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Design and evaluation of amlodipine and losartan potassium immediate release tablets by direct compression method

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Abstract

The principle objective of this investigation was to formulate hypertensive medications Amlodipine and Losartan as a quick discharge tablets. The errand of immediate disintegration tablet is formulated by utilizing an appropriate excipient and super disintegrants. Immediate disintegration of tablets administrated orally limits retention time and improves its bioavailability in less time. the easiest new restorative substance inside the world is of little incentive without a fitting conveyance framework. Tableted drug delivery systems can varies from relatively simple immediate – release formulations to complex extended- or modified release dosage forms. The tablets thus previously formulated elicted a satisfactory physical parameter and it had been resulted with stability. The study includes preformulation studies of drug and excipients, formulation and processing development alongside evaluation of tablets made with the optimized formulation. Finally film coated tablets were evaluated by invitro methods. The results supports the feasibility of developing immediate tablets consisting of Amlodipine and Losartan for the convenience of patients with cardiac disorders.

Keywords: Losartan, Diluents, Immediate release.

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INTRODUCTION

The tablet is that the most freuently used dosage form due to its convenience regarding self-administration, compactness, and ease in manufacturing. However, geriatric and pediatric patients experience discomfort mainly in swallowing conventional tablets, which ended in poor patient compliance. To overcome this weakness, scientists have developed Novice drug delivery systems referred to as "melt in mouth" or "mouth dissolve (MD)" tablets. These are novice sorts of tablets that disintegrate/dissolve/disperse in saliva. Their features advantages like administration without water, anywhere, anytime, cause their acceptability to geriatric and pediatric patients they're also suitable for the unsound , the sicken, and patients who don't have quick access to water. The positive note , in terms of patient compliance, Fast onset of action, increased bioavailability, and good stability, make these tablets popular as a dosage sort of choice within the current market [1,2].

Amlodipine (AD) belongs to the group of calcium channel blockers. The newer calcium channel blockers like dihydropyridines, AD, felodipine, and nisoldipine has improved vascular selectivity and longer durations of action. Their main goal was on receptors during a slow and sustained pattern resulting a smooth onset of action with a 24 h control of vital sign . once in a day dosing of those longer acting calcium channel blockers improves patient compliance and is related to minimum encounter of side effects. The calcium channel blockers are selective for a good range of hypertensive patients including the elderly, black, and people with concomitant diseases that preclude the utilization of other antihypertensives [3].

AD is usually used in the treatment of heart diseases like angina and hypertension [4]. Efforts are made to develop various dosage sorts of AD to enhance its efficacy and stability. Therefore, a comprehensive review of varied formulations of AD reported within the literature has been made which might be useful for pharmaceutical scientists and formulators has identified and developed the foremost suitable dosage sort of AD.

Losartan potassium may be a competitive AT1 angiotensin II receptor antagonist. angiotensin II helps to take care of constant vital sign despite fluctuations during a person's state of hydration, sodium intake and other physiological variables. angiotensin II also performs the regulatory tasks of inhibiting excretion of sodium by the kidneys, inhibiting norephedrine reuptake and stimulating aldosterone biosynthesis. By inhibiting angiotensin II binding to AT1 receptors, losartan disrupts the vasoconstriction mediated by

AT1 receptors. vasoconstriction by angiotensin II has been blocked which is beneficial to patients with hypertension [3]. In the present study losartan potassium immediate release tablet was formulated by following direct compression method.

MATERIALS AND METHODS

Amlodipine besylate, mannitol, microcrystalline cellulose and croscarmellose sodium was obtained from Aizant Drug research solutions pvt. ltd, Roquette pharma and FMC Bio polymer, Mumbai.

Procedure for formulation

In initiative step ,Co-sifting of Amlodipine and Losartan potassium with small quantities of MCC using # 30 ASTM sieve and Mixing remaining MCC with other excipients except lubricants are sifted through 30 ASTM sieve. In Step 2 all ingredients of step 1 are mixed and skilled 30 ASTM sieve. Blending of the above sifted mass for 20 min at 16 rpm is completed .Aerosil was added which was pre sifted through 40 ASTM to the above and blend for 16 rpm for 05 min then Add Magnesium stearate which was pre sifted through 40 ASTM to the blend of above step at 16 rpm for 03 mi. Finally, tablets are compressed with above blend using 11 mm round shaped flat punches in D-toolin [5].

Statistical Analysis

Data were presented as means ± variance (SD). SPSS version 12 was used for statistical analysis. A -test and therefore the one-way ANOVA were performed to look at the differences among the groups.

RESULTS AND DISCUSSIONS

The present study was allowed to formulate Amlodipine and Losartan potassium film coated tablets. The study included preformulation studies of drug and excipients, formulation and processing development alongside evaluation of tablets made with the optimized formulation. Finally film coated tablets were evaluated by invitro methods.

Evaluation of tablets

Table 1: Physical Evaluation (Core tablet)

Formulation	Avg. Weight (Mean± S.D) (n=20)	Hardness (kg/cm^2) (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''

Weight Variation: 20 tablets were weighed; then the upper limit (HL) and lower limit (LL) were calculated as follows: [6,7]

Friability Test: The tablets of this product were weighed, then put within the instrument for 4 minutes, then weighed again. then, the subsequent were calculated: Limit for compressiontablets: less than 1% [6]

Hardness Test: Ten tablets were put in specific place and fixed; then turn it on and wait until the fraction occurs. The limit is 4–8 kg/cm^2 [6].

Disintegration Time Test: The disintegration time is calculated using disintegrator using water as media and therefore the limit of tablet is 5–30 minutes [6].

Statistical Analysis

Data were presented as means ± variance (SD). SPSS version 12 was used for statistical analysis. A -test and therefore the one-way ANOVA were performed to look at the differences among the groups.

Table 2: *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 3: *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

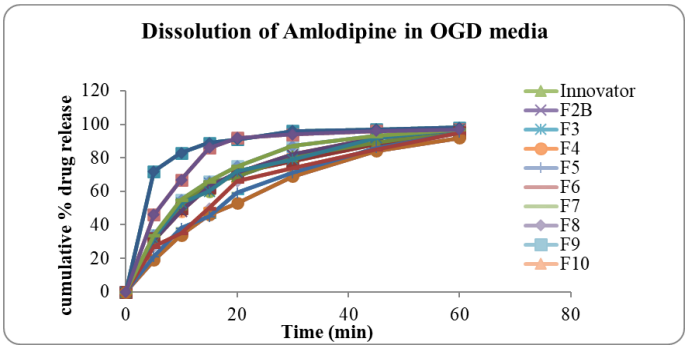

Fig 1: Dissolution of Amlodipine

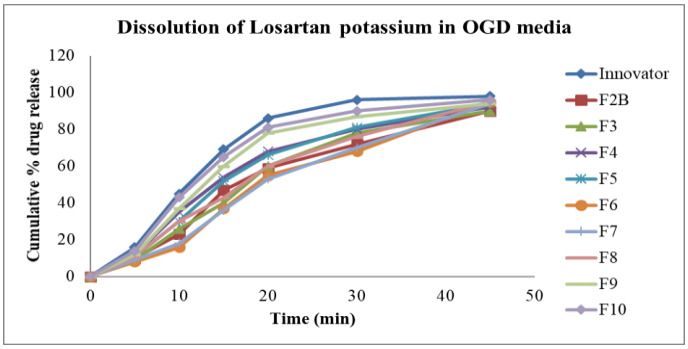

Fig 2: Dissolution of Losartan potassium

CONCLUSION

API studies include pre formulations, solubility, drug-excipient compatibility and flow properties. Direct compression batch is done for all Formulated preparation and compared with wet granulated batch of same composition. Opadry white is used for Film coating to guard Losartan potassium from moisture. The tablets prepared were found to be within the official limits with reference to weight variation, thickness, hardness, friability, disintegration and dissolution. Among the all formulations prepared the discharge profile of trial F6 (Table- 2 & 3) was found to be almost like the marketed product release profile.

Conflict of interest

The authors declare no conflict of interest.

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