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FORMULATION AND EVALUATION OF VILDAFORMIN TABLET SMEDDS

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Abstract
Potential lipid-based formulations that are designed to dissolve a poorly aqueous-soluble drug include self-microemulsifying drug delivery systems (SMEDDS). Vildaformin, a complex of Vildagliptin and Metformin, is correlated with dissolution and solubility issues that affect therapeutic effect. In the present study, the solid SMEDDS (S-SMEDDS) was prepared by dissolving Vildaformin in a liquid SMEDDS formulation composition of Tween 80 (Surfactant), Propylene glycol (Co-surfactant), and White Sesame oil (Oil phase) and adsorbed onto Aerosil 200. Optimized formulation was pressed into tablets with excipients of preference, and evaluated for micromeritics, morphology, thermal and structural properties using Carr index and Hausner ratio, SEM, PXRD, and DSC. The hardness, weight variation, friability, and disintegration of the tablets were satisfactory. The improved solubility and dissolution characteristics were demonstrated by an in-vitro dissolution study that found drug dissolution in T-SMEDDS tablets much greater than drug dissolution in pure drug and marketed tablet. The findings suggest that the tablet formulation of T-SMEDDS should be considered as a potential solution to increase oral bioavailability and adherence to Vildaformin owing to the enhanced dissolution and absorption.
Keywords: Self-microemulsifying drug delivery system, Solid-SMEDDS, Solubility enhancement, Oral bioavailability, Tablet formulation.

1. INTRODUCTION

The most practical and favoured method of administration is the oral route of drug and medicament delivery due to safety, cost, ease of administration, and patient compliance [1]. However, the majority of oral drugs face tremendous problems because they are insoluble in water and exhibit erratic permeability, which typically leads to incomplete absorption, low bioavailability, and unpredictable therapeutic effects [2]. Vildagliptin and Metformin are widely used as a fixed-combination therapy (Vildaformin) in the management of type 2 diabetes mellitus (T2DM). A biguanide derivative, metformin, has an effect predominantly by reducing the hepatic production of glucose and increasing the sensitivity of insulin, but is poorly absorbed across the intestines. Vildagliptin is an inhibitor of the pancreatic enzyme dipeptidyl peptidase-4 (DPP-4) with enhanced incretin activity but has low aqueous solubility [3]. Taken together, all these drugs present major solubility, dissolution, and general bioavailability problems that necessitate the development of advanced formulation plans. Among the various approaches, lipid-based formulations, in particular, a drug delivery system that self-microemulsifies (SMEDDS), have been most encouraging in increasing the solubility, rate of dissolution, and intestinal permeability of drug delivery that is poorly soluble drugs in water [4]. SMEDDS are naturally occurring isotropic blends of oils, co-surfactants, and surfactants that produce fine oil-in-water emulsions in the presence of digestive fluids and thereby multiply the surface area upon which a drug can be released and absorbed. Nonetheless, liquid formulations of SMEDDS are still characterized by some shortfalls such as instability, capsule shell incompatibility, leakage, and unfavourable handling properties, which limit their commercial application [5]. To avoid these limitations, solid SMEDDS (S-SMEDDS) have been suggested, in which liquid SMEDDS are adsorbed onto solid carriers to produce free-flowing powders, which can be easily processed into tablets or capsules. Solidification not only improves the stability and patient acceptability of SMEDDS but also enables the formation of unit-dose solid oral dosage forms with increased mechanical strength, reproducibility, and scalability [6]. In the present study, Propylene glycol, Tween 80, and oil were employed as co-surfactants, surfactants, and lipid phases, respectively, to design an SMEDDS of Vildagliptin and Metformin. An optimization of the liquid SMEDDS was then carried out, and it was converted to a solid dosage form through adsorption onto Aerosil, followed by compression into solid SMEDDS tablets. The effects of the lipid concentration, carrier loading, and tablet excipients on the compressibility and physico-mechanical characteristics of the product were also evaluated in the investigation. In the present study, the solid SMEDDS (S-SMEDDS) was prepared by dissolving

Vildaformin in a liquid SMEDDS formulation composition of Tween 80 (Surfactant), Propylene glycol (Co-surfactant), and White Sesame oil (Oil phase) and adsorbed onto Aerosil 200.

2. MATERIALS AND METHODS

Aerosil200, Microcrystalline cellulose, Polyvinyl Pyrrolidine K-30, Sodium Starch Glycolate, magnesium stearate, and Talc were purchased from Him Laboratory Solan, Himachal Pradesh, India.

2.1. SMEDDS Preparation Method: Based upon the preliminary studies, the optimized concentration of White Sesame oil SMEDDS of surfactant (Tween 80), co-surfactant (Propylene Glycol), and Vildagliptin and Metformin drugs was formulated. The drugs were initially dissolved in the chosen oil, and thereafter the surfactant and co-surfactant were quantitatively weighed and subsequently mixed with the help of a magnetic stirrer for 5min. Then SComix was put in a hot air oven for 60 minutes at 50^0C. Then the drug mixtures were added to Scomix, and then these components were mixed by stirring for 5-10min and in a hot air oven at 50^0C for 1hr, so that it becomes an isotropic mixture. Such isotropic formulations were sonicated until a clear solution was created [7].

2.2. Preparation of adsorbent dried solid SMEDDS: S-SMEDDS was prepared by adding liquid SMEDDS to Aerosil 200 dropwise in a large porcelain dish. It was added, then mixed with the glass rod to even the mixture. Wet mass was sieved on a sieve no. 120, dried at 25°C and kept to be used further [8].

2.3. The flow traits of the solid SMEDDS are described in the Carr technique, which was employed to study the flow characteristics of the solid SMEDDS. All the solid samples were ground to pass through the funnel, and the radius and height of the SMEDDS powder were determined. The formula tan = H/r was used to obtain the repose angle [9].

2.3.1. Micromeritics properties: The utilization of the microparticles in a capsule or a tablet depends on their micromeritics analysis, including the Carr index, Hausner ratio, and angle of repose.

2.3.1.1. Angle of repose (θ): The angle of repose of the microparticles of all the preparations was determined using the glass funnel method. A glass funnel was placed in an upright position, and microparticles were added until a cone with the highest possible height was formed. The height of the cone and the radius of the base were taken. Eq. The angle of repose was obtained using [Eq.1]

$$\theta = \tan^{-1} h/r \quad [1]$$

in which θ = angle of repose, h = height of pile, and r = base radius of cone. An angle of repose of less than 25^0 means that the microparticles are freely flowing.

2.3.1.2. Bulk density. Calculation of the bulk density was done using the tapping method. To determine bulk density, the tapping method was used in a 5 mL graduated measuring cylinder microparticles were measured. Then, the bulk volume and mass were measured by weighing on an electric balance. Eq. [2] was used to find bulk density:

Bulk Density =Weight of Particle/ Solid Bulk Volume of Particles [2].

2.3.1.3. Tapped density: The measuring cylinder was held, and the amount of microparticles was placed in it; the cylinder was tapped one hundred times, and Eq. Tapped density was computed using [eq. 3].

Mass of Particles/Volume of particles after tapping=tapped density [3].

2.3.1.4. Carr index: The Carr index was calculated to identify flow behaviours of microparticles. It was determined by using Eq. [4]

% Compressibility index=Tapped density-bulk density/Tapped density x 100 [4]

When the Carr index value of microparticles is less than or greater than 25%, respectively, then good and poor flow respectively.

2.3.1.5. Hausner ratio: The Hausner ratio was used to calculate the flow behaviour of microparticles. Using the Hausner ratio, bulk and tapped densities, the Hausner ratio of the material was calculated as:

Ratio of Hausner= Tapped density/ Bulk density [5]

When the Hausner ratio of the microparticles is less than 1.11, then the particles have fine flow, and when greater than 1.25, then they have poor flow [10].

2.4. Physical characterization of S-SMEDDS: Surface morphological characteristics of Vildafomin pure powder, Aerosil 200, and Vidaformin-loaded solid- SMEDDS were analysed with an SEM (S-4800, Hitachi, Tokyo, Japan). The samples were placed on the double-sided adhesive tape, and the samples were attached to a brass sampling disc. The platinum sputter coating (6 nm/min) was then transferred to them electrically via an EMI Teck Ion Sputter (K575K) operating in a vacuum (8x103 mbar), depositing it in 4 min at 15 mA [11].

2.5. Crystallinity measurement using Powder X-ray diffractometry (PXRD): The samples had been irradiated with nickel-filtered CuKa radiation and scanned with 2- **θ** of 2-70°. Investigations and analyses of the pure drug and solid SMEDDS samples were conducted using PXRD (MiniFlex 600, Rigaku, Japan) facilities [12].

2.6. Thermal analysis: Differential scanning calorimetry scans (DSC) of the S-SMEDDS were monitored using a different scanning calorimeter (Netzsch, 204 F1 Phoenix). S-SMEDDS samples (3-7 mg) were melted in an aluminium pan with a perforated lid between 0 and 160 C at 10 C/min with a 50 ml/min flow of nitrogen gas. An empty reference pan was used. The values of the output were evaluated by using StarE 9.10 software [13].

3. Development of SMEDDS Tablet: To obtain free-flowing S-SMEDDS granules, the SMEDDS was adsorbed into a porous carrier at the beginning. Microcrystalline cellulose (MCC) was added to the granules as a filler and

compressibility agent, polyvinylpyrrolidone (PVP) as the moist substance through a #44 mesh sieve, the binder, and sodium starch glycolate (SSG) as a super disintegrant. The resultant granules were dried at 60^0 C in a hot air oven until their weight remained constant and were resized to homogeneity with a #60 mesh sieve, tumbled in a tumbling blender with the dried granules and the talc as a glidant and the magnesium stearate as a lubricant, and then the use of magnesium stearate prevented too much lubrication. The entire mixture of granules was pressed to make tablets on a tablet compression machine using a flat, round punch. To a mean weight of 500-1268 mg, the tablets were loaded [14].

4. Characterisation of SMEDDS Tablet: Friability, weight variation, hardness, uniformity of content, were checked on the tablets prepared, in vitro dissolution experiment etc.

4.1. Appearance

The bio-adhesive tablet was also visually identified by establishing differences in shape, colour, and texture [15].

4.2. Measuring the hardness of tablets: The hardness of tablets is measured using a hardness meter. The average of the ten hardness values of the various tablets was calculated on a Monsanto and Pfizer tablet hardness tester. Tablets were all mounted on the hardness tester, and the maximum force was measured in newtons. The length of each tablet was measured when broken [16]**.**

4.3. Friability: A friability apparatus was used to measure the friability of 4 tablets of each of the formulations. The weight of tablets (w1) was measured and placed in a rotating drum, and left to rotate 15 to 100 times [17]. The weight of the tablets was then reweighed (w2), and the resultant percentage weight loss was utilized the next day.

Formula to report: w1 − w2/w1 × 100

Where: W1 = Mass of the tablet collectively before testing, and W2 = Mass of the tablet collectively after testing.

4.4. Weight variation: The variation test on weight was done to determine how the weight of a tablet changed with respect to the mean tablet tested. To determine the weight, 10 tablets were weighed randomly, and afterwards, the average weight was also found. The weight calculation of deviation and percentage deviation was done [18].

4.5. Disintegration: The time of disintegration of tablets (min) was measured in water at 37 ± 2 C using the USP disintegration test instrument. The moment the tablet was measured by using the USP disintegration test apparatus in water at 37 ± 2 C. tablet fell completely to pieces was recorded, and the average time was calculated. was calculated [19].

4.6. Comparative in vitro release study: Marketed Vildaformin, L-SMEDDS, S-SMEDDS tablet, and a commercial product were exposed to in vitro liberation in the dissolution test device of USP type II. 500 mL of phosphate buffer at pH 7.8 was used as the medium, and the test was run with a paddle spinning at 75 rpm. A temperature of 37±0.5°C was maintained. The samples were introduced at preset intervals, and every 5 mL was distilled and replaced with an equivalent volume of brand-new dissolving media. Filtered samples. Then, 0.45 µm Millipore filters were used to obtain them. The spectrophotometric analysis was prepared at 230-240 nm in a UV spectrophotometer [20, 21].

4.7. Drug Kinetic Studies: Drug release kinetics of Vildaformin Solid-SMEDDS tablets were evaluated in the paper in terms of different kinetic models such as zero-order, first-order release kinetics, Higuchi, and Korsmeyer-Peppas models [22].

4.7.1. Zero-order: The zero-order release of F3 formulation is given by the following equation:

$$\mathbf{Qt=Q_0+k_0t}$$

Qt is the amount of drug released cumulatively at time t. Q_0 is the initial amount (usually zero when full release studies are done), and is the constant rate of the zero-order order. The model is generally used in those systems that are set to support a fixed release rate within a specific duration [23].

4.7.2. First-order release kinetics: The rate of drug release is a function of the concentration of the drug in the dosage form, which means that the rate will decrease with time. The first-order release model is mathematically expressed by the following:

$$\mathbf{\ln(Q_0-Q_t) =\ln Q_0-k_1t}$$

where Q_0 is the initial amount of drug, Q_t is the quantity discharged at time t, the k_1 first rate order constant [24].

4.7.3. Higuchi: The Higuchi model is among the frequently applied release kinetics of SMEDDS tablets. The Higuchi model is a diffusion mechanism that defines drug release as the square root of time, i.e., diffusion through a matrix is predominant [25].

Higuchi Model Formula

$$\mathbf{Qt=kHt}$$

Where Qt = the cumulative amount of drug that is released at time t, and kH Higuchi dissolution rate constant.

4.7.4. Korsmeyer-Peppas models: The Korsmeyer-Peppas model is also commonly employed to investigate drug release through SMEDDS tablets, particularly when the process is not merely a simple case of Fickian diffusion.

SMEDDS Tablet Korsmeyer-Peppas Model explains the release of drugs in terms of where

$$\mathbf{Mt/\ M\infty=ktn}$$

Mt/M∞ is the amount of drug released at time t, k is a constant of kinetic energy, and n is (release exponent) represents the release mechanism [26].

5. RESULTS

5.1. Flow Characteristics of Solid SMEDDS: The angle of repose was employed to test the solid SMEDDS powder flow characteristics. technique. Table 1 provides the values. The measured values of the angles of repose of the three formulae were between 16.27deg and 20.87deg, which means fine flow properties. Through Powders having an angle of repose of less than 25 deg are freely flowing USP. To this end, the solidified SMEDDS displayed good flowability and are therefore amenable. To be processed into tablet dosage forms.

A B C

Figure 1 A). Images of Solid SMEDDS, B) Determination of flow Properties of powder, C) Solid SMEDDS Tablet.

Table 1. Micrometric properties of Solid SMEDDS powder.

Sample	Height (cm)	Radius (cm)	H/R	Angle of Repose (°)	Flow Property
1	2.2	7.5	0.29	16.27	Excellent
2	2	7.5	0.37	20.57	Excellent
3	2.5	6.5	0.38	20.87	Excellent

Table 2. Flow Properties & Compressibility of Solid-SMEDDS.

Parameter	Standard Range – Excellent	Standard Range – Good	Standard Range – Fair	Standard Range – Poor	Result	Interpretation
(%) Carr's Index	≤ 10	11 – 15	16 – 20	> 20	13	Good compressibility
Hausner's Ratio	≤ 1.11	01.12 – 1.18	01.19 – 01.25	> 01.25	1.15	Good flow

Bulk Density (g/cm³)	—	—	—	—	0.867	Acceptable
Tapped Density (g/cm³)	—	—	—	—	1	Acceptable

5.2. Solid SMEDDS Morphological description: The solidified morphology was examined using a scanning electron microscope. SEM image: porous, irregularly sized, rough particles. surface morphology, indicating that liquid SMEDDS had appropriately adsorbed onto the solid with the carrier (Aerosil 200). The particles had low aggregation and were not spherical. These are typical characteristics of good dispersion of the liquid SMEDDS on the carrier surface. Its morphology should be porous and rough because the latter gives it more surface area, which is likely to. Is readily emulsified in the presence of aqueous media. Whereas the pure drug had a smooth crystalline surface texture, the granules loaded with SMEDDS had a transparent amorphous surface texture that determines transformation between crystalline and semi-amorphous or solidification at the molecularly dispersed state.

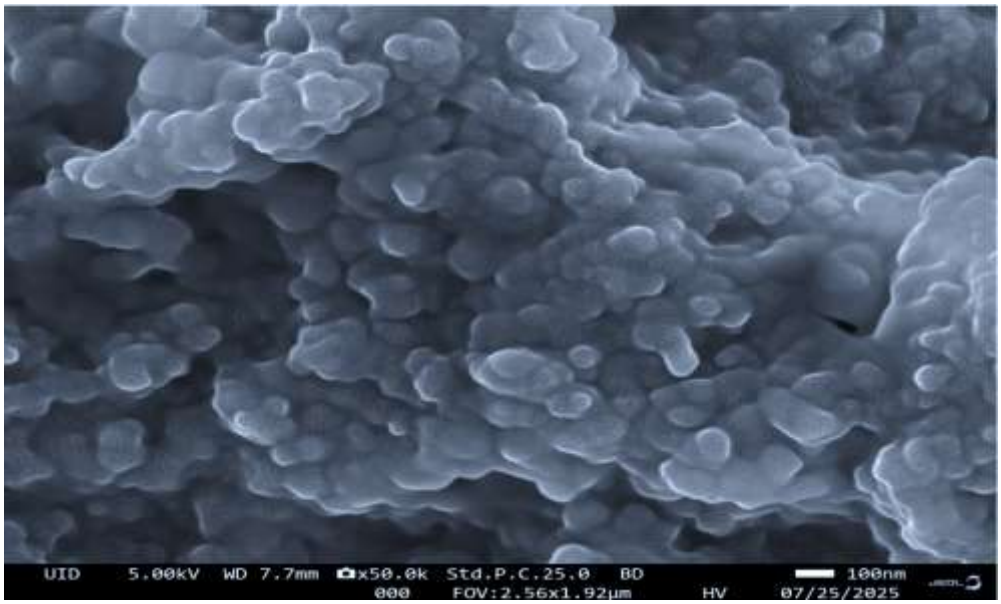
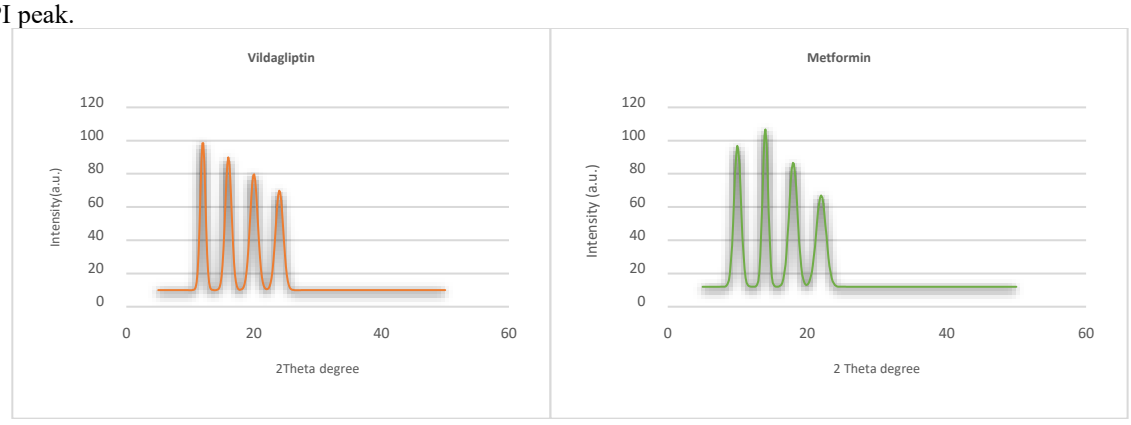


Figure 2. SEM images of Solid SMEDDS, which reflect the surface properties of Vildaformin-Solid-SMEDDS.

5.3. Powder-XRD of Solid SMEDDS: The solid SMEDDS and the pure APIs were tested for Powder X-ray diffractometry (MiniFlex 600, CuK, 2 = 2 70). Diffractograms of pure drugs exhibited typical sharp peaks, which are characteristic of the crystallinity of a drug, whereas the diffractogram of S-SMEDDS had a wide halo with no API peak.



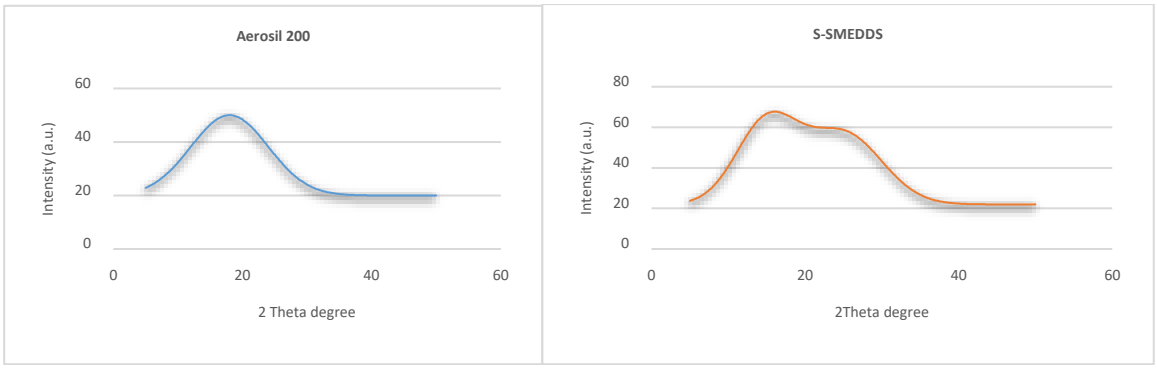


Figure 3. (a) XRD of Pure API vildagliptin, (b) Metformin HCl, (c) Aerosil 200, (d) Powder SMEDDS.

5.4. Thermoanalysis Differential Scanning Calorimetry (DSC): DSC thermograms of the pure Vildagliptin, the pure Metformin HCl, Aerosil 200, and the prepared powder SMEDDS. Pure Vildagliptin exhibited a sharp endothermic peak at 156 K, implying that it is in crystalline form. Another intense endothermic transition peak was observed at 231ºC also with Metformin HCl equivalent to the melting of its crystalline material. Oppositely dehydrated Aerosil 200 gave a nearly flat base without any endothermic events, which are signs of its amorphous and thermally resistant qualities.

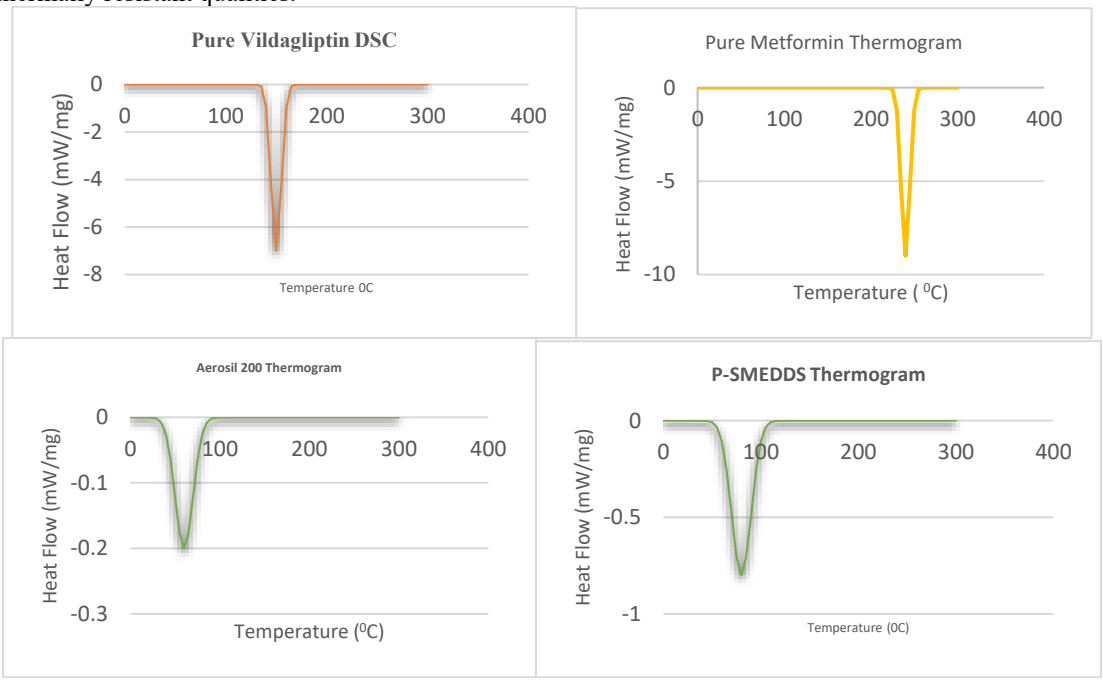


Fig.4 (a) DSC thermograms of pure Vildagliptin, (b) Pure Metformin, (c) Aerosil 200, and (d) Powder SMEDDS

5.5. Formulation Development of SMEDDS Tablets.
The Vildagliptin (30 mg) containing SMEDDS liquid formulation of Metformin HCl (300 mg) was adsorbed on Aerosil 200 to transform it into a solid intermediate powder. The solidified blend was then mixed with excipients like microcrystalline cellulose (MCC), polyvinylpyrrolidone (PVP), sodium starch glycolate, and magnesium stearate to formulate directly compressible tablet formulations. Four formulations (F1–F4) were formulated to maximize the concentration of excipients in order to achieve optimal compressibility, flow, and tablet properties. The formulation composition for each of the formulations is outlined in Table 3.

Table 3. Solid-SMEDDS Tablet Formulation Composition (F1–F4).

Chemicals	**F1**	**F2**	**F3**	**F4**
Liquid SMEDDS (ml)	1.2 (24 ml/20)	0.10 (2 ml/20)	0.08 (1.6 ml/20)	0.08 (1.6 ml/20)

Aerosil 200	120	90	300	300
MCC	800	300	170	100
PVP	15	10	20	90
Sodium Starch Glycolate	10	5	5	5
Mg Stearate	7	5	6	4
Talc	3	5	5	6
Final weight (mg)	1275	515	500	500

5.6. Appearance of Tablet: The bio-adhesive tablets developed were physically examined by the naked eye to establish their physical appearance. The formulations (F1-F4) were all identified.

Table 4. Physical appearance of formulated Tablets

Formulation	Shape	Colour	Texture
F1	Round	White	Smooth, slightly glossy
F2	Round	Off-white	Smooth
F3	Round	White	Smooth
F4	Round	White	Smooth

5.7 Tablet Hardness: The tablet's hardness was assessed using a Monsanto hardness tester. All formulations produced hardness in the range 4-6 kg/cm^2, with good mechanical properties. strength.

Table 4. The tablet hardness, friability, and disintegration, as shown in the below mentioned table time of Tablet SMEDDS.

Formulation Code	Hardness (kg/cm²)	Friability (%)	Disintegration Time (min)
F1	3.5 ± 0.2	0.62	14.5 ± 0.3
F2	3.0 ± 0.3	0.50	13.8 ± 0.5
F3	5.5 ± 0.2	0.46	12.6 ± 0.2
F4	4.5 ± 0.2	0.48	13.6 ± 0.4

5.8 Variation in weight: The table below details the weight change of SMEDDS Tablets. The tablets of all the formulations (F1-F4) were found to have a mean weight of 495-505. mg. Individual tablets defined by the deviation of the mean weight by more than 5% was incompliance with USP pharmacopeial standards for tablets that weigh more than 250 mg.

Table 6. Variation in the weight of SMEDDS Tablets.

Formulation	Average Weight (mg)	Minimum (mg)	Maximum (mg)	% Deviation Range
F1	1275 ± 3.5	1268	1282	±0.55 %
F2	515 ± 2.8	510	520	±0.97 %
F3	500 ± 3.2	494	505	±1.10 %
F4	500 ± 2.5	496	504	±0.80 %

5.9. *In-vitro* dissolution of Vildaformin SMEDDS tablets: Dissolution of Vildaformin SMEDDS tablets was carried out at 37 ± 0.5 °C with the USP Type II paddle apparatus spinning at 50 rpm in 900 mL of 0.1 N HCl (pH 1.2) and phosphate buffer pH 6.8. Five millilitres of the samples were collected throughout the following intervals: 5, 10, 15, 30, 45, and 60 minutes. They were then filtered using a 0.45micron filter and estimated spectrophotometrically at 235 nm.

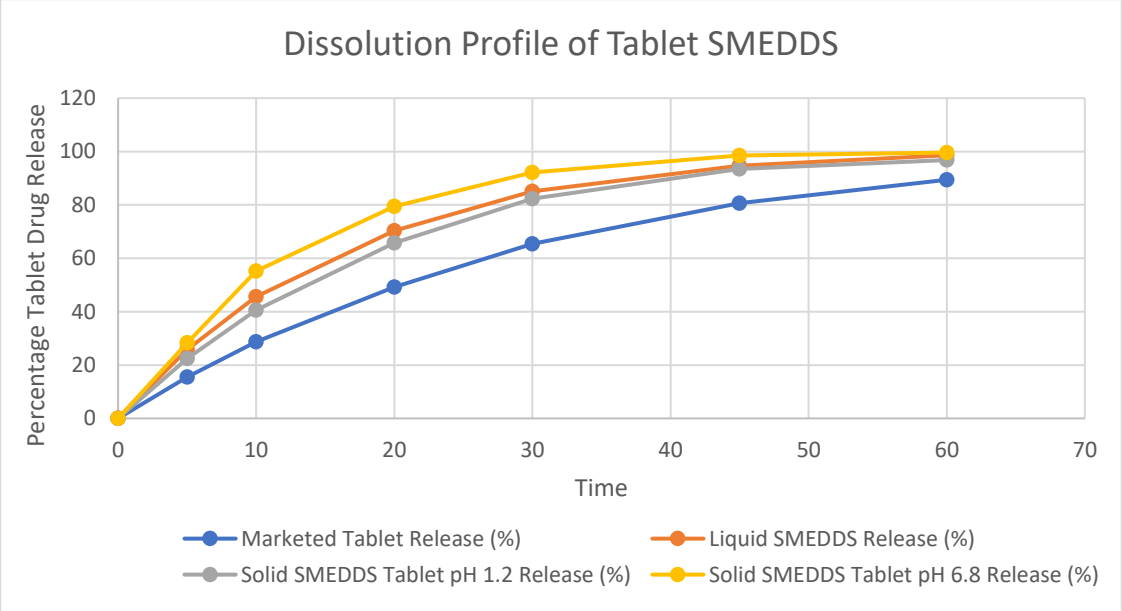


Figure 5. Dissolution of Marketed Tablets, Liquid SMEDDS, and Solid SMEDDS Tablet formulation In-Vitro.

5.10 Drug Release Kinetic Studies: Zero-order, First-order, Higuchi, and Korsmeyer-Peppas models were used in the analysis of the kinetic behavior of Vildaformin Solid-SMEDDS tablet (F3). The rate and mechanism of drug release of the solidified lipid matrix were assessed using each of the models.

5.10.1 Zero-order Kinetics: A zero-order plot was plotted by cumulative plotting of percent drug release as a function of time. The graph indicated that the drug released was almost in linear proportion to time, indicating that the rate at which the drug was released was constant in the dissolution process.

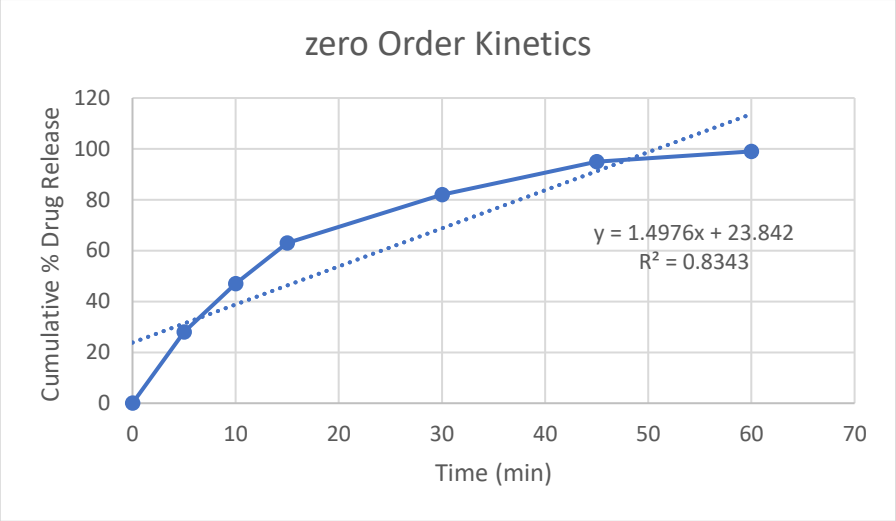


Figure 6. Graph of zero-order release kinetics.

5.10.2 First-order Kinetics: The plot of [100-percent release] versus time on a log scale, first-order showed a close linear decrease in percentage content of the drug over time.

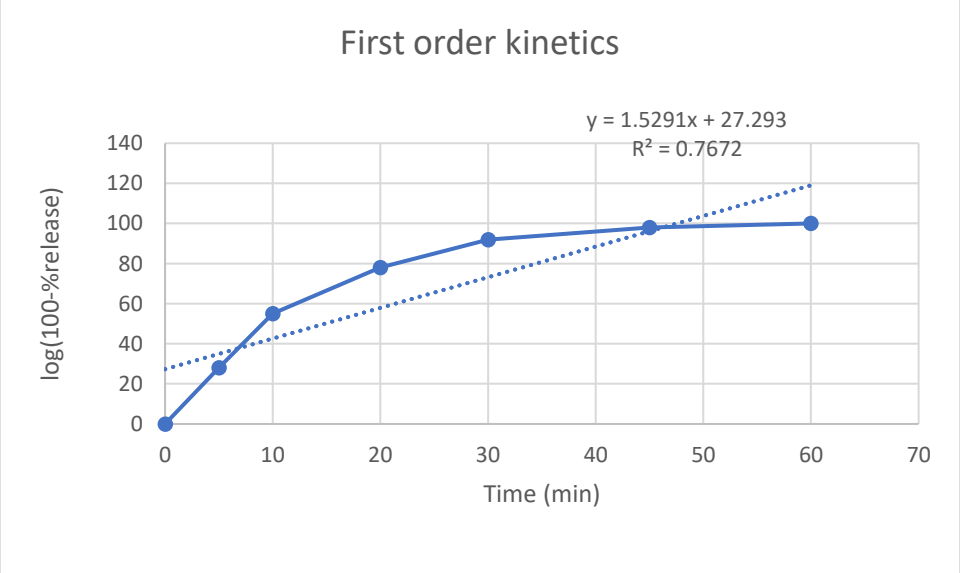


Figure 7. Graph of First-Order Release Kinetics.

5.10.3 Higuchi Model: It was discovered that the Higuchi plot of percent cumulative release versus 1/time was very linear (theoretical R^2 = 0.97–0.99). Such intensity of linearity proves that the mechanism of release is controlled mainly by Fickian diffusion in which the drug diffuses through the hydrated layer of the solidified SMEDDS, which is the matrix layer.

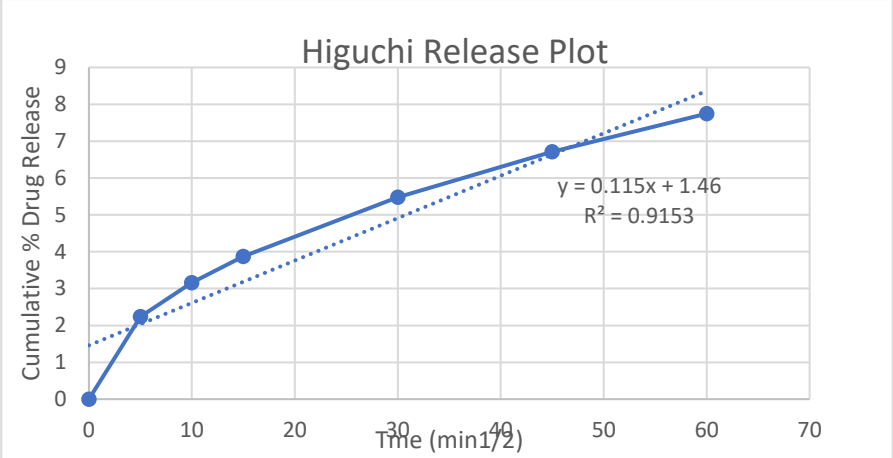


Figure 8. Graph of Higuchi Release Plot.

5.10.4 Korsmeyer -Peppas Model: The mechanism behind the release has been understood using the Peppas model (log Mt/M∞ vs log t). The line slope (n = 0.450.70) showed a non-Fickian (anomalous) mode of transportation, i.e., both diffusion and erosion aided in the release of the drug.

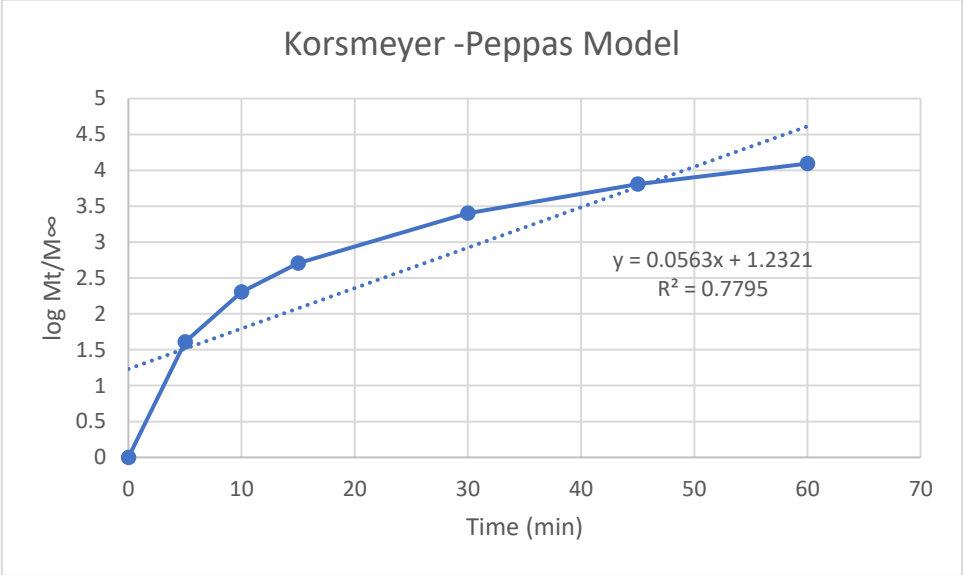


Figure 9. Graph of the Korsmeyer-Peppas model.

6. DISCUSSION

The results showed that the prepared powders of S-SMEDDS have good micromeritic properties, good for uniform filling of the die, compression, and mass production of tablets. The improvement could be due to the incorporation of Aerosil 200 as a carrier to improve flowability through reduced inter-particle adhesion. X-ray diffractograms of pure Vildagliptin and Metformin hydrochloride with solid SMEDDS (S-SMEDDS). Sharp, intense peaks of diffraction were typical of these reflections of the crystalline structure of pure drugs, and (P-SMEDDS) showed a diffuse broad halo devoid of any characteristic peaks, which points to a change to amorphous form that was dispersed at the molecular level upon solidification over Aerosil 200. The powder flow properties were discussed before the preparation of the formulation to be compressed. They were identified based on the Hausner ratio, Carr index, tapped density, and bulk density, which indicated that F3 and F4 are good compressors relative to F1 and F2. Formulation F3 had the optimal trade-off between the liquid SMEDDS adsorption capacity and the ratio of excipient, and could be further compacted into tablets. These results indicate that the formulated SMEDDS tablets possessed the best physical and performance characteristics suitable to be given orally. Percent variation is small, which means that the die filling and blends are uniform. The weights of F3 and F4 formulations were more consistent, just as is the case with their more favourable flow and compressibility behaviour. After 45 min, 98% of the liquid SMEDDS had been released, which focused on the fact that solubilization effect. Solid SMEDDS Tablet (F3) was very similar to liquid SMEDDS. Performance. At pH 6.8, overall release was 99% by 45-60 min, slightly faster than the marketed formulation. Amorphization was the reason behind the improved release of SMEDDS tablets in GI fluids, high surface area, and self-emulsification was more effective than traditional marketed tablets. The in vitro graph indicated that there was almost a linear growth of the amount of drug released with time, and this implied that the rate of release was nearly constant throughout the dissolution. This action was

an indicator that the matrix system enables the release of drugs to be sustained without dependency on drug concentration.

7. CONCLUSION

The current paper was able to show how solid self-microemulsifying drug delivery system (S-SMEDDS) tablets of Vildaformin could be developed using Aerosil 200 as a solid carrier. SEM, PXRD, and DSC analyses confirmed that the optimized formulation had desirable thermal and structural stability, uniform morphology, and optimized micromeritic properties. Tablet tests demonstrated good hardness, friability, disintegration, and weight variation, which ensure mechanical strength and acceptability by the patient. Enhanced solubility and dissolution rate were confirmed by in vitro dissolution studies that showed a markedly greater release of the drug in S-SMEDDS tablets relative to the pure drug and marketed formulation. The findings indicate that the S-SMEDDS-formulated tablet form of Vildaformin is a promising oral delivery system to enhance bioavailability, therapeutic effect, and compliance in the treatment of type 2 diabetes mellitus. The results of the study are consistent with those reported previously for other poorly soluble drugs developed in SMEDDS and S-SMEDDS methodologies. The Solid-SMEDDS tablet (F3) of Vildaformin conforms to a diffusion-controlled sustained-release mechanism, which guarantees enhanced dissolution, bioavailability, and therapeutic activity, where improved dissolution was found to be associated with improved oral bioavailability. Notably, conversion of liquid SMEDDS to a solid dosage form not only gave the compound stability and ease of administration, but also increased the patient acceptability and compliance by eliminating the drawback of liquid lipid systems.

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Conflicts of Interest

The authors declare no conflicts of interest.

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