RESEARCH ARTICLE

Development and Characterization of Oral Disintegrating Tablets of Sitagliptin

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Abstract

Objective: The current study's objective is to develop and evaluate oral disintegrating tablets (ODT) for sitagliptin. Sitagliptin, a selective DPP-4 Inhibitor. Once DPP-4 mediated incretins are inactivated effects the glucose regulation in the body. It is necessary to develop oral disintegrating tablet addressing the specific need for convenience and enhanced drug delivery, helpful for diabetic patients with a fast-paced lifestyle.

Methods: Using various quantities of croscarmellose sodium & sodium starch glycolate as superdisintegrants, ODT formulations of sitagliptin 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 formulation F8, which is considered the best formulation, contained 5 mg of croscaramellose sodium and 7.5 mg of sodium starch glycolate. Formulation (F8) follows first order (r=0.999), whereas the release mechanism is found to be non-Fickian type (n= 0.540).

Keywords: Sitagliptin, superdisintegrants, Sodium starch glycolate, Croscaramellose sodium, non-fickian.

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Introduction

The pharmaceutical market gives oral disintegrating tablets (ODT) a unique place. ODT was regularly replaced with melt-in-the-mouth pills and fast-dissolving tablets, 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.

Sitagliptin is a DPP-4 Inhibitor. Inhibition of DPP-4 by sitagliptin slows DPP-4-mediated inactivation of incretins like GLP-1 and GIP. Incretins are released throughout the day and upregulated in response to meals as part of glucose homeostasis. Reduced inhibition of incretins increases insulin synthesis and decreases glucagon release in a manner dependant on glucose concentrations. These effects lead to an overall increase in blood glucose control, which is demonstrated by reduced glycosylated hemoglobin (HbA1c) [2-5].

Hence, an effort was made to formulate it as an oral disintegrating tablet to boost its bioavailability as well as to treat type-II diabetes mellitus and also useful for reducing the water load or burden for renal impaired patients for the same.

An attempt was made to maximize the drug delivery from formulation with the help of a combination of super disintegrants at various concentrations (Croscaramellose sodium, Sodium starch glycolate) by formulating the oral disintegrating tablets of sitagliptin. 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.

Materials and Methods

Materials

Sitagliptin was a gift sample procured from Microgel Labs Pvt Ltd, India. Microcrystalline Cellulose, Sodium starch glycolate, Croscaramellose sodium were procured from Aman Scientifics, India. Other excipients were procured from Merck Chemicals Ltd, India.

Preparation of Sitagliptin Oral Disintegrating Tablets

The direct compression approach was used in the production of Sitagliptin ODT as per the Formulae shown in Table 1. All of the components were sifted using 40 mesh (#40) to produce a uniform fine blend. Lubricants were screened through #60, combined with the mixture above, and mixed well. These blends were subjected to compression to produce ODT using a tablet minipress (8 stations) and circular punches that measure 10 mm in diameter. 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.

Evaluation of Sitagliptin oral disintegrating 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). 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 sitagliptin was weighed, added to a 100 mL volumetric flask with 60 mL

Table 1: Formulae for the Preparation of Sitagliptin Oral Disintegrating 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
Sitagliptin	100	100	100	100	100	100	100	100	100
Microcrystalline Cellulose	38	39.25	40.5	39.25	40.5	41.75	40.5	41.75	43
Mannitol	38	39.25	40.5	39.25	40.5	41.75	40.5	41.75	43
Croscaramellose Sodium	10	10	10	7.5	7.5	7.5	5	5	5
Sodium Starch Glycolate	10	7.5	5	10	7.5	5	10	7.5	5
Talc	2	2	2	2	2	2	2	2	2
Magnesium Stearate	2	2	2	2	2	2	2	2	2
Total Weight	200	200	200	200	200	200	200	200	200

Table 2: Post-Compression Parameters

Formulation Code	*Hardness (kg/cm^2)*	*Thickness (mm)*	*Friability (%)*	*Average Weight (mg)*	*Drug Content (%)*	*Wetting Time (sec)*	*Disintegration Time (sec)*
F_1	5.28 ± 0.15	2.72 ± 0.42	0.48 ± 0.01	205 ± 0.43	98.46 ± 0.49	14 ± 0.54	40 ± 0.32
F_2	5.31 ± 0.12	2.61 ± 0.45	0.3 ± 0.01	204.5 ± 0.245	98.98 ± 1.02	12.5 ± 0.44	37 ± 0.12
F_3	5.28 ± 0.4	2.54 ± 0.4	0.49 ± 0.01	204 ± 0.425	99.11 ± 0.93	14 ± 0.41	39 ± 0.31
F_4	5.09 ± 0.25	2.84 ± 0.17	0.83 ± 0.02	200 ± 0.485	98.07 ± 0.73	12.5 ± 0.17	39 ± 0.37
F_5	5.12 ± 0.22	2.73 ± 0.2	0.66 ± 0.02	199.5 ± 0.3	98.68 ± 1.32	11 ± 0.07	36 ± 0.17
F_6	5.09 ± 0.5	2.67 ± 0.15	0.85 ± 0.02	199 ± 0.48	98.73 ± 1.19	12.5 ± 0.04	38 ± 0.36
F_7	5.21 ± 0.54	2.68 ± 0.28	0.64 ± 0.01	201.5 ± 0.44	98.14 ± 0.6	12.5 ± 0.19	36.5 ± 0.48
F_8	5.24 ± 0.51	2.57 ± 0.32	0.46 ± 0.01	201 ± 0.26	98.68 ± 1.13	11 ± 0.085	33.5 ± 0.28
F_9	5.21 ± 0.79	2.5 ± 0.27	0.65 ± 0.01	200.5 ± 0.44	98.82 ± 1.03	12.5 ± 0.06	35.5 ± 0.47

Table 3: Statistical Parameters

S.NO	Formulation Code	Statistical Parameters											
		Zero order			First order			Higuchi			Korsmeyer-peppas		
		a	b	r	a	b	r	a	b	r	a	b	r
1	F_1	23.291	2.143	0.915	2.246	0.056	0.968	1.129	16.124	0.984	1.224	0.493	0.976
2	F_2	22.401	1.964	0.908	1.962	0.026	0.989	1.508	14.929	0.988	1.166	0.514	0.985
3	F_3	23.121	1.920	0.903	1.946	0.024	0.981	2.456	14.655	0.986	1.209	0.481	0.984
4	F_4	22.213	2.068	0.921	2.050	0.035	0.993	0.874	15.551	0.990	1.191	0.505	0.987
5	F_5	21.734	1.855	0.902	1.936	0.021	0.983	1.726	14.170	0.986	1.131	0.525	0.977
6	F_6	22.453	1.810	0.899	1.925	0.020	0.978	2.674	13.896	0.987	1.179	0.489	0.983
7	F_7	22.477	2.131	0.921	2.171	0.048	0.976	0.637	15.984	0.988	1.201	0.505	0.984
8	F_8	20.969	2.005	0.924	2.007	0.028	0.999	0.308	15.069	0.993	1.128	0.540	0.989
9	F_9	21.688	1.961	0.920	1.985	0.026	0.998	1.256	14.795	0.993	1.173	0.505	0.992

Table 4: Dissolution/ Kinetic Parameters

S.NO	Formulation Code	Kinetic Parameters (Min)				
		$t_{10\%}$	$t_{25\%}$	$t_{1/2}$	$t_{75\%}$	$t_{90\%}$
1	Table	0.810	2.210	5.326	10.653	17.699
2	F_2	1.782	4.866	11.726	23.452	38.965
3	F_3	1.884	5.144	12.395	24.789	41.187
4	F_4	1.308	3.570	8.603	17.206	28.588
5	F_5	2.201	6.008	14.477	28.955	48.108
6	F_6	2.304	6.291	15.159	30.319	50.375
7	F_7	0.953	2.602	6.269	12.538	20.832
8	F_8	1.618	4.418	10.645	21.290	35.374
9	F_9	1.733	4.733	11.404	22.808	37.895

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 PBS pH 6.8 to make up the required volume. Prepare a further 2 mL aliquot from that for dilution in 100 mL of PBS pH 6.8. Using a UV-visible spectrophotometer, the resulting solution was analyzed for its absorbance at 267 nm.[3-5]

Thickness

It was measured with the help of vernier calipers.

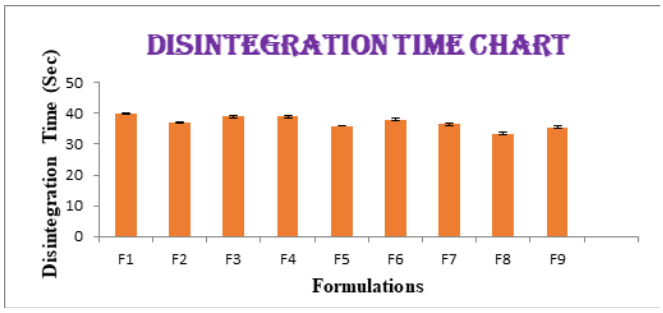

Figure 1: Wetting Time Chart

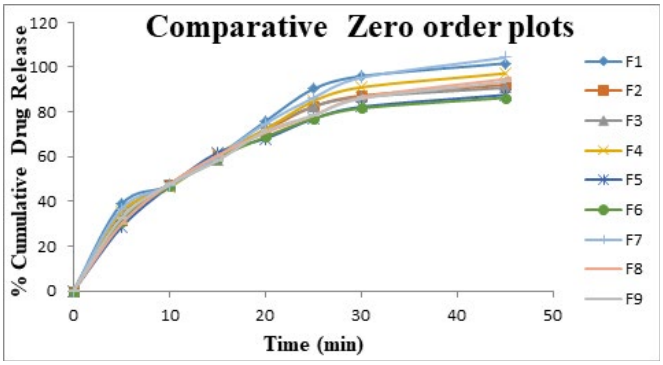

Figure 2: Disintegration Time Chart

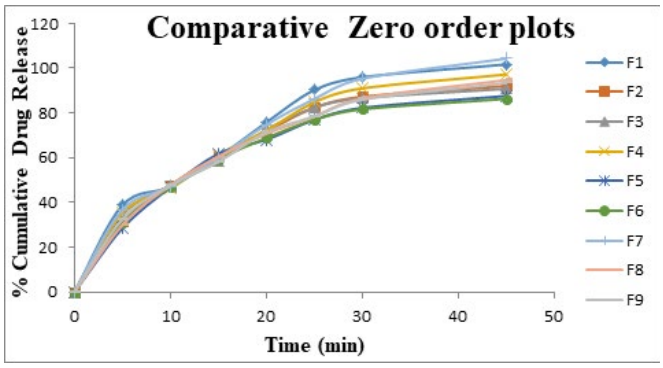

Figure 3: Comparative Zero order plots

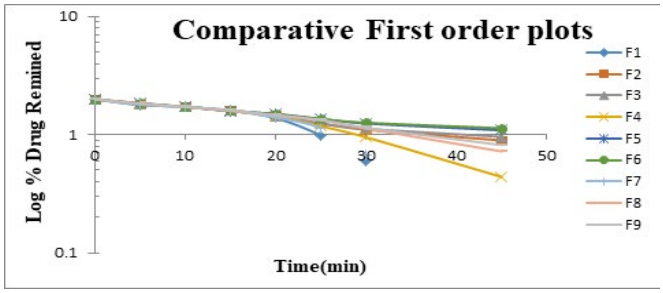

Figure 4: Comparative First order plots

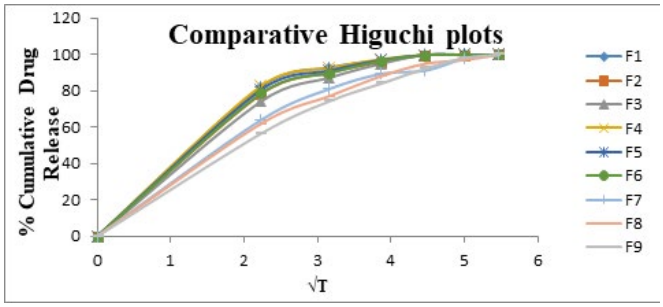

Figure 5: Comparative Higuchi plots

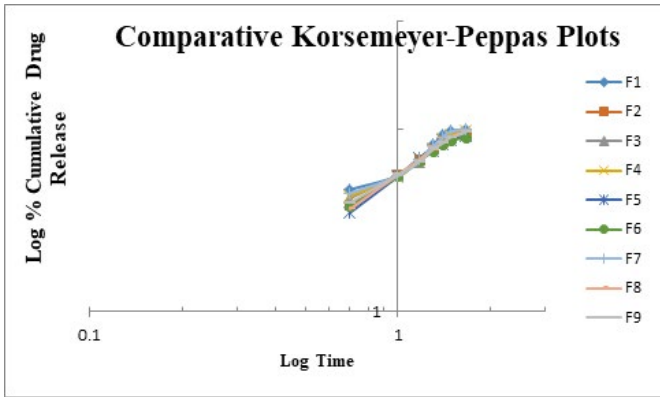

Figure 6: Comparative Korsmeyer-Peppas plots

Wetting time

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

In-vitro Dissolution Study

Sitagliptin ODT was analyzed for a drug release study utilizing a Lab-India USP type-II tablet dissolution test apparatus and 900 mL of 0.1 N HCl in accordance with the recommended method as outlined in the monograph. Using a UV-visible spectrophotometer, the samples' absorbance was measured at 267 nm, and the data were subjected to kinetic modeling.

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.[6]

Results and Discussion

About 9 different formulations of sitagliptin oral disintegrating tablets were prepared utilising 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.

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 11 ± 0.07 to 14 ± 0.54 seconds. All the formulations showed disintegration time in the range of 33.5 ± 0.28 to 40 ± 0.32 sec and the same was represented as Figures 1 and 2.

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

F_8 is regarded as the best formulation among all batches (based on Desirability). F_8, which contained 5 mg of croscaramellose sodium and 7.5 mg of sodium starch glycolate, 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.

Conclusion

The current study focuses on the impact of using superdisintegrants for the development of sitagliptin ODT, such as sodium starch glycolate and croscarmellose sodium. F_8 follows first-order type of kinetics (r = 0.999), Higuchi type model (r = 0.993), whereas the mechanism of drug release follows non-Fickian diffusion (n = 0.540). The best formulation, F_8, may be used for the effective management

of type-2 diabetes mellitus, which also contributes to reduce frequency of water intake, thereby providing patient compliance.

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