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Formulation, Development and Evaluation of Anti-Diabetic Chewable Tablets

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Abstract: *The present study focuses on the formulation, development, and evaluation of Saxagliptine Phosphate chewable tablets intended for effective management of diabetes mellitus. Preformulation studies confirmed the drug's purity with a melting point of 210–212 °C and demonstrated favorable solubility in aqueous media, supporting its suitability for oral administration. Chewable tablets were formulated using wet granulation, incorporating excipients such as lactose, mannitol, starch, and sweeteners to ensure palatability and mechanical strength. Comprehensive pre-compression evaluations indicated excellent flow properties, facilitating uniform tablet formation. Post-compression studies showed that the tablets met pharmacopeial standards for general appearance, hardness, weight variation, friability, and drug content uniformity. In vitro dissolution studies revealed rapid drug release in 0.1N HCl, simulating gastric conditions, ensuring prompt availability for absorption. Overall, the formulation successfully delivered a stable, palatable, and effective chewable dosage form of Saxagliptine Phosphate, offering a promising alternative for enhancing patient compliance in diabetic therapy.*

Keywords: Saxagliptine Phosphate, chewable tablets, wet granulation, preformulation studies, diabetes mellitus, in vitro dissolution, patient compliance

I. INTRODUCTION

Diabetes mellitus is a chronic metabolic disorder characterized by persistent hyperglycemia resulting from defects in insulin secretion, insulin action, or both. According to the International Diabetes Federation, the global prevalence of diabetes is projected to rise dramatically, imposing a significant burden on healthcare systems and patients' quality of life. Among the various strategies employed to manage type 2 diabetes mellitus (T2DM), dipeptidyl peptidase-4 (DPP-4) inhibitors have emerged as effective therapeutic agents due to their glucose-dependent mechanism of action, which minimizes the risk of hypoglycemia and enhances glycemic control.[1,2]

Saxagliptine Phosphate, a potent and selective DPP-4 inhibitor, has gained widespread acceptance for its efficacy in reducing postprandial and fasting glucose levels. However, patient compliance remains a challenge in chronic therapies, particularly when conventional tablet formulations are difficult to swallow, especially among pediatric and geriatric populations. Chewable tablets present a practical solution, offering advantages such as ease of administration without water, improved palatability through the incorporation of sweeteners and flavors, and faster disintegration, thereby enhancing patient acceptance and adherence to long-term therapy.[3,4]

Before embarking on the formulation of a new dosage form, it is essential to conduct comprehensive preformulation studies. These investigations provide critical insights into the physicochemical properties of the drug, including its purity, thermal stability, solubility profile, and compatibility with various excipients, all of which guide the rational selection of formulation components and processing parameters. Saxagliptine Phosphate, with a melting point around 210–212 °C and favorable aqueous solubility, is well-suited for oral solid dosage forms. Its compatibility with common excipients further supports its development into a chewable tablet formulation.[5,6]

The formulation process, particularly employing the wet granulation technique, aims to produce granules with good flow and compressibility, ensuring uniform weight and content in the final tablets. The choice of excipients such as lactose, mannitol, starch, and lubricants is pivotal in achieving the desired mouthfeel, mechanical strength, and stability. Subsequent evaluation through pre-compression parameters like bulk density, tapped density, Carr's index, Hausner's

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ratio, and angle of repose ensures processability, while post-compression assessments confirm compliance with pharmacopeial quality standards.[7]

Furthermore, in vitro dissolution studies are indispensable to predict the release behavior of Saxagliptine from the chewable matrix, simulating its availability for absorption under gastric conditions. A formulation that ensures rapid and efficient drug release can offer prompt glycemic control, a critical requirement in managing postprandial glucose excursions.[8]

This study was therefore designed to systematically develop, characterize, and evaluate chewable tablets of Saxagliptine Phosphate, aiming to deliver a stable, effective, and patient-friendly dosage form that could potentially improve therapeutic outcomes and patient compliance in the long-term management of diabetes mellitus.

II. MATERIALS AND METHODS

Saxagliptine Phosphate, the active pharmaceutical ingredient (API) and other excipients employed in the study were of analytical grade. The identity and authenticity of the drug were confirmed through evaluation of its physical state, color, and odor. Comprehensive preformulation studies were conducted, including determination of melting point using a capillary tube method, solubility assessments in various solvents, and compatibility analysis with excipients. The calibration curve for Saxagliptine Phosphate was established by preparing a series of standard solutions through serial dilutions of a stock solution and measuring their absorbance at the λmax of approximately 225–230 nm using a UV-Visible spectrophotometer; linear regression analysis yielded the calibration equation and correlation coefficient to confirm method linearity. Further, the drug's functional groups were identified using FTIR spectroscopy by the potassium bromide (KBr) pellet method. These studies collectively provided critical data to support the formulation, development, and evaluation of anti-diabetic chewable tablets, ensuring optimal selection of formulation parameters and excipients for achieving desirable quality attributes.[9,10]

Formulation Development:

Saxagliptine chewable tablets were prepared by the wet granulation method, wherein accurately weighed ingredients were blended to form a homogeneous damp mass, which was then passed through a #14 mesh sieve to produce uniform granules. These granules were dried to eliminate excess moisture and subsequently mixed with lubricants like stearic acid and magnesium stearate to enhance flow and prevent sticking. The final blend was compressed into tablets using an 8-station rotary tablet press, ensuring uniform weight, content, and mechanical properties, thus yielding high-quality chewable tablets optimized for oral anti-diabetic therapy.[11,12]

Table 1: Formulation Development

Ingredient	F1	F2	F3	F4	F5	F6
Saxagliptine (mg)	50	50	50	50	50	50
SLS (mg)	15	15	15	15	15	15
PVP (mg)	10	10	10	10	10	10
Lactose (mg)	218	221	224	-	-	-
Mannitol (mg)	-	-	-	218	221	224
Magnesium stearate	10	10	10	10	10	10
(mg)						
Stearic acid (mg)	5	5	5	5	5	5
Starch (mg)	47	47	47	47	47	47
Vanilla flavour (mg)	15	15	15	15	15	15
Sodium saccharin (mg)	4	4	4	4	4	4
Total weight (mg)	380	380	380	380	380	380

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Evaluation:

The prepared Saxagliptine chewable tablets were subjected to comprehensive pre-compression and post-compression evaluations to ensure quality and performance. Pre-compression studies included determination of bulk density by measuring the mass and volume of granules in a graduated cylinder, tapped density using a mechanical tapper to achieve minimum volume, followed by calculation of Carr's Index and Hausner's Ratio to assess flow properties, along with the angle of repose to evaluate interparticulate friction. Post-compression tests assessed the general appearance of tablets for shape, color, texture, and odor, while hardness was determined using a Monsanto tester. Weight variation was checked by individually weighing 20 tablets against their average weight, ensuring compliance with pharmacopeial limits. Friability was tested by rotating tablets in a friabilator for 100 revolutions and noting weight loss. Drug content was estimated by spectrophotometric analysis at 226 nm after preparing suitable dilutions in 0.1N HCl. In vitro dissolution studies were conducted using USP type II apparatus in 900 mL of 0.1N HCl at 37 ± 0.5°C and 50 rpm, with samples withdrawn at predetermined intervals up to 30 minutes, replaced with fresh medium, and analyzed for drug release, collectively confirming the tablets' quality, uniformity, and release behavior.[13,14]

III. RESULTS AND DISCUSSION

Melting Point and Solubility:

The melting point of Saxagliptine Phosphate was determined to be 210–212 °C, closely aligning with reported literature values, which indicates the drug's purity, absence of major impurities, and thermal stability, thus confirming its suitability for formulation. Solubility studies revealed that Saxagliptine Phosphate is highly soluble in phosphate buffer pH 6.8 (8.5 mg/mL), moderately soluble in distilled water (5.2 mg/mL), and poorly soluble in ethanol (1.1 mg/mL), highlighting its preferential solubility in aqueous media that mimic intestinal conditions, which is beneficial for enhancing oral absorption and overall bioavailability in chewable tablet formulations.

The comprehensive evaluation of Saxagliptine Phosphate chewable tablets demonstrated that the formulation approach was successful in achieving the desired quality and performance attributes. Preformulation studies confirmed the drug's purity, thermal stability, and favorable aqueous solubility, supporting its suitability for oral delivery. Pre-compression parameters, including good flow properties as indicated by acceptable Carr's Index, Hausner's Ratio, and angle of repose values, ensured uniform die filling during compression. Post-compression tests revealed tablets with consistent appearance, optimal hardness, low friability, and minimal weight variation, all within pharmacopeial limits, indicating mechanical robustness and uniformity. Drug content analysis confirmed homogeneous distribution of Saxagliptine within the tablets, while in vitro dissolution studies showed rapid and efficient drug release in 0.1N HCl, simulating gastric conditions, ensuring immediate availability for absorption. Overall, these results validate the formulation's capability to provide a stable, palatable, and effective chewable dosage form for managing diabetes.

Table 2: Pre-Compressional Studies

Formulation	Bulk Density	Tapped Density	Compressibility Index	Hausner's Ratio	Angle of Repose
F1	0.4	0.476	19	1.19	36.7
F2	0.408	0.50	22.5	1.22	42
F3	0.4	0.487	21.7	1.21	41.7
F4	0.416	0.512	23.2	1.23	42.5
F5	0.4	0.512	28	1.28	46
F6	0.416	0.512	23.27	1.23	43.2

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Table 3: Evaluation of tablet

Sr. No	Parameter	F1	F2	F3	F4	F5	F6
1	Colour	White	White	White	White	White	White
2	Odour	Pleasant	Pleasant	Pleasant	Pleasant	Pleasant	Pleasant
3	Taste	Vanilla like	Vanilla like	Vanilla like	Vanilla like	Vanilla like	Vanilla like
4	% Weight variation	1.3195 ± 0.7905	1.3205 ± 0.2575	1.3255 ± 0.2525	1.3195 ± 0.7905	1.3575 ± 0.5875	1.3205 ± 0.2575
5	Diameter (cm)	0.9 ± 0.05	0.9 ± 0.05	0.9 ± 0.05	0.9 ± 0.05	0.9 ± 0.05	0.9 ± 0.05
6	Thickness (cm)	0.5 ± 0.02	0.5 ± 0.02	0.5 ± 0.02	0.5 ± 0.02	0.5 ± 0.02	0.5 ± 0.02
7	Hardness	3 kg	4.2 kg	2.6 kg	3.8 kg	3 kg	3.2 kg
8	Disintegration time	14 min	18 min	21 min	17 min	20 min	25 min
9	% Drug content	93.16	96.47	100.81	98.78	97.56	102.58

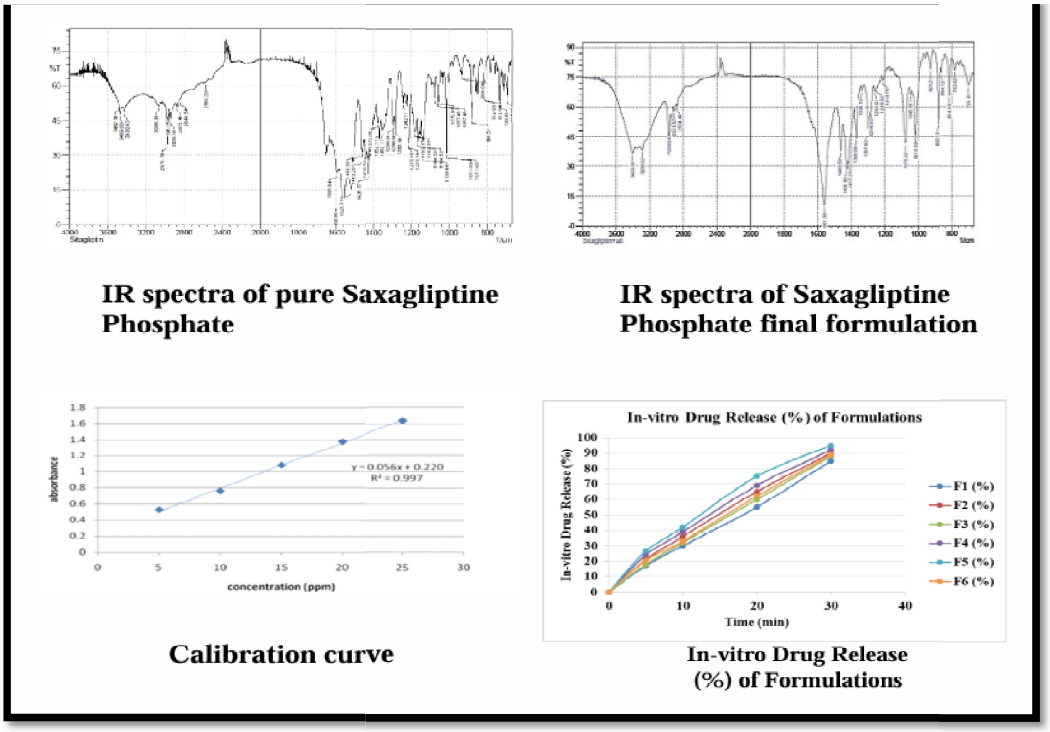

Fig 1: Evaluation of tablet

IV. CONCLUSION

The study successfully developed and evaluated chewable tablets of Saxagliptine Phosphate employing a systematic formulation strategy supported by robust preformulation data. The prepared tablets exhibited excellent physicochemical characteristics, including uniform appearance, optimal mechanical strength, minimal friability, and consistent drug content. Superior flow properties of the granules ensured efficient tablet compression, while dissolution studies confirmed rapid drug release, indicating potential for immediate therapeutic action. These findings underscore the

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suitability of the formulated chewable tablets as an effective and patient-friendly dosage form for managing diabetes, potentially improving adherence and therapeutic outcomes.

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