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Design, Development and Evaluation Controlled Release Tablet of Vildagliptin with Natural Polymers

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A B S T R A C T

The Aim of work is to formulate and evaluate controlled-release Vildagliptin tablets in vitro using natural polymers like guar gum and xanthin gum in different ratios. Controlled release tablets with good physical strength and tablets with the highest possible concentration of active pharmaceutical ingredients without variation in the content unit/tablet are the goals of pharmaceutical formulation that were intended to be accomplished during the work.Maintaining the medication concentration within the therapeutic range, improving patient compliance, and avoiding frequent dosage intervals are the pharmacological goals that were intended to be accomplished during the work.This controlled release tablet works well to improve glucose management in people with type II diabetes. The natural polymer used in the controlled release system was chosen to maintain the drug's release. Various polymers are used to achieve the appropriate release profile during a 12-hour period. The direct compression method was used to create several batches of controlled release.

Keywords: Controlled release tablet, Sustained release tablet, Anti Diabetic medicine, Type II diabetes.

1. Introduction

The primary goal of drug delivery systems is to deliver precisely the right amount of medication to the site of action so that the body can respond appropriately to treatment (7). Two kinds of distribution techniques are often employed. The rapid and unimpeded drug release rate and release kinetics are the characteristics that define conventional drug delivery methods, often known as immediate release drug delivery systems. The other kind of medication delivery mechanism is modified-release. In these kinds of drug delivery systems, the rate, location, and kinetic performance of the API delivered inside the body are altered in order to provide specific therapeutic responses. These consist of the following: prolonged or extended drug delivery systems (8) (controlled release, sustained release, and long-acting dosage forms); delayed or repeated drug delivery systems; and targeted drug delivery systems. Since we chose a controlled release drug delivery matrix system for this review paper, only one subject will be covered in depth.

In contrast to their conventional counterparts, which may require three or four daily doses to get the same therapeutic impact, controlled release tablets and capsules are often taken just once or twice daily. With controlled-release formulations, the medication releases the appropriate therapeutic impact immediately, and then more drug is released gradually over a specified length of time to maintain this effect. Patients and carers both benefit from the controlled release dosage form's maintained medication levels in plasma, which frequently do away with the requirement for nighttime administration. The pharmaceutical industry is becoming more interested in oral medication delivery systems with controlled release. Additionally, designing a dosage product that permits maximum drug loading is highly desired, especially for medications with high water solubility. Due to its simplicity of use, comfort, increased design flexibility for dosage forms, ease of manufacture, and cheap cost of production, oral administration is the most widely utilised method for controlled release delivery. The majority of controlled release delivery methods for oral use are solid dosage forms, which regulate drug release via diffusion, dissolution, or a combination of the two modes (9).

2. Material and Methods

Apparatus and chemicals: Vildagliptin by Apex Laboratorychennai, Guar Gum, Lactose and magnesium stearate by Nice Laboratories, Hyderabad, Xanthan Gum, PVK 30, bySD fine Chemical, Mumbai,

Methods:Preparation of controlled release tablet with various natural polymers

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According to the chart, various batches of Vildagliptin controlled release tablets (F1 through F9) were made with differing amounts of various formulation components. All of the material must pass through 80 meshes. Add binder after thoroughly mixing the lactose, polymer, and API. Mix well to create a cohesive mixture, then bake to dryness. Additionally, run the granules through 18 meshes. The granules were crushed in a proton mini press 10-station tablet punching machine after being lubricated with magnesium stearate. The following table provides the amount needed for formulation.

Table 1: Formulation for CR Tablet formulation

Ingredients	F1 mg	F2 mg	F3 mg	F4 mg	F5 mg	F6 mg	F7 mg	F8 mg	F9 mg
Vildagliptin	50	50	50	50	50	50	50	50	50
Guar Gum	50	100	150	-	-	-	50	50	100
Xanthan Gum	-	-	-	50	100	150	50	100	50
Lactose	148	98	48	148	98	48	98	48	48
PVK 30	3%	3%	3%	3%	3%	3%	3%	3%	3%
Magnesium Sterate	2	2	2	2	2	2	2	2	2
Total	**250**	**250**	**250**	**250**	**250**	**250**	**250**	**250**	**250**

3. Experimental work

3.1 Preformulation Studies

The study of a medical ingredient's physical and chemical properties, both alone and in conjunction with excipients, is known as preformulation. Preformulation studies aim to identify the physicochemical properties and excipients that may affect the manufacturing process, formulation design, and pharmacokinetic-biopharmaceutical aspects of the final product.

3.2 Determination of Solubility

Solubility was tested in various media including ethanol, methanol, absolute ethanol, acetone, chloroform, ether, water, 10% v/v HCl and 10% w/v sodium hydroxide.

3.3 UV and FTIR Spectroscopy

The wavelength of maximum absorbance was then found by scanning the solution containing 10µg/ml at 232 nm.
The reference standard FT-IR spectra of piperine and the acquired FT-IR spectrum of piperine were compared.

4. Result and discussion

4.1 Preformulation Study

4.1.1 Description

Vildagliptin iswhite crystalline solid and it is odour less.

4.1.2 Result of Solubility

Insoluble in waters, Vildagliptin is soluble in ethanol, dimethyl sulfoxide, and DMF and other organic solvent.

4.2 Result of Melting Point

The medicine's melting point was determined to be comparable to the stated value, confirming that the drug samples that were received met the stated specifications. The melting point of a particular pharmacological ingredient will vary depending on any impurities that may be present. Vildagliptin has a reported melting point of 150°C.

4.3 UV Spectroscopy

A peak with an absorbance was seen at 232 nm in a solution of 10µg/ml in methanol. The identity of the vildagliptin molecule is confirmed by the absorbance maxima at 232 nm, which is one of its hallmarks.

4.3.1FT-IR Spectroscopy

The drug's infrared spectrum was found to be comparable to Vildagliptin's normal infrared spectrum, indicating that the sample was pure. This validates the Vildagliptin identity.

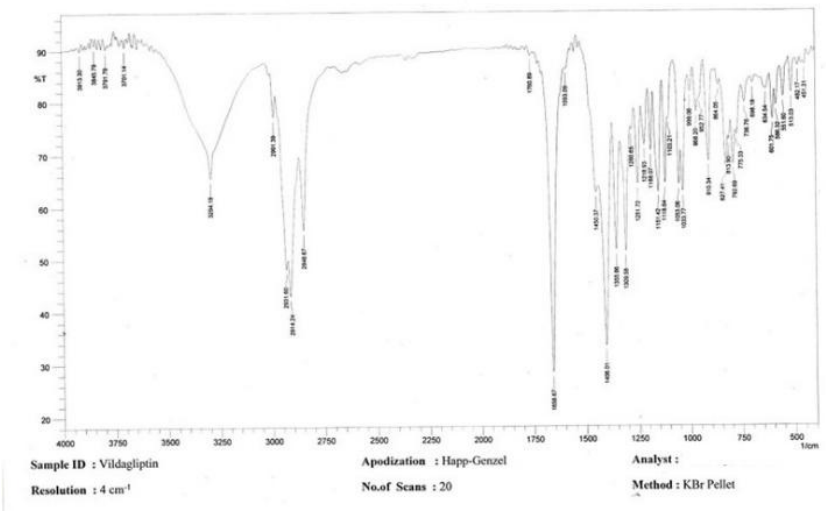

Fig 3. FT-IR of Vildagliptin

4.4 Drug - Excipients Compatibility Study

FT-IR Spectroscopy

The drug and excipients were found to be compatible after FTIR analysis of the physical mixes of the drug and excipients.

When the IR spectra of vildagliptin, excipients, and their combination are compared, all of theVildagliptin's distinctive bands are discovered to be intact.

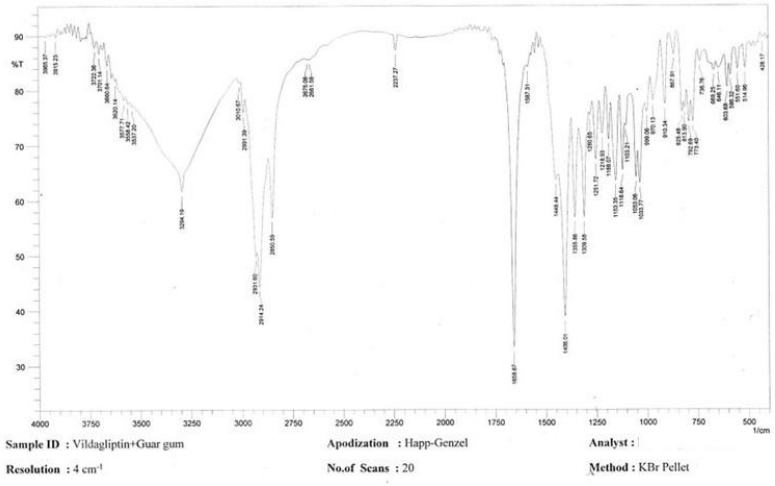

Figure 3 FT-IR Spectra ofVildagliptin and Guar Gum

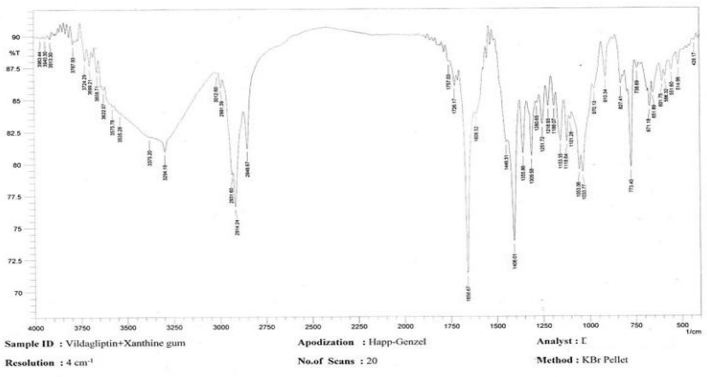

Figure 3 FT-IR Spectra ofVildagliptin and Xanthan Gum

4.5 Evaluation of Emulgel

4.5.1 Pre compression parameters

Table.No.:2. Evaluation parameters of powder blend.

Formulation	Angle of repose	Bulk density (gm/cc)	Tapped density (gm/cc)	Compressibili ty index (%)
F1	2505	0.39	0.43	11.2
F2	2609	0.40	0.44	11.5
F3	2506	0.41	0.45	12.9
F4	2905	0.39	0.43	10.7
F5	2404	0.39	0.42	11.2
F6	2605	0.38	0.42	12.5
F7	2906	0.41	0.45	10.8
F8	2801	0.39	0.43	12.2
F9	2802	0.40	0.44	11.6

Table.No.:3. Physical Parameters of Vildagliptin Controlled release Tablets

Formulation	Weight variation**	Thickness*	Drug content*
F1	250.5±0.50	3.48±0.113	101.23±0.05
F2	251.3±1.3	3.42±0.214	101.53±0.06
F3	249.2±0.8	3.61±0.063	102.04±0.01
F4	250.4±0.4	3.63±0.017	103.21±0.04
F5	251.0±1.0	3.62±0.082	99.71±0.04
F6	252.1±2.1	3.52±0.129	99.43±0.04
F7	251.5±1.5	3.50±0.064	101.38±0.01
F8	250.5±0.5	3.45±0.164	101.23±0.02
F9	251.5±1.5	3.42±0.144	101.53±0.06

Table.No.:4. Evaluation parameters of formulations

Formulation	Hardness (kg/cm2)	Friability (%)
F1	9.2	0.75
F2	9.3	0.21
F3	9.2	0.13
F4	9.4	0.19
F5	9.4	0.22
F6	9.5	0.16
F7	9.5	0.14
F8	9.3	0.17
F9	9.4	0.18

4.5.7 In-vitro release of study

The dissolution release profile of different formulations was examined in vitro. The formulations F1 through F9 were shown to dissolve in vitro based on the findings of controlled release tests. Formulation F8, which has a 12-hour release profile, was chosen to formulate the CR pill. The combination of natural polymers, guar gum and xanthan gum, was found to have a higher rate of drug release.

Table.No.:5. In vitro Dissolution profile Vildagliptin Controlled release tablets

Time in Hours	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
1	21.56	18.34	16.82	24.16	17.22	15.41	18.24	14.81	16.49
2	37.32	31.97	27.11	33.89	28.91	26.62	27.04	20.69	22.31
3	49.69	44.84	35.76	41.65	36.24	34.28	36.92	29.04	33.08
4	60.14	56.27	48.78	54.22	49.37	48.87	46.47	37.42	44.85
5	74.82	65.75	61.19	68.56	63.92	60.72	59.24	45.92	51.08
6	85.69	76.14	73.64	79.23	74.12	71.29	70.65	51.74	59.22
7	98.24	88.63	80.47	89.22	81.48	78.62	80.11	59.93	66.82
8		99.18	91.24	98.73	90.23	84.23	85.69	64.24	70.96
9			98.93		99.69	91.45	90.67	73.82	78.21
10						98.31	99.22	84.76	89.47
11								92.04	98.26
12								99.67	

4.6 Stability Studies of best formulation F8

Table.No.:6. Stability studies of optimized formulation F8

Time (days)	25oC ± 2oC/60% RH ± 5% RH, 30oC ± 2oC/65% RH ± 5% RH, 40oC ± 2oC/75% RH ± 5% RH		
	Hardness(kg/cm2)	Drug content (%)	% Drug release
0	9.4	101.3	99.67
30	9.4	101.3	99.42
60	9.4	101.2	99.35
90	9.4	101.2	99.21

5. Conclusion

The medication release from the dosage form was regulated by varying the polymer content.This controlled release pill works well to improve glucose management in people with type II diabetes. The natural polymer used in the controlled release system was chosen to maintain the drug's release. Various polymers are used to achieve the appropriate release profile during a 12-hour period. The direct compression method was used to create several batches of controlled release.Physical attributes, precompression qualities, in vitro dissolution research, kinetic study, and stability were all assessed for each formulation. The current investigation has led to the following findings.The physical characteristics of every blended composition were favourable.When evaluated for Friability, thickness, weight fluctuation, and Assay, the produced tablets were found to be within the permissible limits.In vitro dissolving studies were performed on each of the CR formulations.

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