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DESIGN DEVELOPMENT AND ASSESSMENT OF VILDAGLIPTIN FAST DISSOLVING TABLET

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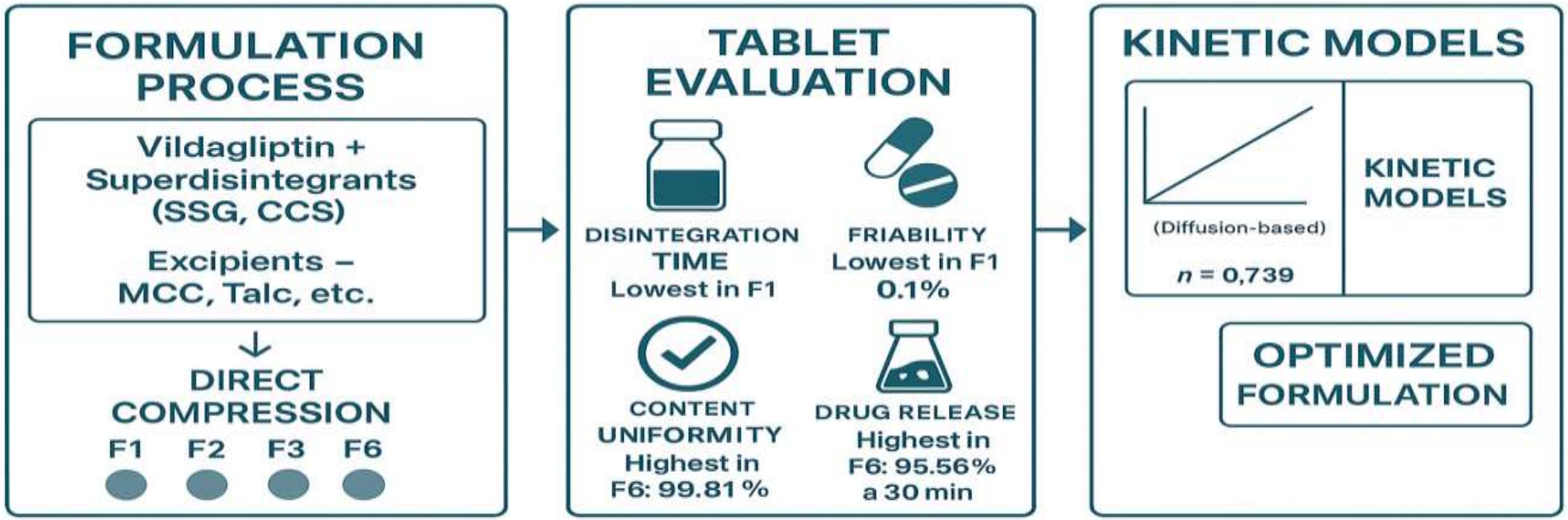
Graphical Abstract



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Abstract: Fast-dissolving tablets (FDTs) have gained significant attention in pharmaceutical research due to their ability to disintegrate rapidly in the oral cavity without the need for water. The present study formulated and evaluated FDTs using various Superdisintegrants to enhance drug dissolution and bioavailability. The tablets were prepared by direct compression, employing sodium starch glycol ate, croscarmellose sodium, and crospovidone as Superdisintegrants at different concentrations. The results revealed that all formulations exhibited satisfactory pre-compression and post-compression characteristics. However, formulation F6 (containing 15 mg of crospovidone) had the shortest disintegration time (3 min 10 s) and the highest drug release (99.56% in 30 minutes) compared to the other formulations. F6 also showed the lowest friability (0.11%), indicating excellent mechanical strength; its content uniformity was highest (99.81%), ensuring uniform drug distribution in each tablet. In vitro dissolution studies demonstrated that drug release significantly improved with increasing Superdisintegrants concentration, with crospovidone being the most effective among those tested. Kinetic analysis indicated that the formulations followed zero-order release kinetics and fit the Higuchi diffusion model, F6 is recommended for further in vivo evaluation and potential commercialization, offering significant advantages in improving drug bioavailability and patient compliance.

Keywords: Fast-dissolving tablets, Superdisintegrants, Crospovidone, in-vitro drug release, direct compression, first-order kinetics, Higuchi model, patient compliance.

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Introduction

- A fast-dissolving tablet (FDT), also known as an orally disintegrating tablet (ODT), is a solid dosage form that dissolves or disintegrates quickly in the mouth without the need for water, typically within 30 seconds to 3 minutes.

- Bioavailability of drug increases due to bypass of first pass metabolism. These tablet are suitable for pediatric and geriatric patients and those having problem in swallowing.

- **Ideal Properties of FDT**
- Rapid disintegration
- Ease of administration
- Improved bioavailability
- Pleasant Taste

Results and discussion

Formulation table of Vildagliptin Fast Dissolving Tablet

INGREDIENTS	F1	F2	F3	F4	F5	F6
Vildagliptin	50	50	50	50	50	50
Sodium starch glycolate	10	15	-	-	-	-
Crosscarmellose sodium	-	-	10	15	-	-
Crosspovidone	-	-	-	-	10	15
Microcrystalline Cellulose	190	185	190	185	190	185
Sodium Saccharine	5	5	5	5	5	5
Talc	2.5	2.5	2.5	2.5	2.5	2.5
Magnesium stearate	2.5	2.5	2.5	2.5	2.5	2.5
Total	260	260	260	260	260	260

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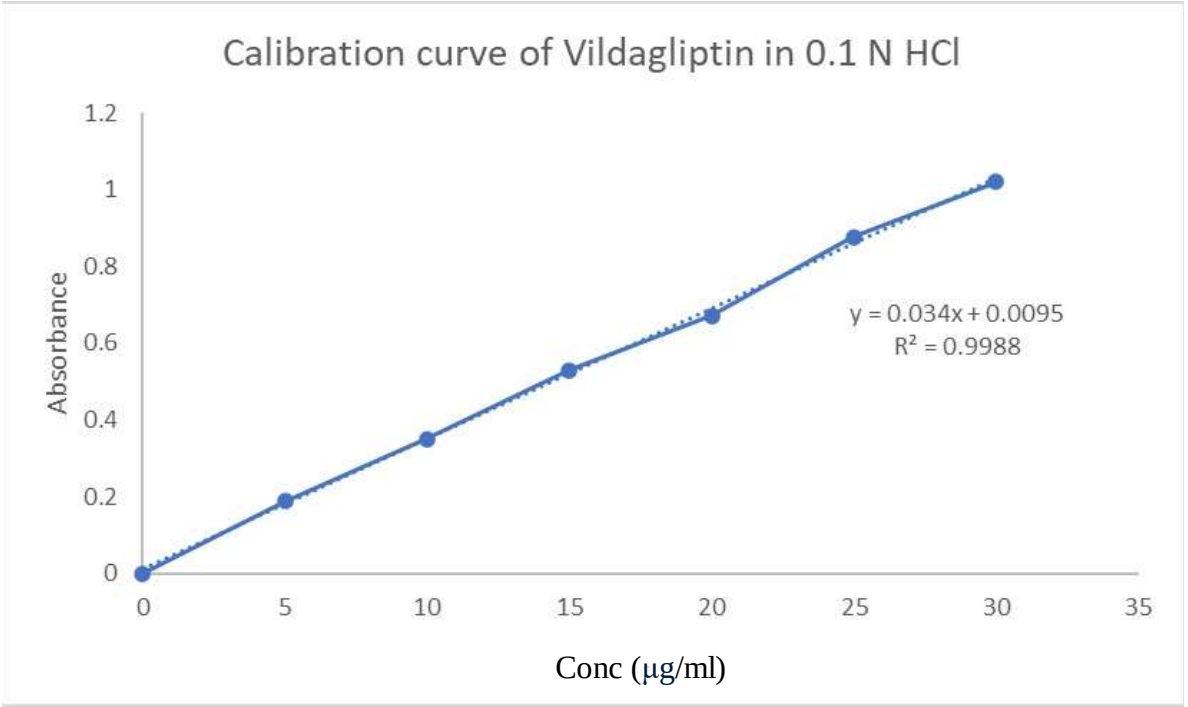
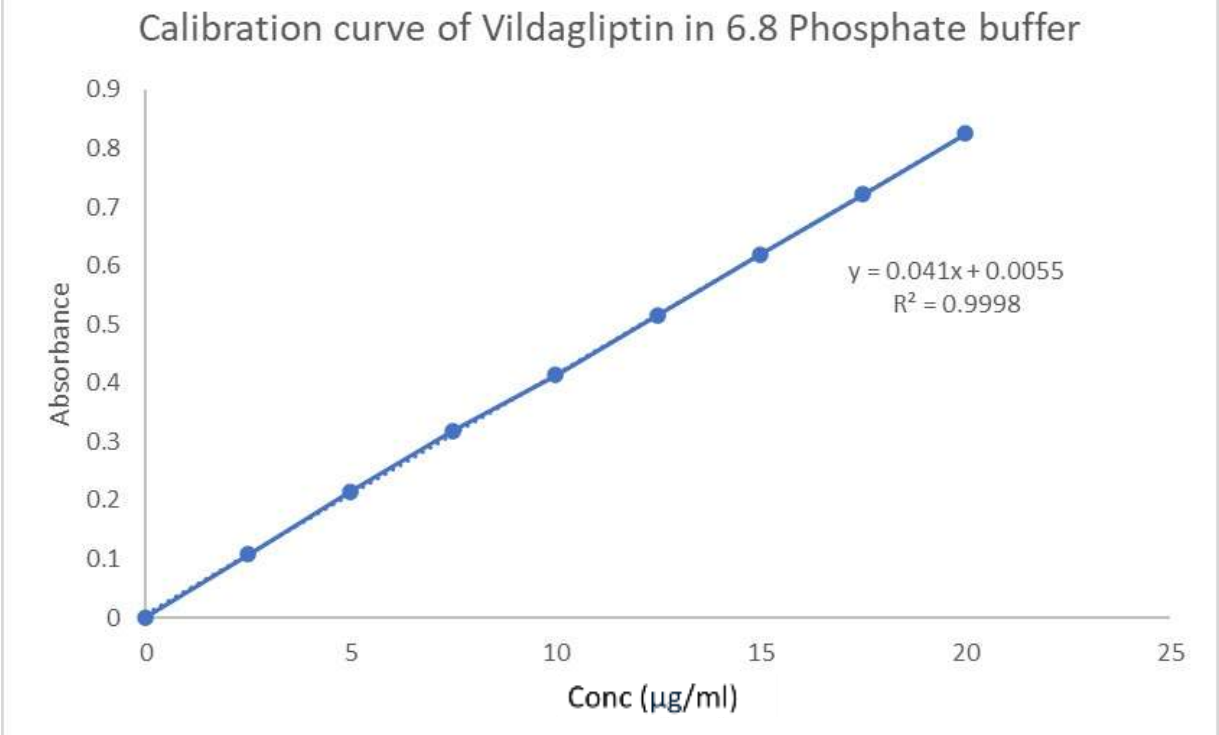
Calibration curve data for Vildagliptin in 0.1N HCl at 210nm

Sr No	Concentration (µg/ml)	Absorbance
1	0	0
2	5	0.188
3	10	0.351
4	15	0.529
5	20	0.671
6	25	0.877
7	30	1.021

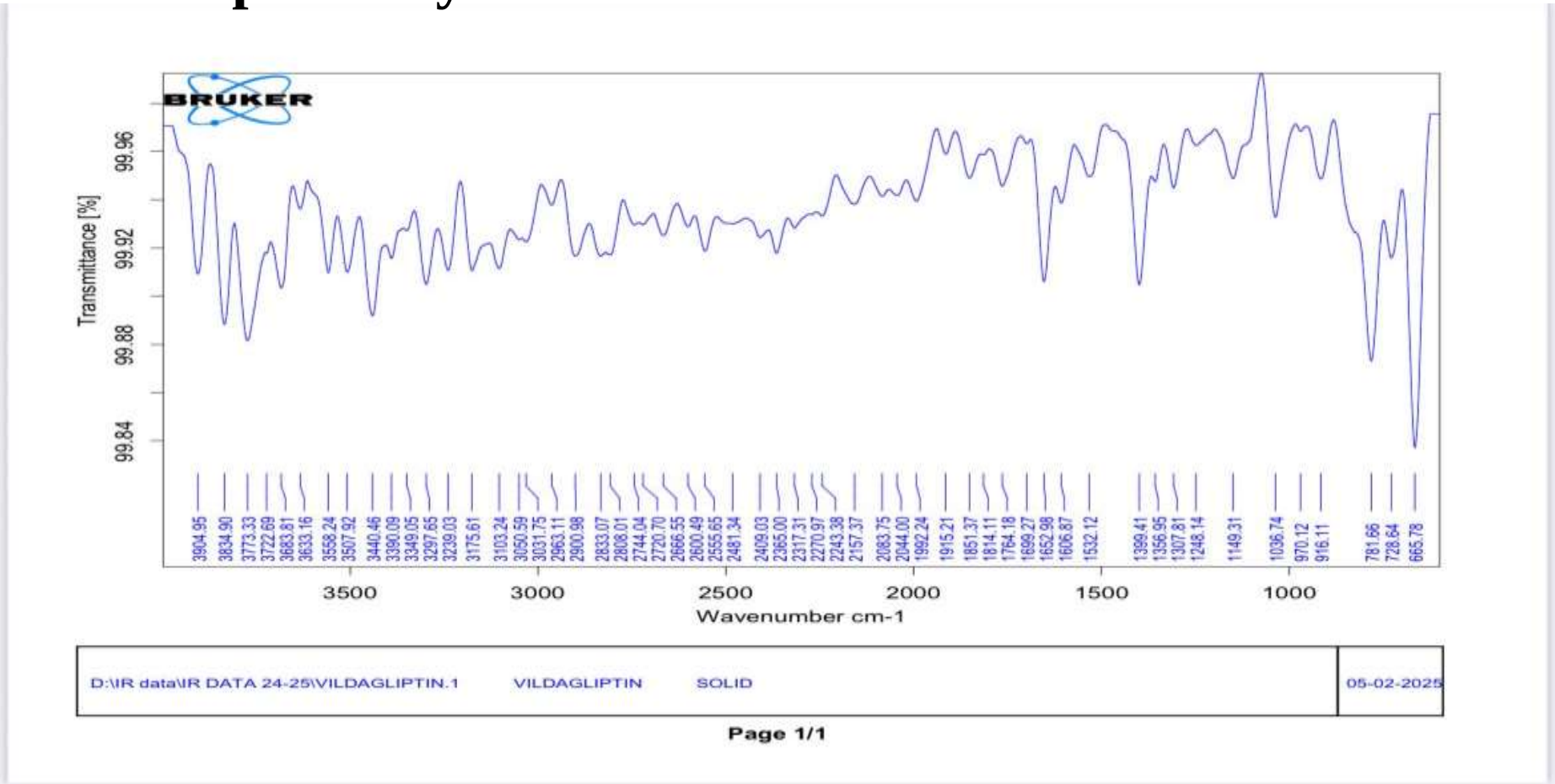


Calibration Curve data of Vildagliptin in 6.8 Phosphate Buffer

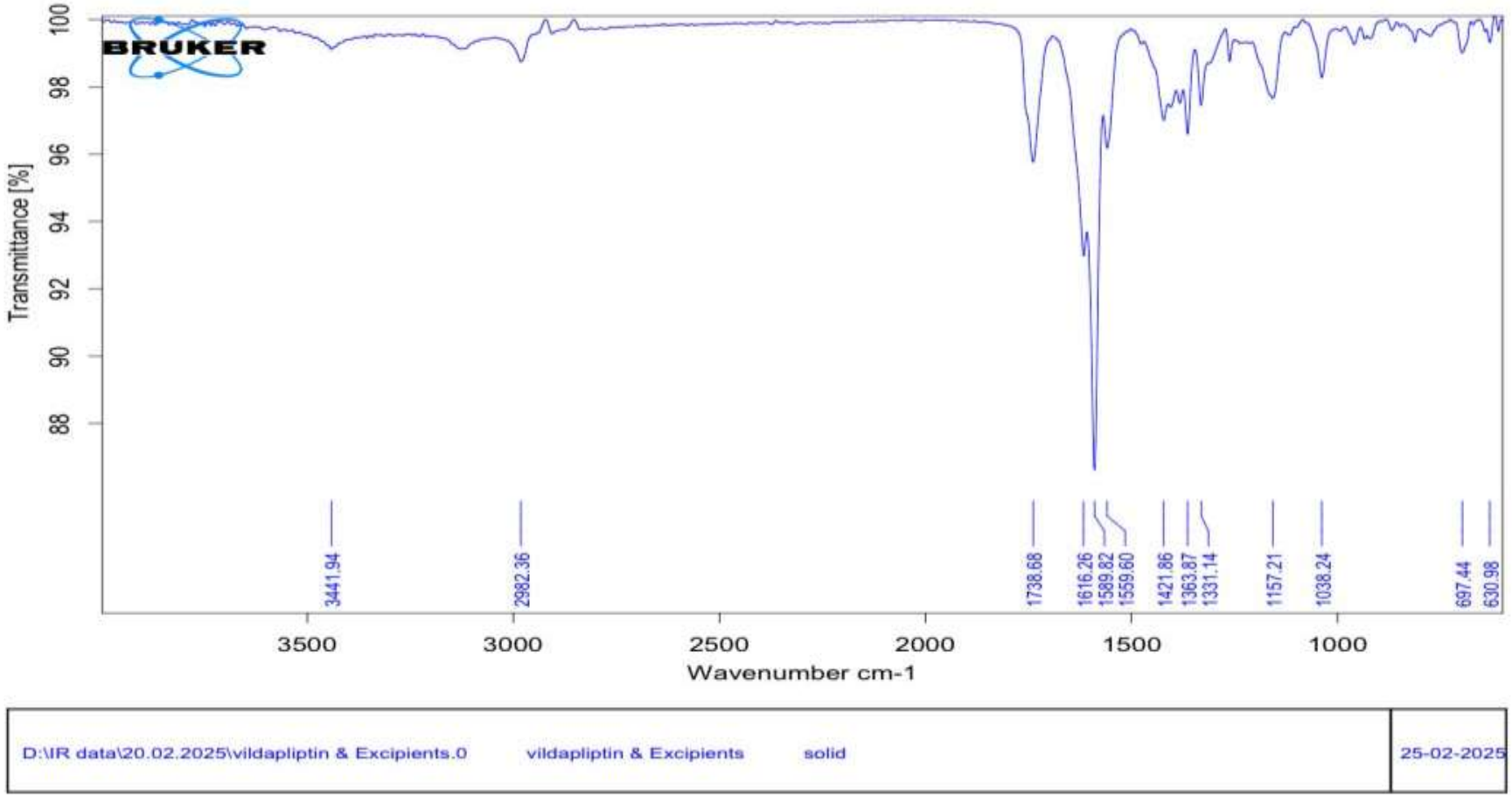
Sr No	Concentration (µg/ml)	Absorbance
1	0	0
2	2.5	0.108
3	5	0.215
4	7.5	0.319
5	10	0.412
6	12.5	0.516
7	15	0.619
8	17.5	0.722



Compatibility Studies : FTIR Method



FTIR Of Vildagliptin mixture



FTIR Of Vildagliptin

Evaluation Studies of Precompression properties of Vildagliptin Fast dissolving tablet

Mean ± S.D, n = 3

Formulation Code	Angle of Repose (ɵ)	Bulk Density (gm/cc)	Tap Density (gm/cc)	Compressibility index (%)	Hausners Ratio
F1	29.6 ± 0.46	0.53 ± 0.16	0.66 ± 0.18	12.96	1.18
F2	29.35 ± 0.75	0.49 ± 0.14	0.67 ± 0.14	14.6	1.14
F3	28.62 ± 0.45	0.55 ± 0.17	0.65 ± 0.16	11.42	1.15
F4	31.67 ± 0.56	0.53 ± 0.16	059 ± 0.18	13.11	1.19
F5	29.97 ± 0.65	0.47 ± 0.12	0.63 ± 0.12	11.66	1.15
F6	27.65 ± 0.89	0.42 ± 0.18	0.7 ± 0.14	10.71	1.13

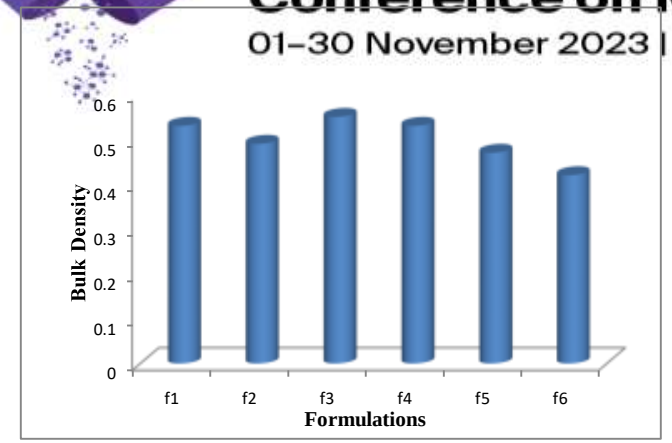


Fig.1. Bulk Density of Vildagliptin fast dissolving tablets of formulation F1-F6

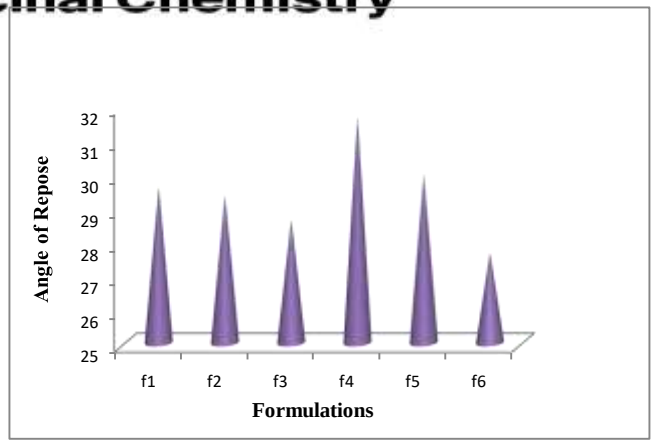


Fig.3. Angle of Repose of Vildagliptin fast dissolving tablets of formulation F1-F6

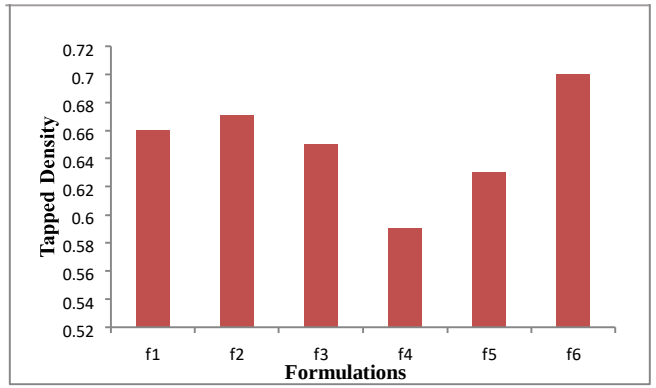


Fig.2. Tapped density of Vildagliptin fast dissolving tablets of formulation F1-F6

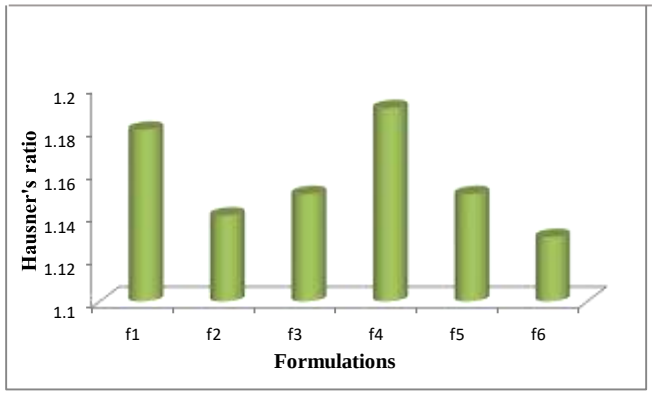


Fig. 4. Hausner's ratio of Vildagliptin fast dissolving tablets of formulation F1-F6

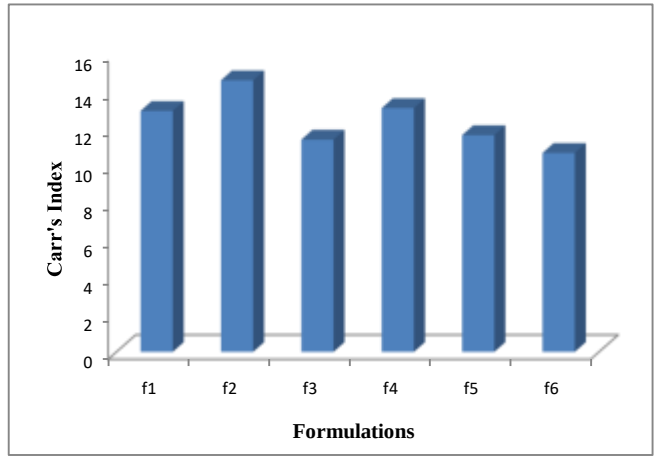


Fig.5. Carr's Index of Vildagliptin fast dissolving tablets of formulation F1-F6

Evaluation of Post-compression parameters of formulation

Formulation Code	Weight Variation (mg)	Thickness (mm)	Hardness (Kg/cm2)	Friability (%)
F1	262.22±2.64	4.72±0.04	3.33±0.34	0.18
F2	236.66±1.15	4.41±0.035	3.42±0.38	0.18
F3	261.33±3.05	4.56±0.02	3.36±0.06	0.22
F4	260.66±2.98	4.87±0.034	3.33±0.47	0.18
F5	262.22±1.52	4.44±0.026	3.41±0.23	0.18
F6	261.21±3.08	4.563±0.011	3.33±0.25	0.11

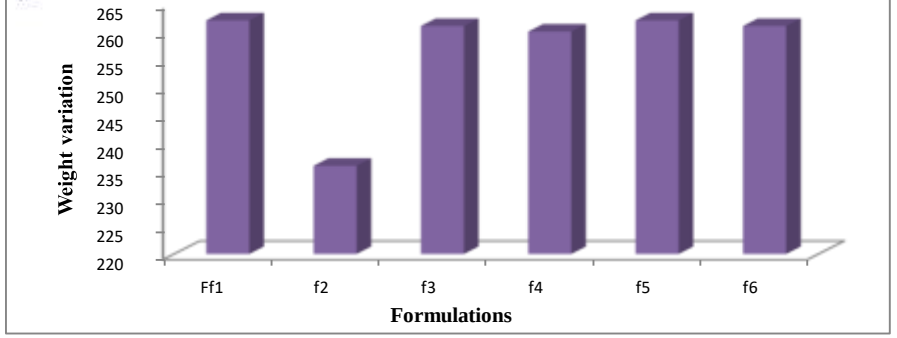


Fig.6. Weight variation of Vildagliptin fast dissolving tablets of formulation F1-F6

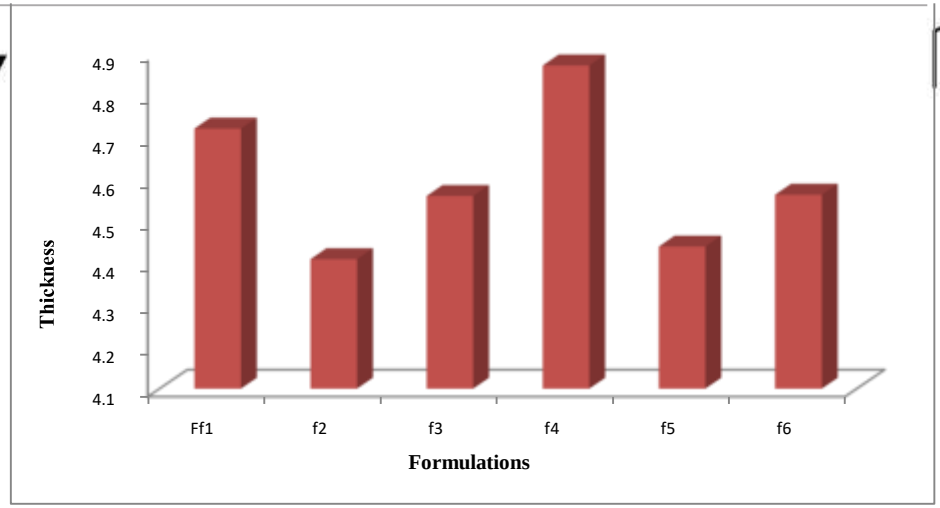


Fig.8. Thickness of Vildagliptin fast dissolving tablets of formulation F1-F6

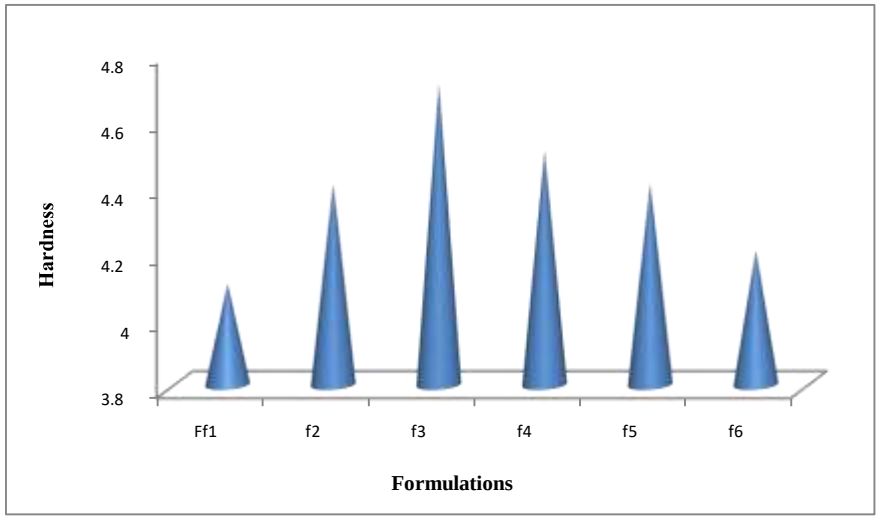


Fig.7. Hardness of Vildagliptin fast dissolving tablets of formulation F1-F6

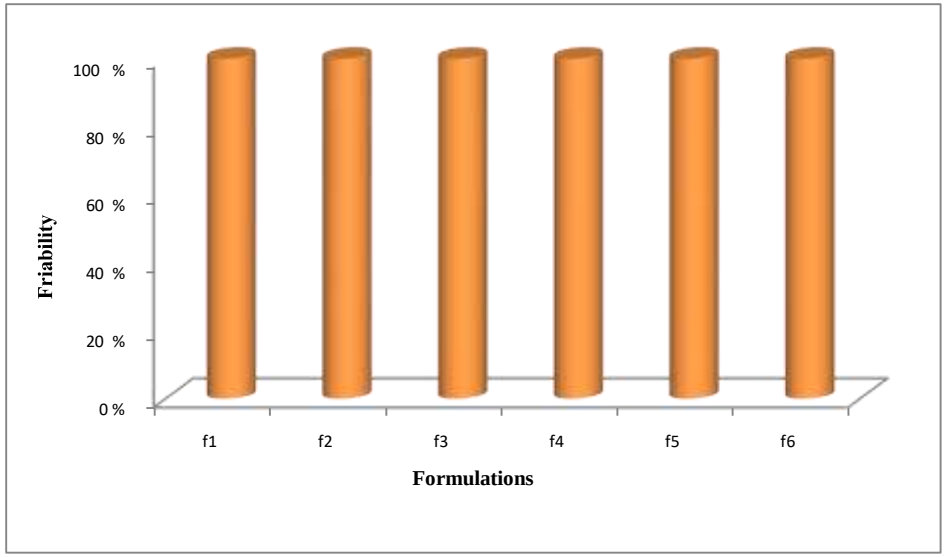


Fig.9. Friability of Vildagliptin fast dissolving tablets of formulation F1-F6

Evaluation of Vildagliptin FDTs using Superdisintegrants

Formulation Code	Drug Content (%)	Wetting Time (sec)	Water Absorption Ratio (%)	Disintegration Time (min.sec)
1	96.99	63.67 ±0.58	63.68 ±1.20	5. 2±1.15
2	88.9	61.67 ±1.53	61.63 ±2.79	4.10 ±1.73
3	97.81	58.67 ±0.58	64.35 ±0.64	3.20 ±2.52
4	86.99	64.67 ±1.53	63.63 ±1.02	3.15 ±3.61
5	98.92	61.33 ±2.08	62.33 ±2.45	3.12 ±1.53
6	99.81	59.33 ±2.08	64.31 ±1.19	3.10 ±0.58

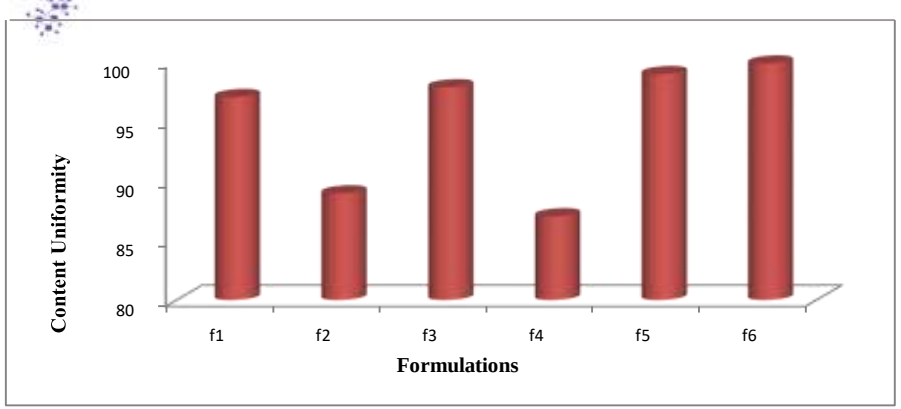


Fig.10. Content Uniformity of Vildagliptin fast dissolving tablets of formulation F1-F6

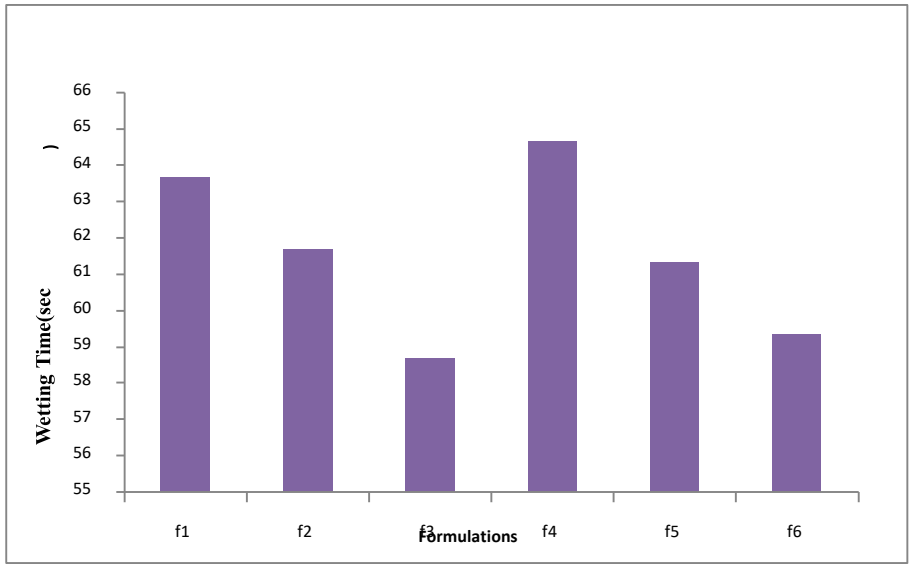


Fig.11. Wetting time of Vildagliptin fast dissolving tablets of formulation F1-F6

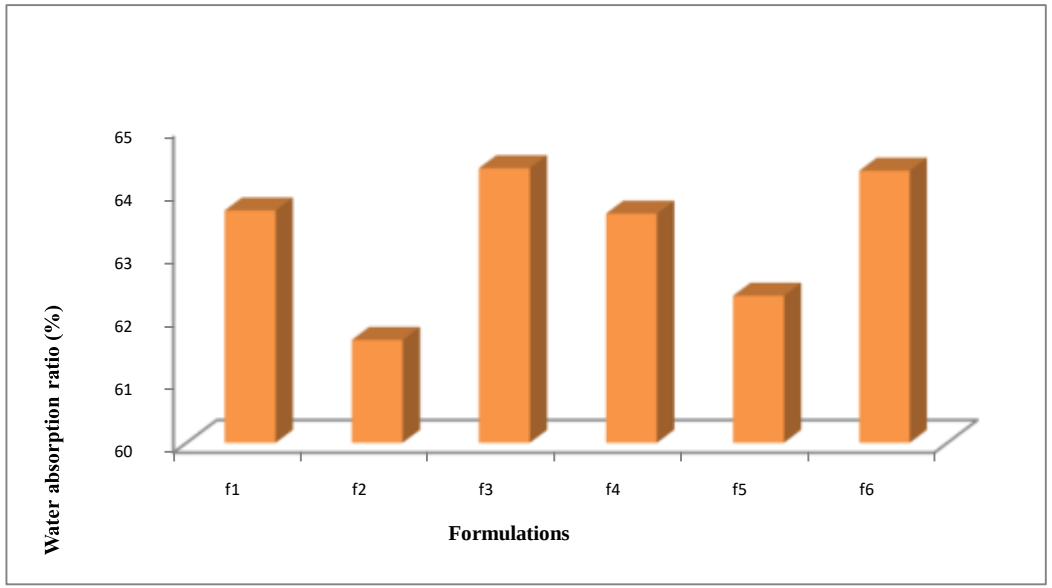


Fig 12 : Water absorption ratio of Vildagliptin fast dissolving tablets of formulation F1-F6

Dissolution profile of the formulation F1 - F6

TIME	F1	F2	F3	F4	F5	F6
0	0	0	0	0	0	0
5	19.29±0.45	17.4±0.21	15.32±0.24	20.94±0.26	21.22±0.25	28.5±0.26
10	22.91±0.25	28.58±012	25.33±0.22	30.06±0.21	39.41±0.24	42.64±0.24
15	37.4±0.12	44.14±0.32	38.24±0.24	45.61±0.22	57.07±0.22	60.21±0.23
20	50.28±0.12	50.62±0.21	51.44±0.21	61.66±0.23	78.94±0.24	73.3±0.22
25	60.98±0.21	61.65±0.22	60.98±0.23	74.28±0.24	82.83±0.21	89.88±0.22
30	71.2±0.31	76.2±0.21	72.52±0.25	78.95±0.22	86.41±0.22	99.56±0.24

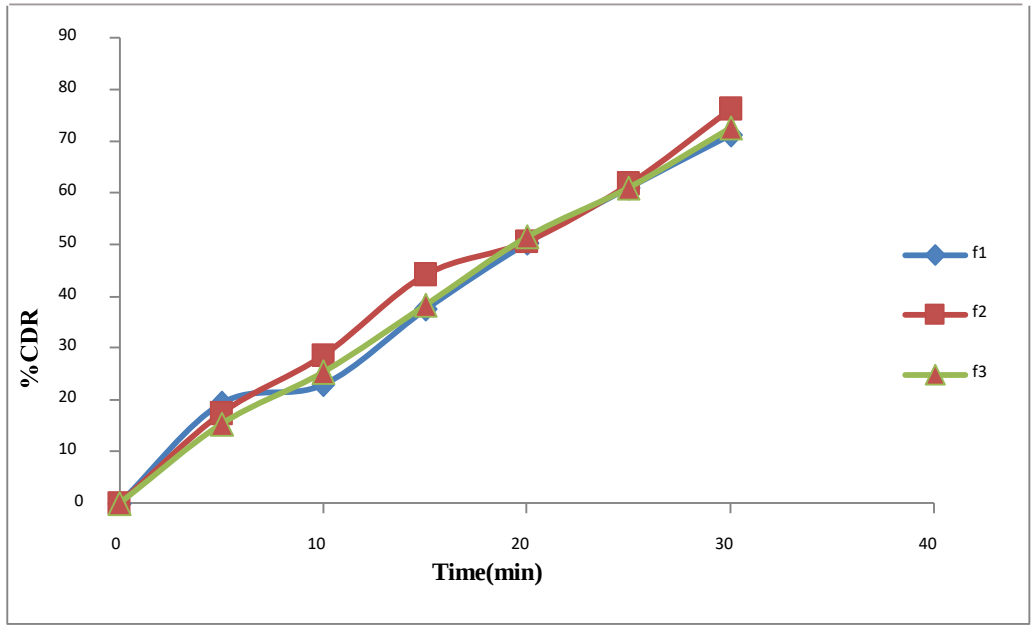


Fig13 : Dissolution Profile of Formulations F1-F3

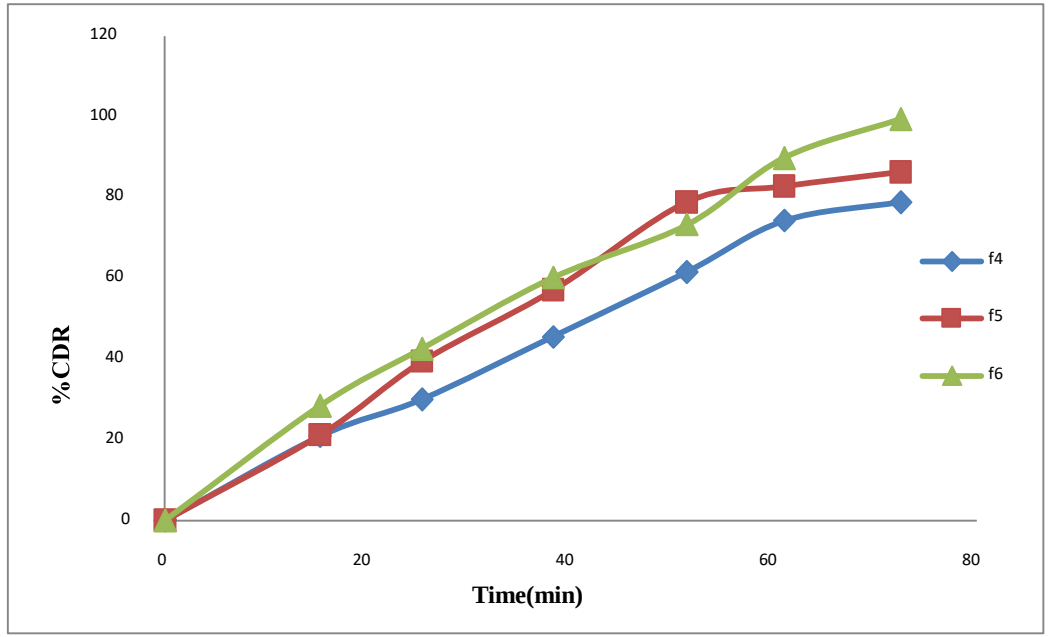


Fig 14 : Dissolution Profile of Formulations F4-F6

Formulation code	R^2 Values of mathematical models of dissolution studies				
	Zero order	First order	Higuchi model	Peppas model	
				R^2	N
F1	0.984	0.971	0.954	0.942	0.886
F2	0.983	0.960	0.978	0.990	0.838
F3	0.992	0.977	0.932	0.990	0.992
F4	0.975	0.974	0.930	0.980	0.812
F5	0.933	0.973	0.952	0.979	0.720
F6	0.995	0.945	0.969	0.994	0.739

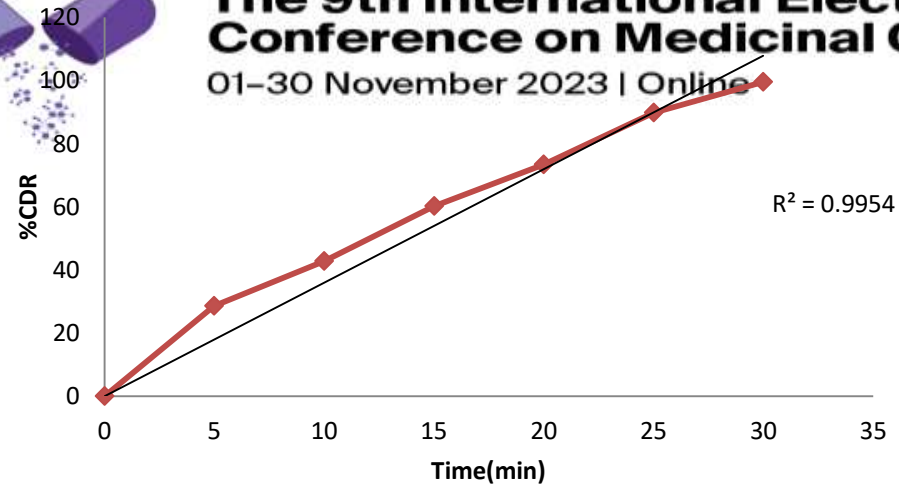


Fig.15 : Zero order drug release profile of Vildagliptin fast dissolving tablets of formulation F9

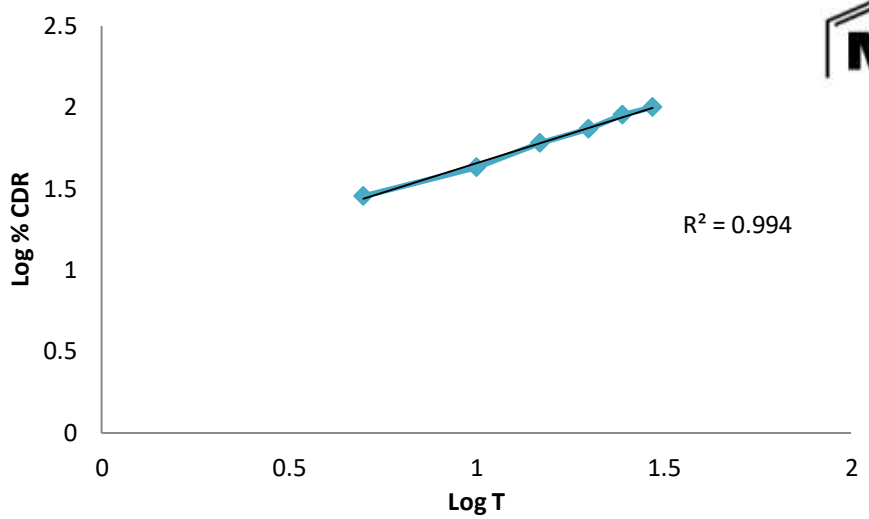


Fig.17. Kosmeyer-Peppas model drug release profile of Vildagliptin fast dissolving tablets of formulation F9

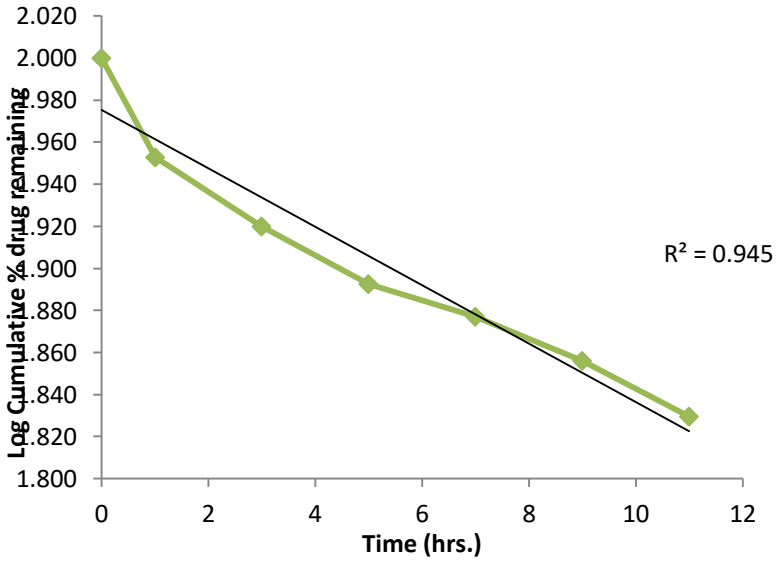


Fig.16: First order drug release profile of Vildagliptin fast dissolving tablets of formulation F9

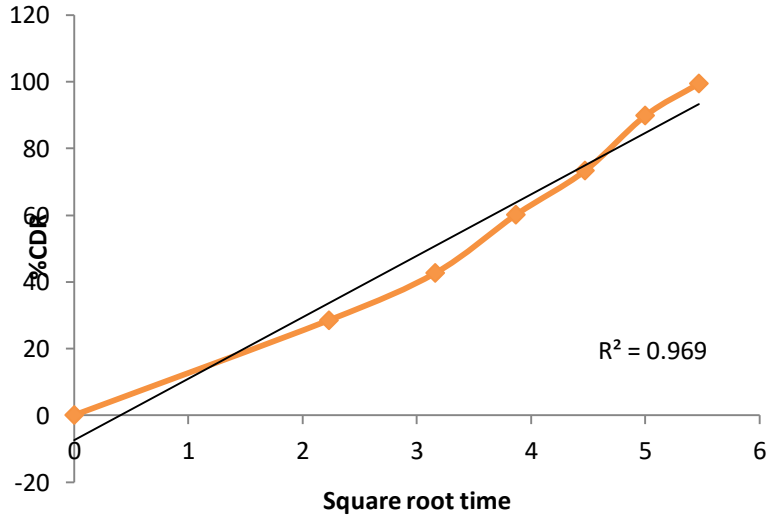


Fig.17 : Kosmeyer-Peppas model drug release profile of Vildagliptin fast dissolving tablets of formulation F9

Discussion

- The evaluation of kinetic models for Vildagliptin fast-dissolving tablet formulations indicated that drug release primarily followed Zero-order and Korsmeyer–Peppas mechanisms. This suggests a consistent and controlled release independent of concentration, governed by diffusion along with matrix relaxation and erosion mechanisms.
- The ‘n’ values of all formulations were found to be between 0.72 and 0.992, indicating anomalous (non-Fickian) diffusion behavior. Notably, F3 showed an ‘n’ value of 0.992, representing a Super Case-II transport mechanism, which implies a significant contribution of polymer swelling and chain relaxation.
- Formulations F2 and F6 also performed well, exhibiting desirable kinetic characteristics and fast drug release. F6, in particular, showed almost complete drug release (99.56%) within the test period and matched closely with both Zero-order and Peppas models, highlighting its potential as an optimized formulation.

- F5 displayed slightly lower correlation values, possibly due to differences in excipient behavior or formulation uniformity. Overall, the results support the applicability of Zeroorder and Korsmeyer–Peppas models in predicting the drug release profile of Vildagliptin fast-dissolving tablets.

- Overall, Formulation F6 demonstrated excellent release characteristics, with Zero-order $R^2 = 0.995$, Korsmeyer–Peppas $R^2 = 0.994$, and an n value of 0.739, again confirming anomalous (non-Fickian) diffusion. F6 had the highest cumulative drug release (99.56%) at 30 minutes, indicating it is the most effective formulation among all.

- F6 provided the most desirable release kinetics, balancing rapid onset with complete drug dissolution, making it the most optimized formulation

Conclusion

- The study successfully formulated and evaluated fast-dissolving tablets using three different superdisintegrants: Sodium Starch Glycolate, Cross Carmellose Sodium, and Crosspovidone.
- Among all formulations, F6 (containing 15 mg of Crosspovidone) demonstrated the best results in terms of disintegration time (3 min 10 sec), friability (0.11%), drug content (99.81%), and drug release (99.56% within 30 minutes).
- The kinetic studies confirmed that drug release followed first-order kinetics with diffusion-controlled mechanisms.
- The log-transformed drug release data indicated that F6 followed first-order release kinetics, where the drug dissolution rate was concentration-dependent.

- The Higuchi model analysis revealed that drug release was diffusion-controlled, suggesting that superdisintegrants played a crucial role in breaking the tablet matrix and facilitating drug dissolution.

- The Korsmeyer-Peppas model suggested that the release mechanism followed a non-Fickian diffusion, meaning both erosion and diffusion processes were involved.

- These findings suggest that F6 is the most promising formulation for developing an effective fast-dissolving tablet with enhanced patient compliance and rapid therapeutic action.

- Overall, F6 provided the most desirable release kinetics, balancing rapid onset with complete drug dissolution, making it the most optimized formulation

THANK YOU