	W	W	W	W	Compatible
18	Mannitol	1:0:2	W	W	W	W	W	W	Compatible
19	Lactose anhydrous	1:10:20	W	W	W	Y	W	Y	Not Compatible
20	Cross povidone	1:10:05	W	W	W	W	W	W	Compatible

Note:-WM: without moisture,5%M:5% moisture, W: white, Y:yellow.

Table No. 8: Lubricated Blend Properties

Formulation	Blend Property				
	B.D (gm/ml)	T.D (gm/ml)	C.I (%)	H.R	Property
F1	0.710	0.873	19.714	1.251	Fair
F2	0.710	0.873	19.714	1.251	Fair
F3	0.483	0.681	29.03	1.409	Passable
F4	0.483	0.681	29.03	1.409	Passable
F5	0.461	0.714	35.385	1.548	Fair
F6	0.461	0.714	35.385	1.548	Fair
F7	0.500	0.600	23.22	1.295	Passable
F8	0.500	0.600	23.22	1.295	Passable
F9	0.541	0.691	21.62	1.276	Passable
F10	0.541	0.691	21.62	1.276	Passable

Table No. 9: Comparison of Related substances of initial batches

Formulation	Related substances (%)	
	Initial at RT	After 7 days at 50°C
F1A	0.45	0.68
F1B	0.29	0.43
F2A	0.32	0.36
F2B	0.33	0.37
F3	0.52	0.72

Table No. 10: Physical Evaluation (Core tablet)

Formulation	Avg. Weight (Mean± S.D) (n=20)	Hardness (kg/cm²) (n=3)	Friability (n=20)	Disintegration time (min' sec")
F1A	410±5.64	6.2±0.2	0.206	9' 15"
F1B	406±4.24	6.5±0.2	0.212	9' 23"
F2A	394±5.23	6.6±0.1	0.227	8'54"
F2B	402±6.14	6.8±0.2	0.111	8'48"
F3	398±3.15	6.8±0.2	0.225	8'52"
F4	404±4.87	7.±0.4	0.155	9'02"
F5	394±3.65	7±0.2	0.211	9'26"
F6	392±4.22	6.8±0.5	0.202	12'43
F7	399±5.42	6.7±0.3	0.186	13'04"
F8	402±3.68	6.9±0.4	0.193	11'43"
F9	402±4.31	7.0±0.2	0.212	9'52"
F10	401±4.33	6.9±.03	0.198	6'48"

Table No. 11: Physical Evaluation (Film Coated tablets)

Formulation	Avg. Weight (Mean± S.D) (n=20)	Hardness (kg/cm²) (n=3)	Disintegration time (min' sec")
F2A	414±4.43	7.6±0.2	8'54"
F2B	412±5.74	7.8±0.2	8'48"
F3	409±3.85	7.8±0.3	8'52"
F4	413±3.87	8.1±0.4	9'02"
F5	411±4.45	8.2±0.2	9'26"
F6	413±4.26	7.9±0.3	12'43
F7	410±4.52	7.8±0.1	13'04"
F8	412±4.48	7.9±0.4	11'43"
F9	412±4.17	8.0±0.2	9'52"
F10	413±3.63	7.9±.03	6'48"

Table No. 12: In-vitro Dissolution profile of Amlodipine Besylate

Time (min)	Innovator	F2B	F3	F4	F5	F6	F7	F8	F9	F10
0	0	0	0	0	0	0	0	0	0	0
5	72	32	30	31	32	19	21	27	34	46
10	83	50	52	48	53	34	38	35	55	67
15	89	62	65	63	60	46	45	50	66	86
20	91	71	69	71	72	53	59	66	75	92
30	96	78	81	82	79	69	71	74	87	94
45	97	88	89	92	92	84	86	85	93	96
60	98	95	96	97	97	92	95	95	97	97

Table No. 13: In-vitro Dissolution profile of Losartan potassium

Time (min)	Innovator	F2B	F3	F4	F5	F6	F7	F8	F9	F10
0	0	0	0	0	0	0	0	0	0	0
5	16	10	9	12	11	8	9	11	12	14
10	45	23	26	35	30	16	18	30	37	43
15	69	47	40	54	52	37	36	43	60	65
20	86	59	60	68	66	55	53	60	78	81
30	96	72	78	80	81	68	70	76	87	90
45	98	90	90	92	94	95	94	95	94	96

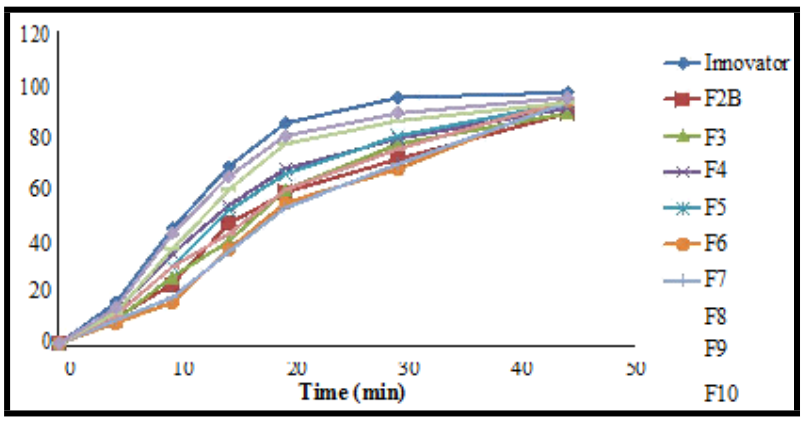

Fig. 3: Comparison of Dissolution profile of Losartan Potassium in Formulations with Innovator

Table No. 14: Comparison of Similarity and dissimilarity factors of Formulations with innovator (Losartan potassium)

Factor/Formulation	F2b	F3	F4	F5	F6	F7	F8	F9	F10
Similarity Factor (f1)	31	31	40	38	26	26	52	52	66
Difference Factor (f2)	22	22	14	15	26	26	8	8	4

Table No. 15: Stability condition % Assay results of F9 and F10

Stability condition	Description	F9		F10	
		AB	LP	AB	LP
Room temperature Initial	Light white colored film coated Tablets	99.3	99.72	99.52	99.76
40° C / 75% RH (1 month)	Light white colored film coated Tablets	98.69	98.47	98.79	98.62
40° C / 75% RH (2 month)	Light white colored film coated Tablets	97.85	97.93	98.10	98.16

Note: AB-Amlodipine Besylate; LP-Losartan Potassium.

Table No. 16: In-vitro Dissolution profile of Amlodipine in optimized formulation F10 at 40°C and 75% RH

Time (min)	Innovator	1 month	2 months
0	0	0	0
5	16	15	13
10	45	43	42
15	69	67	65
20	86	84	82
30	96	93	91
45	98	95	95
60	98	97	97

Table No. 17: In-vitro Dissolution profile of Losartan potassium in optimized formulation F10 at 40°C and 75% RH

Time(min)	Innovator	1month	2 month
0	0	0	0
5	72	70	68
10	83	82	79
15	89	89	86
20	91	90	90
30	96	95	93
45	97	96	95
60	98	98	97

DISCUSSION

The purpose of formulation of Amlodipine and Losartan potassium Immediate release tablets 5/100 mg was to provide treatment of hypertension effectively by the synergistic effect of Calcium channel blocker i.e., amlodipine and Angiotensin II inhibitor i.e., Losartan potassium.

From the results of solubility studies , Amlodipine has maximum solubility in the pH range of 3-5.5(1-1.3mg/ml). solubility is low pH<2 and pH>6.However the solubility is sufficient to be classified as highly soube drug as per BCS classification (10 mg of dose is souble in 250 ml of buffers of pH1-7.4).

Solubility of losartan potassium was also found to be pH dependent and increases as the pH increases. Solubility at pH 1.5 was low (0.27 mg/ml)and was maximum at pH 7.4 (477.48 mg/ml).As per BCS classification, at low dose (50 mg), losartan can be classified as highly soluble and at high dose 100 mg it falls under low soluble category.

In the initial stage of development a single prototype was taken and experiments were conducted. In the F1 the wet granulation process was followed and is done by using water as a granulating agent in F1A and Isopropyl alcohol as a granulating agent in F1B. The best suited process is selected by analyzing the tablets for % of Related substances initially and after 7 days storing in 50°C.

Then the selected formulation was coated with opadry white dispersed in isopropyl alcohol in F2A and water in case of F2B and the tablets were analyzed for % of Related substances initially and after 7 days storing in 50°C . The results shown that coating dispersion with water and isopropyl alcohol was similar hence it was decided to go with dispersion in with water. The selected F2B was compared with the direct compression batch coated with Opadry white dispersed in water and related substances were analyzed.

Then the diluent combination was selected by comparing formulations containing soluble diluent Mannitol in F4 and insoluble diluent Dicalcium phosphate dihydrate in F5 along with microcrystalline cellulose as another diluent in common.

Then disintegrant concentration was optimized by taking Croscarmellose sodium at intra granular or extra granularly and/or both in the F6-F10.Disintegrant Croscarmellose sodium wasadded in intra granular portion (1.5%) in F6 , and (1.5%) extra granular portion in F7, and F8 contains disintegrant in both intragranular(2%) and extragranular(2%) portions. Formulation F9 contains concentrations of disintegrating agent 3.5% intra granular portion and 3% extra granular portion. The dissolution profile Losartan potassim in F9 was near to innovator and further F10 was taken by including Croscarmellose sodium 5% extra granular and 3.5% intra granular concentrations were used.

All the tablets were prepared under similar conditions. The values of pre- compression parameters evaluated were found to be within prescribed limits indicating good flow properties. The data obtained for post compression parameters such as weight variation, thickness, hardness, friability are shown in table . Hardness was found to be in range of kp in all the formulations indicating good mechanical strength. In all the formulations the friability value was less than 0.5 % giving an indication that tablets formulated are mechanically stable. % weight variation was within the limits. The disintegration of different formulations complies with the pharmacopeia specifications.

The stability study was performed for F9 and F10 formulations as per ICH guidelines. Stability study was carried out for 2 months at 40°C/75%RH. The tablets were tested for release and results were found within the limits. Among the all formulations the release profile of trial **F10** was found to be similar to the marketed product release profile.

SUMMARY AND CONCLUSION

1. Summary:

The summary of the study is as follows:

- In the pre formulation studies, solubility, drug-excipient compatibility and flow properties of API were studied.
- All formualtions were prepared by wet granulation method by using microcrystalline cellulose, povidone, Dicalcium phosphate dihydrate, mannitol, colloidal silicon dioxide, and magnesium stearate. On direct compression batch was taken and results were compared with wet granulated batch of same composition. Film coating was done by using Opadry white to protect Losartan potassium from moisture.
- The tablets prepared were found to be within the official limits with respect to weight variation, thickness, hardness, friability, disintegration and dissolution.
- The stability study was performed for F6 formulation as per ICH guidelines. Stability study was carried out for 2 months at 40°C/75%RH. The tablets were tested for release and results were found within the limits.
- Among the all formulations the release profile of trial F10 was found to be similar to the marketed product release profile.

2. Conclusion:

Attempts were made in the present investigation to develop a pharmaceutically stable formulation of Amlodipine and Losartan potassium immediate release tablets. Amlodpine and Losartan potassium were indicated for the treatment of hypertension. In this study, Amlodipine and Losartan potassium immediate release tablets were formulated by wet granulation method and moisture protective film coating was given. These results clearly reflect that the prepared formulation releasing the drug immediately within the specifications. The final formulation also shows good comparative dissolution profile with marketed preparation.

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How to cite this article:

Venkatesh Naik S et al.,: Formulation and Evaluation of Immediate release Amlodipine Besylate and Losartan Potassium Film coated Tablets, J. Pharm. Res., 2015; 4(12): 399-405**.**

Conflict of interest: The authors have declared that no conflict of interest exists.

Source of support: Nil