RESEARCH ARTICLE

Formulation and Evaluation of Fast Dissolving Tablets of Lisinopril

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Abstract

Objective: The current study's objective is to develop and evaluate fast-dissolving tablets (FDT) of lisinopril. Lisinopril, an angiotensin converting enzyme inhibitor (ACEI), prevents the conversion of angiotensin I to angiotensin II. To improve patient compliance, making convenience is crucial. hence an effort was made by formulating it as the fast dissolving tablet to reduce the water intake for chronic kidney patients suffering from hypertension.

Methods: Using various quantities of Vivasol & Explotab as Superdisintegrants, FDT formulations of lisinopril were prepared utilizing the Direct Compression technique. Nine trials were developed and assessed for Pharmaceutical Product Performance.

Results: Findings indicate that all formulations meet the acceptance criteria, and kinetic modeling was applied to the in-vitro dissolution profiles.

Conclusion: The best formulation (F1), which contained 5 mg of Vivasol and 5 mg of Explotab, showed promising results for obtaining quicker disintegration and may produce patient compliance by means of rapid onset of action and preventing the first-pass effect too. Formulation (F1) follows first order (r= 0.934), whereas the release mechanism is found to be Fickian type (n= 0.267).

Keywords: Lisinopril, superdisintegrants, Explotab, Vivasol, Fickian.

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Introduction

The pharmaceutical market gives fast-dissolving tablets (FDT) a unique place. FDT was regularly replaced with oral disintegrating tablets, melt-in-the-mouth pills and oral/mouth dissolving Tablets.[1]

Rapid disintegrating tablets can be readily available for disintegration; they breakdown in the mouth within 60 seconds. Based on the manufacturing process, they show changes in typical organoleptic features, including masking sweetness or taste and better palatability. Additionally, they show changes in quality control metrics like breaking index, drug release from formulation, stability, and clinical results. FDTs can be prepared using a variety of procedures, some of which are the cotton candy process, granulation techniques, named technologies (Durasolv, Orosolv), spray drying, trituration, molding, lyophilization/freeze drying, and mass extrusion.

Lisinopril is a selective ACE Inhibitor, preventing the conversion of angiotensin I to angiotensin II. This action prevents myocyte hypertrophy and vascular smooth muscle cell proliferation seen in untreated patients. Increased levels of bradykinin also exhibit vasodilating effects for patients taking ACEIs. Lisinopril also inhibits renin's conversion of angiotensin to angiotensin I. Hence, an effort was made to enhance its absorption by formulating it as the fast dissolving tablet. The objective of the present work is to develop fast-dissolving lisinopril tablets and to study the effect of functionality differences of super disintegrants (Vivasol, Explotab) on the tablet properties.[2-5]

Tablets by direct compression techniques have a unique nature in the form of less time consumption, rapid production, and economy in the operational management among the many methods of manufacturing techniques available.[1]

Materials and Methods

Materials

Lisinopril was a gift sample procured from Microgen Pharma Pvt Ltd, India. Avicel, Explotab, and Vivasol were procured

from Aman Scientifics, India. Other excipients were procured from High Chemie Ltd, India.

Preparation of Lisinopril Fast-Dissolving Tablets

The direct compression approach was used in the production of lisinopril FDT as per the formulae presented in Table 1. All the ingredients were mixed step by step with the drug and triturated continuously for 15 minutes. Subsequently, aerosil and magnesium stearate were mixed and passed through a sieve no—#60. The powder was compressed using 8 station rotary tablet punching machine (RIMEK minipress) using 8 mm circular punches and same hardness was used for the required number tablets. In-Process Quality Control (IPQC) tests were performed on the acquired tablets. For storage and subsequent processing, finished tablets were transferred to airtight, light-resistant containers.[5]

Evaluation of Lisinopril Fast Dissolving Tablets

Hardness

It was carried out with the help of the Monsanto Tablet Hardness Tester.

Friability/ Durability

Twenty tablets were weighed and noted as W_0 cumulatively (Initial weight). The pills were then dedusted with a Roche Friabilator for 4 minutes at a speed of 25 rpm, and weighed again, recorded as (W). The following equation was used to obtain the percentage of friability (%Friability ≤1).

$$\text{Friability (\%)} = (W_0 - W) / W_0 \times 100$$

Assay

About 20 tablets were chosen and ground in an impartial manner. The powder corresponding to 100 mg of lisinopril was weighed, added to a 100 mL volumetric flask with 60 mL of Phosphate Buffer Solution (PBS) pH 6.8, and then sonicated for 10 minutes to completely solubilize the medication. The resulting solution was then diluted with Phosphate Buffer Solution (PBS) pH 6.8 to make up the required volume. The concentration was diluted to 10 µg/mL. Using a UV-visible spectrophotometer, the resulting solution was analyzed for its absorbance at 220 nm.

Thickness

It was measured with the help of vernier calipers.

Table 1: Formulae for the Preparation of Lisinopril Fast Dissolving Tablets

Name of Ingredients	*Quantity of Ingredients per each tablet (mg)*								
	F_1	F_2	F_3	F_4	F_5	F_6	F_7	F_8	F_9
Lisinopril	10	10	10	10	10	10	10	10	10
Avicel PH 102	38	38.5	39	38.5	39	39.5	39	39.5	40
Pearlitol 200 SD	38	38.5	39	38.5	39	39.5	39	39.5	40
Vivasol	5	4	3	5	4	3	5	4	3
Explotab	5	5	5	4	4	4	3	3	3
Aerosil	2	2	2	2	2	2	2	2	2
Magnesium Stearate	2	2	2	2	2	2	2	2	2
Total Weight	100	100	100	100	100	100	100	100	100

Table 2: Post-Compression Parameters

Formulation Code	*Hardness (kg/cm2)*	*Thickness (mm)*	*Friability (%)*	*Average Weight (mg)*	*Drug Content (%)*	*Wetting Time (sec)*	*Disintegration Time (sec)*
F1	3.6 ± 0.265	2.7 ± 0.02	0.37 ± 0.01	100.05 ± 0.62	98.44 ± 0.5	38 ± 1.09	29.5 ± 0.4
F2	3.65 ± 0.26	2.71 ± 0.03	0.33 ± 0.01	100.65 ± 1.09	98.975 ± 1.04	38.5 ± 1.08	31 ± 0.36
F3	3.55 ± 0.25	2.71 ± 0.02	0.32 ± 0.01	101.425 ± 1.15	99.1 ± 0.92	40.5 ± 1.17	33 ± 0.5
F4	3.7 ± 0.255	2.71 ± 0.04	0.34 ± 0.02	101.675 ± 0.61	98.065 ± 0.77	39 ± 1.11	31 ± 0.36
F5	3.75 ± 0.25	2.71 ± 0.05	0.3 ± 0.01	102.275 ± 1.08	98.6 ± 1.3	39.5 ± 1.1	32.5 ± 0.31
F6	3.65 ± 0.24	2.71 ± 0.04	0.29 ± 0.01	103.05 ± 1.14	98.725 ± 1.19	41.5 ± 1.19	34.5 ± 0.45
F7	3.55 ± 0.25	2.70 ± 0.02	0.36 ± 0.01	100.4 ± 0.56	98.14 ± 0.59	40 ± 1.18	33 ± 0.59
F8	3.6 ± 0.245	2.71 ± 0.034	0.32 ± 0.01	101 ± 1.03	98.675 ± 1.12	40.5 ± 1.18	34.5 ± 0.54
F9	3.5 ± 0.235	2.70 ± 0.02	0.31 ± 0.01	101.775 ± 1.09	98.8 ± 1.01	42.5 ± 1.27	36.5 ± 0.68

Table 3: Statistical Parameters

S. No	Formulation code	Kinetic Parameters											
		Zero Order			First Order			Higuchi			Korsmeyer-Peppas		
		A	B	R	A	B	R	A	B	R	A	B	R
1	F1	34.698	1.592	0.802	1.812	0.019	0.934	13.548	13.193	0.950	1.529	0.267	0.984
2	F2	34.701	1.541	0.791	1.802	0.018	0.911	13.858	12.863	0.945	1.531	0.260	0.977
3	F3	34.522	1.490	0.782	1.798	0.016	0.895	14.073	12.513	0.940	1.532	0.253	0.973
4	F4	34.172	1.536	0.796	1.809	0.017	0.918	13.567	12.780	0.947	1.527	0.260	0.981
5	F5	34.175	1.485	0.784	1.801	0.016	0.895	13.878	12.450	0.941	1.529	0.253	0.974
6	F6	33.996	1.434	0.775	1.798	0.015	0.878	14.092	12.101	0.936	1.530	0.246	0.968
7	F7	32.394	1.532	0.809	1.824	0.017	0.920	12.310	12.624	0.953	1.495	0.275	0.981
8	F8	32.397	1.480	0.797	1.817	0.015	0.898	12.621	12.295	0.947	1.497	0.268	0.974
9	F9	32.218	1.429	0.789	1.815	0.014	0.884	12.835	11.945	0.943	1.498	0.261	0.970

Wetting time

Tablets were placed on a petri dish containing paper that had been soaked in 5mL of distilled water to measure the wetting time of the tablets. The tablet's wetting time was measured in seconds.

In-vitro Dissolution Study

Lisinopril FDT was analyzed for drug release study utilising a Lab-India USP type-II tablet dissolution test apparatus and 900 mL of PBS pH 6.8 in accordance with the official method. Using a UV-visible spectrophotometer, the samples' absorbance was measured at 220 nm and the data were subjected to kinetic modeling.[6,7]

Disintegration test

According to the guidelines of the modified disintegration test for tablets, this test was conducted. Only 2 mL of medium was allowed to fall below the sieve in a cylindrical cylinder with 10 #. Time of disintegration was noted.[8]

Results and Discussion

Over 9 different formulations of Lisinopril fast dissolving tablets were prepared utilizing the direct compression method using varying ratios of super disintegrants in accordance with the formulae shown in Table 1. Pharmaceutical product performance tests were conducted on the developed formulations. Table 2 displayed the information.

Table 4: Kinetic Parameters

Formulation code	Kinetic/ Dissolution Parameters (min)				
	t10%	t25%	t1/2	t75%	t90%
F1	2.361	6.446	15.533	31.066	51.616
F2	2.601	7.101	17.111	34.221	56.858
F3	2.847	7.772	18.728	37.456	62.234
F4	2.636	7.198	17.345	34.691	57.639
F5	2.884	7.874	18.974	37.949	63.052
F6	3.142	8.579	20.673	41.346	68.696
F7	2.760	7.535	18.155	36.311	60.331
F8	3.005	8.205	19.772	39.544	65.702
F9	3.263	8.910	21.470	42.939	71.343

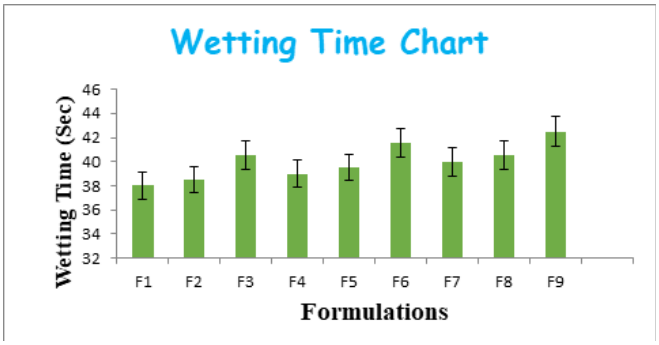

Figure 1: Wetting Time Chart

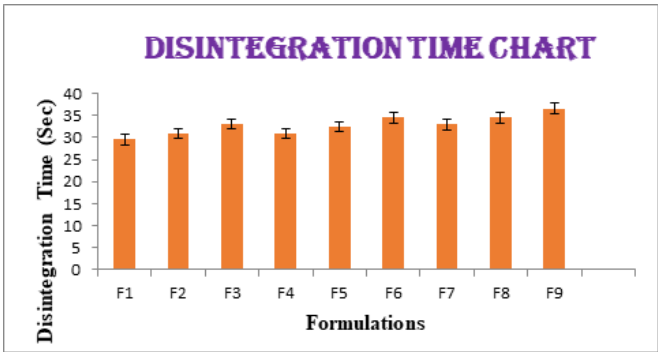

Figure 2: Disintegration Time Chart

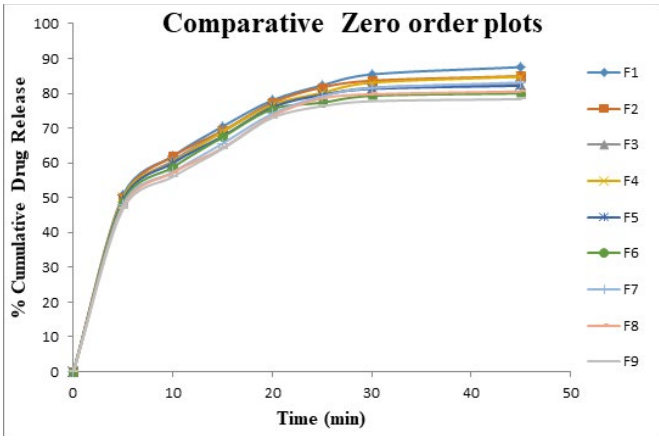

Figure 3: Comparative Zero order plots

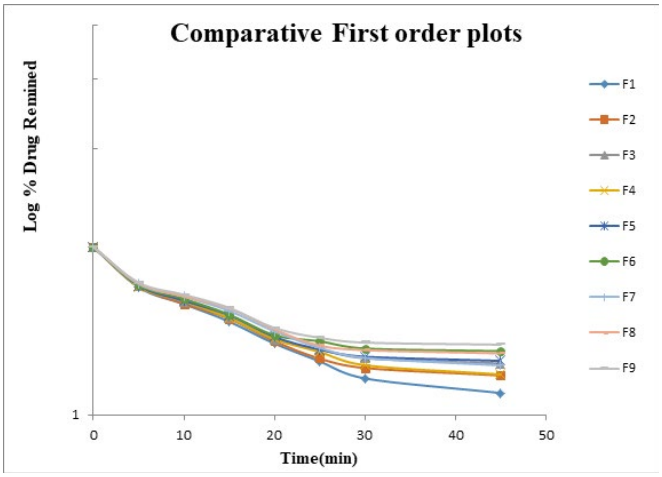

Figure 4: Comparative First order plots

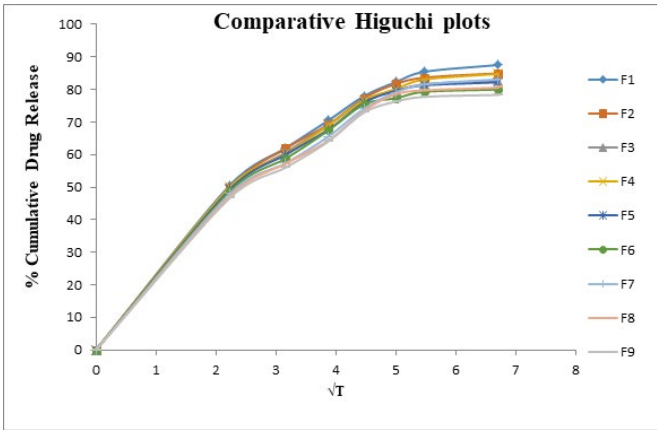

Figure 5: Comparative Higuchi plots

All tablets were discovered to be less brittle and to have acceptable mechanical strength. The produced tablets' uniformity of weight and drug content were both within acceptable ranges. All the formulations showed wetting time in the range of 38 ± 1.09 to 42.5 ± 1.27 sec and the same was represented in Figure 1. All the formulations showed Disintegration time in the range of 29.5 ± 0.4 to 36.5 ± 0.68 sec and the same was represented as Figure 2.

Dissolution profiles of Lisinopril fast dissolving tablets were well fit to kinetic modeling, results presented in Table 3 and the same was shown in Figures 3-6.

F_1 is regarded as the best formulation among all batches (based on Desirability). F_1, which contained 5 mg of Explotab and Vivasol in equal amounts, produced promising dissolution characteristics that aid in achieving the goal of the study through faster disintegration and rapid dissolution. Table 4 provides a summary of the data for the derived kinetic parameters.

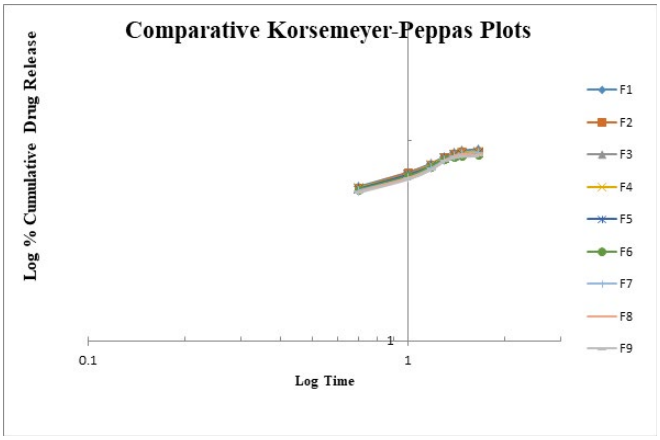

Figure 6: Comparative Korsmeyer-Peppas plots

Conclusion

The current study focuses on the impact of using superdisintegrants for the development of lisinopril FDT, such as Explotab and Vivasol. F_1 follows first-order kinetics (r = 0.934), the Higuchi model (r = 0.950), whereas the mechanism of drug release follows Fickian diffusion (n = 0.267). The kinetic parameters was observed as 2.36, 6.45, 15.53, 31.07, 51.62 minutes for $t_{10\%}$, $t_{25\%}$, $t_{50\%}$, $t_{75\%}$, $t_{90\%}$, respectively. The best formulation, F_1, may be used for the effective management of hypertension and adjuvant in the therapy of renal failure patients.

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