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Research Article

Formulation Optimization and Evaluation of Immediate Release Tablet of Linagliptin

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ABSTRACT

The present study focuses on the formulation, optimization, and evaluation of immediate release tablets of Linagliptin, a dipeptidyl peptidase-4 (DPP-4) inhibitor used in the treatment of type 2 diabetes mellitus. The primary objective was to develop a robust and effective formulation that ensures rapid disintegration and optimal drug release to achieve prompt therapeutic action. Various formulations were prepared using wet granulation technique with different concentrations of superdisintegrants such as crosspovidone and Banana Powder. A Central Composite design (CCD) was employed to optimize the formulation parameters As well as Sixteen batches (LB1 to LB16) by Design of Expert software were done using binder (PVPK30) and natural super disintegrant (Banana Powder), Crosspovidone at different concentrations were formulated and evaluated for pre-compression and post-compression parameters. Batch LB1 is considered as optimized batch based on results analysis of responses mentioned in DOE Software. The tablets were evaluated for pre-compression and post-compression parameters including hardness, friability, weight variation, disintegration time, and in vitro drug release. The optimized formulation showed rapid disintegration within 35 seconds and 97.67% drug release within 60 minutes, indicating immediate release behavior. Stability studies conducted under and confirmed the physical and chemical stability of the optimized formulation. The study concludes that a carefully designed formulation strategy can significantly enhance the release profile of Linagliptin, improving patient compliance and therapeutic efficacy.

INTRODUCTION

The oral route of administration is the most popular method for achieving systemic effects due to its ease of ingestion, lack of pain, versatility, and, most importantly, high patient compliance. Additionally, solid oral delivery systems do not require sterile conditions, making them less

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expensive to manufacture. The combination of patient compliance, precise dosing, and manufacturing efficiency makes tablets the preferred solid dosage form. However, there is a growing need for new oral drug delivery systems due to poor patient acceptance of invasive methods, the need to explore new markets for drugs, and the rising cost of disease management. Developing innovative drug delivery techniques and incorporating them into product development is essential for pharmaceutical companies to remain competitive and thrive in the future. Linagliptin is one of the most recent additions to incretin-based therapies for Type 2 diabetes. Unlike other DPP-4 inhibitors, linagliptin is excreted chiefly via the enterohepatic system and can be used without dose adjustment in patients with renal or hepatic impairment. Type 2 diabetes mellitus (T2DM) is a progressive disease, and it occurs with increasing prevalence in the elderly and those with other comorbidities. Blood glucose control presents a challenge that is magnified by these co-existing problems. To achieve glycemic targets, many patients need more than one antidiabetic drug, and additional medications are often required as glucose control deteriorates. Consequently, the development of new antidiabetic drugs that can help meet this challenge has been an area of intensive research. The dipeptidyl peptidase-4 (DPP-4) inhibitors are one of the recently developed therapeutic classes for treatment of hyperglycemia in T2DM. The various agents in the class have differing chemical structures, but all act by inhibiting the DPP-4 enzyme, thus prolonging the life of incretin hormones, which in turn raise insulin levels and suppress glucagon secretion in a glucose-dependent manner. As a class, DPP-4 inhibitors have been shown to provide significant improvements in glycosylated hemoglobin (HbA1c), and to have a good safety profile. In addition, their glucose-dependent mechanism of action is associated with a low rate of hypoglycemic events.

MATERIALS AND METHOD:

Materials:

Linagliptin received as a gift sample from Pinnacle Life Sciences, New Mumbai, India. PVPK30, Crosspovidone, Medley Pharma LTD., Andheri. Banana Powder Prepare in Lab Preparation, Jamner and other excipients were received from S.D. Fine Chem. Ltd., Mumbai & Jinendra Scientific, Jalgaon.

Methods:

Procedure for Immediate release tablet of Linagliptin Tablet Batches Prepared Using Wet Granulation Method

All the ingredients were accurately weighed. Linagliptin pure drug powder is Micronized by mortal pestle and passed through sieve #100. MCC, PVPK30 and super disintegrants was passed through sieve #60. Binding solution was prepared by dissolving PVPK30 in mixture of Purified water. Add binder solution to mixture. Binded the above step 2 dry mix by using the binding solution. Then passed the wet granules through sieve #22. Allowed the wet granules to air dry. Passed the dried granules through sieve # 22. Magnesium stearate and talc were sifted through 60#. The dried granules sifted through 22 # and lubrication materials sifted through 60 # mixed in a polybag for 2 min. The lubricated blend was compressed onto 200 mg weight of tablet by using 8 mm (FFBE) punch on 12 station multi tooling CIP Lab Press. / (Use of Hydraulic Press also).

Preformulation Studies

Preformulation means determination of properties combined of both physical chemical properties of

drug alone and when drug combined with excipients used in preparation of final product because these properties may greatly affect the design of formulation, production method, and biopharmaceutical properties of finished product.

Solubility Studies

Solubility Studies Solubility of Linagliptin was determined in Ethanol, Methanol, Water & 0.1 N HCl.

Scanning and Determination of Maximum Wavelength (λmax)

A solution of Linagliptin was prepared in 0.1 N HCL & UV spectrum was recorded using UV visible spectrophotometer (Shimadzu 1800). The spectra of Linagliptin in 0.1 N HCL scanned in the range of 200-400 nm & wavelength was observed at 297 nm.

Drug Polymer Compatibility Studies by FTIR Spectroscopy

The interaction between the Linagliptin and natural superdisintegrant & binder were determined by using the FT-IR spectrophotometer.

Experimental Design:-

Central Composite Design (CCD): Central composite design (CCD) is a statistical optimization method commonly used in pharmacy and pharmaceutical research. It is a subset of response surface methodology (RSM) and is widely used to study the relationship between multiple variables and their effect on the response or outcome of interest. The Central Composite Design (CCD) was employed to systematically study the experimental design to investigate the effect of three independent variables (factors), i.e., concentration of PVPK30 (XA), Concentration of Banana Powder (XB), Concentration of Cross Povidone (XC) on the dependent variables, i.e., % drug release profile (Y1), disintegration time (Y2). In this study concentration of PVPK30 (XA), Concentration of Banana Powder (XB), Concentration of Cross Povidone (XC) were considered as formulation variables which varied, as required by experimental design & the number of other excipients were kept constant. The % drug release profile (Y1), disintegration time (Y2) were selected as response variables. All analysis was performed by using the Design Expert Version 13.0.5.0 software.

Formulation Linagliptin IRT Batches by DOE:-

Table No.1: Formulation Linagliptin IRT Batches by DOE:-

Sr. No.	Linagliptin	MCC	PVPK30	Purified Water	Cross Povidone	Banana Powder	Mg. Stearate	Talc	Avg. Wt.
LB1	10	163	7.5	q.s.	5.5	11	1	2	200
LB2	10	161	5	q.s.	1	20	1	2	200
LB3	10	174	7.5	q.s.	5.5	--	1	2	200
LB4	10	158.8	11.7	q.s.	5.5	11	1	2	200
LB5	10	156	10	q.s.	1	20	1	2	200
LB6	10	174	10	q.s.	1	2	1	2	200
LB7	10	165	10	q.s.	10	2	1	2	200
LB8	10	168.5	7.5	q.s.	--	11	1	2	200
LB9	10	147	10	q.s.	10	20	1	2	200
LB10	10	179	5	q.s.	1	2	1	2	200
LB11	10	152	5	q.s.	10	20	1	2	200
LB12	10	148	7.5	q.s.	5.5	26.1	1	2	200

LB13	10	167.3	3.2	q.s.	5.5	11	1	2	200
LB14	10	163	7.5	q.s.	5.5	11	1	2	200
LB15	10	170	5	q.s.	10	2	1	2	200
LB16	10	155.5	7.5	q.s.	13	11	1	2	200

*All ingredients in mg

Table No.2: Response Variables with Their Actual Coded Values

Response Variable	Actual Coded Values	Unit
% Drug Release	Y1	%
Disintegration Time	Y2	Seconds

Table No.3: Organoleptic Properties of Linagliptin

Sr. No.	Properties	Specification	Observation
1	Colour	A white Crystalline Powder	A White Crystalline Powder
2	Odour	Odourless	Odourless
3	Taste	Bitter	Bitter

RESULT & DISCUSSION:-

Preformulation parameters:

Standard Calibration Curve of Linagliptin in 0.1N HCL:

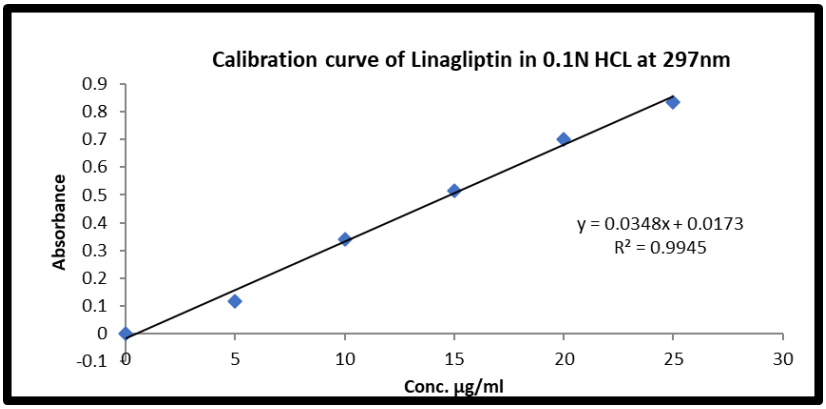

Fig. No.1: Calibration Curve of Linagliptin

FTIR Spectra of Linagliptin:

Fourier Transform Infrared Spectroscopy

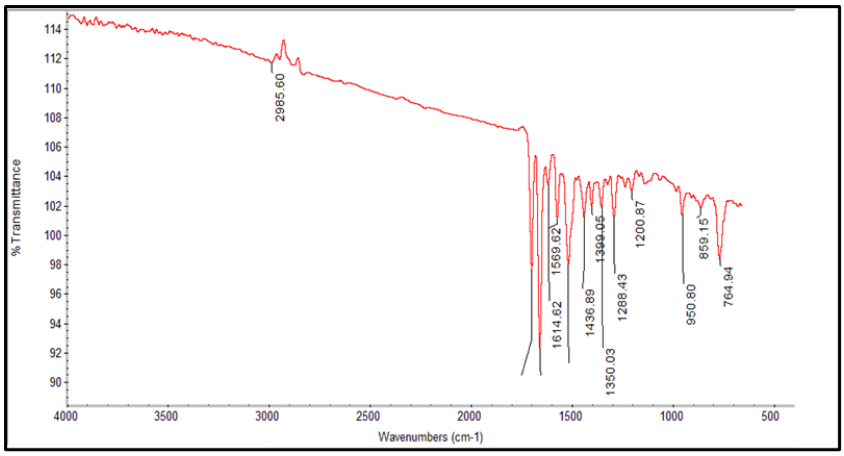

Fig. No.2: FTIR Spectra of Linagliptin

FTIR Spectrum of All Blend :-

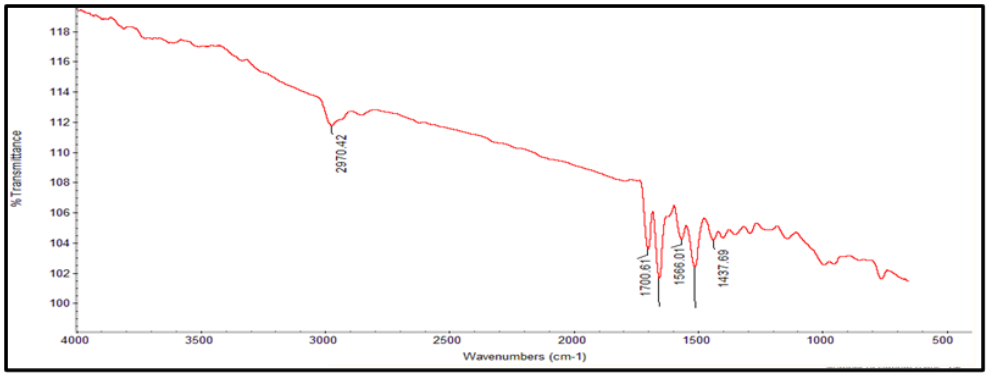

Fig. No.3: FTIR Spectra of All Blend

Differential Scanning Colorimetry **DSC Spectrum of Linagliptin:-**

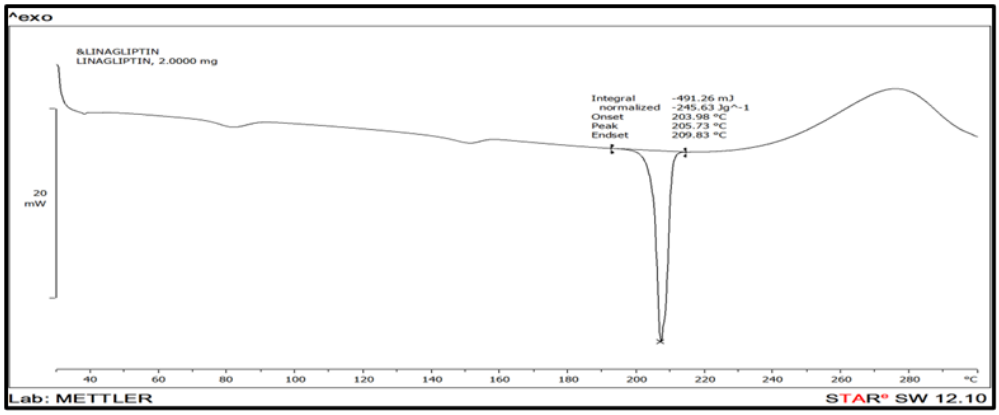

Fig. No. 4: DSC Spectrum of Linagliptin

DSC Spectrum of all Blend:-

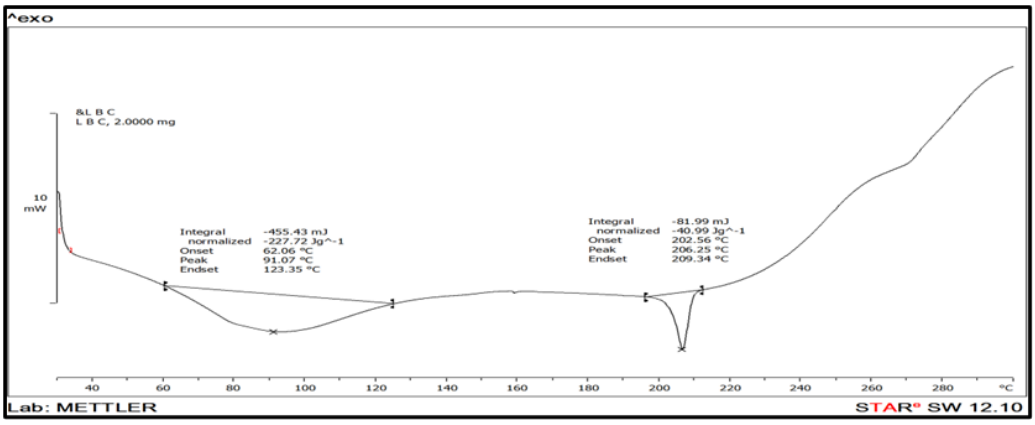

Fig. No. 5: DSC Spectrum of All Blend

Evaluation of Batches of IRT of Linagliptin Generated by CCD

Table No.4:- Pre-compression Parameter of Batches Generated by CCD: -

Batches	Bulk Density (gm/ml)	Tapped Density (gm/ml)	Compressibility Index (%)	Hausner`s Ratio	Angle of Repose (degree)
LB1	**0.43 ±0.03**	**0.47 ±0.04**	**12.50 ±0.05**	**1.13 ±0.03**	**25.19 ±0.02**
LB2	0.40 ±0.07	0.46 ±0.05	12.33 ±0.04	1.14 ±0.02	26.26 ±0.04
LB3	0.39 ±0.02	0.42 ±0.03	15.63 ± 0.02	1.15 ±0.04	26.37 ±0.06
LB4	0.42 ±0.04	0.49 ±0.04	16.12 ±0.06	1.14 ±0.02	26.28 ±0.05
LB5	0.42 ±0.05	0.48 ±0.06	12.11 ±0.03	1.13 ±0.05	27.74 ±0.03
LB6	0.39 ±0.03	0.46 ±0.04	18.04 ±0.07	1.14 ±0.07	27.63 ±0.03
LB7	0.38 ±0.02	0.48 ±0.02	16.64 ±0.01	1.15 ±0.03	28.16 ±0.02
LB8	0.41 ±0.04	0.45 ±0.05	18.69 ±0.02	1.16 ±0.02	26.74 ±0.04
LB9	0.42 ±0.05	0.51 ±0.03	12.54 ±0.03	1.16 ±0.04	26.28 ±0.05
LB10	0.42 ±0.05	0.48 ±0.06	12.11 ±0.03	1.13 ±0.05	27.74 ±0.03
LB11	0.38 ±0.02	0.48 ±0.02	16.64 ±0.01	1.15 ±0.03	28.16 ±0.02
LB12	0.37 ±0.02	0.42 ±0.02	16.64 ±0.01	1.15 ±0.03	26.16 ±0.02
LB13	0.40 ±0.07	0.46 ±0.05	12.33 ±0.04	1.14 ±0.02	26.26 ±0.04
LB14	0.39 ±0.02	0.42 ±0.03	15.63 ± 0.02	1.15 ±0.04	26.37 ±0.06
LB15	0.42 ±0.05	0.51 ±0.03	12.54 ±0.03	1.16 ±0.04	26.28 ±0.05
LB16	0.42 ±0.05	0.48 ±0.06	12.11 ±0.03	1.13 ±0.05	27.74 ±0.03

Table No.5: Post-Compression Parameter of Batches Generated by CCD

Batches	Hardness (kg/cm^2)	Thickness (mm)	Weight Variation (mg)	DT (sec)	Wetting Time (sec)
LB1	**4.35 ± 0.01**	**4.23 ± 0.01**	**200 ± 0.2**	**32.5**	**36**
LB2	4.62 ± 0.01	4.31 ± 0.01	200 ± 0.5	31	30
LB3	4.48 ± 0.01	4.61 ± 0.01	200 ± 0.70	22	25
LB4	4.59 ± 0.01	4.46 ± 0.01	200 ± 0.70	28	30
LB5	4.54 ± 0.01	4.25 ± 0.01	198 ± 0.70	26.5	30
LB6	4.55 ± 0.01	4.46 ± 0.01	198 ± 0.39	28	40
LB7	4.49 ± 0.01	4.23 ± 0.01	200 ± 0.70	25.5	42
LB8	4.59 ± 0.01	4.25 ± 0.01	199 ± 0.70	22	33
LB9	5.29 ± 0.01	4.31 ± 0.01	198 ± 0.70	22	32
LB10	4.50 ± 0.01	4.47 ± 0.01	200 ± 0.70	28	30
LB11	4.67 ± 0.01	4.35 ± 0.01	199 ± 0.5	23	28
LB12	4.57 ± 0.01	4.24 ± 0.01	197 ± 0.70	26.5	33
LB13	4.53 ± 0.01	4.35 ± 0.01	200 ± 0.5	25	22
LB14	4.40 ± 0.01	4.63 ± 0.01	198 ± 0.70	22	27
LB15	4.52 ± 0.01	4.48 ± 0.01	200 ± 0.39	28	30
LB16	4.60 ± 0.01	4.23 ± 0.01	199 ± 0.70	22	25

Table No.6: Post-Compression Parameter of Batches Generated by CCD

Batches	Friability (% w/w)	Diameter (mm)	Weight Absorption Ratio (%)	Drug Content (%)
LB1	**0.43 ± 0.01**	**8.09**	**69.19**	**98.20%**
LB2	0.58 ± 0.01	8.05	70.35	96.06%
LB3	0.68 ± 0.01	8.09	73.36	98.42%
LB4	0.65 ± 0.01	8.08	70.70	100.78%
LB5	0.49 ± 0.01	8.06	73.97	98.91%
LB6	0.51 ± 0.01	8.14	85.07	92.20%
LB7	0.61 ± 0.01	8.12	81.09	90.55%

LB8	0.62 ± 0.01	8.07	78.78	88.97%
LB9	0.71 ± 0.01	8.09	72.08	97.63%
LB10	0.51 ± 0.01	8.17	85.07	92.20%
LB11	0.42 ± 0.01	8.14	88.03	99.55%
LB12	0.50 ± 0.01	8.07	74.97	98.91%
LB13	0.78 ± 0.01	8.24	80.36	98.42%
LB14	0.49 ± 0.01	8.06	75.97	98.91%
LB15	0.71 ± 0.01	8.15	78.08	97.63%
LB16	0.70 ± 0.01	8.10	87.75	98.78%

Table No.7: % In-vitro Drug Release of Optimized Batches by DOE Software

Batches	**%Drug Release of Linagliptin of Optimized Batches Time (Min.)**						
	0	**5**	**10**	**15**	**30**	**45**	**60**
LB1	**00**	**50.74**	**66.04**	**74.04**	**82.86**	**85.77**	**97.67**
LB2	00	62.35	70.36	72.79	85.55	89.75	91.33
LB3	00	64.10	70.89	76.30	81.25	86.30	90.56
LB4	00	55.30	58.36	67.09	75.63	81.87	85.42
LB5	00	50.87	62.54	68.82	75.16	80.12	85.54
LB6	00	45.70	50.54	66.48	74.51	81.54	88.65
LB7	00	41.81	50.80	58.89	65.30	78.20	87.12
LB8	00	42.44	54.12	61.54	75.73	87.15	90.43
LB9	00	40.77	42.88	55.15	70.23	82.16	88.76
LB10	00	55.70	57.53	74.67	80.79	87.53	90.12
LB11	00	58.37	66.10	78.34	87.56	92.28	95.45
LB12	00	54.31	61.21	70.67	82.24	88.53	95.45
LB13	00	56.31	62.43	72.84	86.12	91.10	97.17
LB14	00	56.31	61.82	70.39	81.51	88.65	90.12
LB15	00	50.80	61.21	67.33	78.16	85.15	91.57
LB16	00	56.31	60.59	71.61	78.12	85.08	90.56

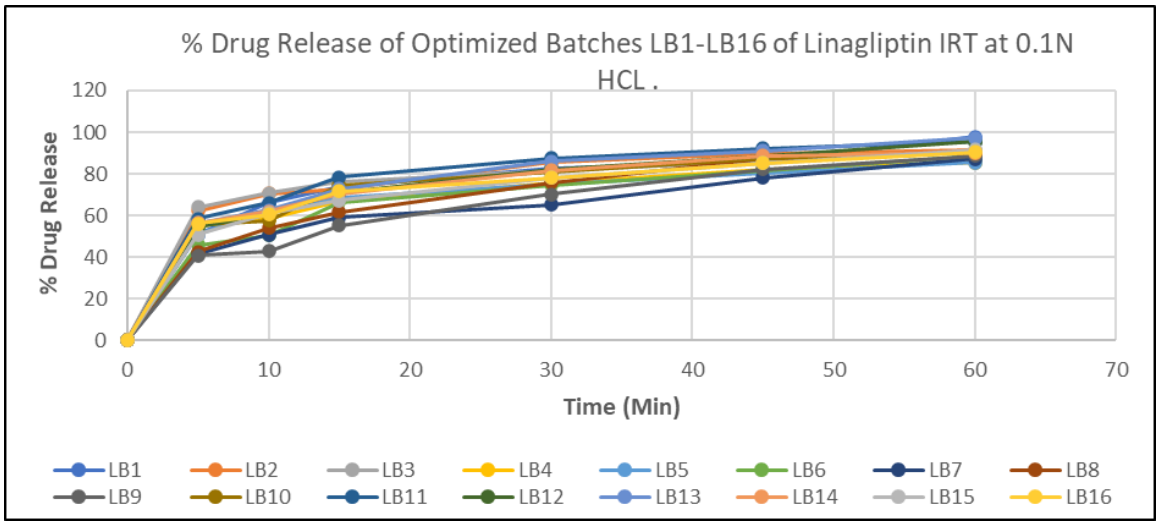

Fig No 6: In-Vitro Drug Released Study of Optimized Batches of Linagliptin IRT Generated by CCD (LB1-LB16)

Optimization and Data Analysis **A) %Drug Release:**

Final regression equation in terms of coded form,

% DR= +97.67 + 2.07A – 0.7133B + 0.0475AB – 0.5181A2 + 0.2669B2

Concerning dissolution, the results of multiple linear regression analysis showed that the coefficients X1 bear positive sign and X2 bear a negative sign. It revealed that % drug release increases with increases in Banana Powder and while % drug release decrease with increase in Pvpk-30. ANOVA was used to identify the significant effect. The result was found to be significant at that level of probability (p=0.0118).

Final equation in terms of coded form,

DT= +8.45 – 0.2023A + 0.3116B

Concerning disintegration time, the results of multiple linear regression analysis showed that the coefficients A1 bear negative sign and B1 bear a positive sign. It revealed that disintegration time decreases with increase in Banana Powder and while disintegration time increase with increase in Pvpk30. ANOVA was used to identify the significant effect. Obtained value of F is larger than critical F-value, the result was found to be significant at that level of probability (p=0.0223).

B) Disintegration Time:

Table No.8: Result of Analysis of Variance for Batches by CCD of Linagliptin Immediate Release Tablet

	DF*	SS*	MS*	F*	P Value	
Y1=%DR.						
Model	111.59	3	37.20	5.67	0.0118	significant
Residual	78.70	12	6.56	__	__	
Total	190.29	15	__	__	__	
Y2=Disintegration						
Model	157.95	3	52.65	4.64	0.0223	significant
Residual	136.05	12	11.34	__	__	
Total	294.00	15	__	__	__	

*** DF indicates degree of freedom; SS (Sum of Square); MS (Mean Sum of Square) and F is (Fischer's Ration)**

Graphical Representation:

Response Disintegration (Y2)

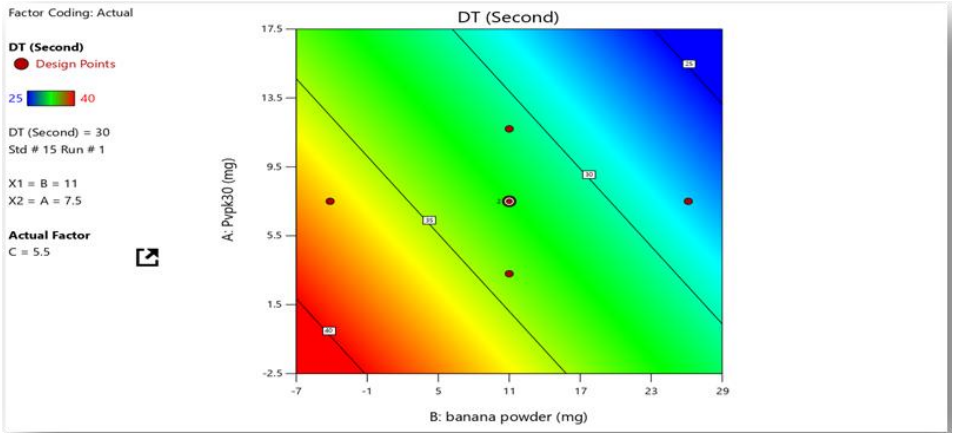

Fig No 7: Response Surface Contour Graph Showing the Influence of PVPK30 (A) and Banana Powder (B) on DT (Y2)

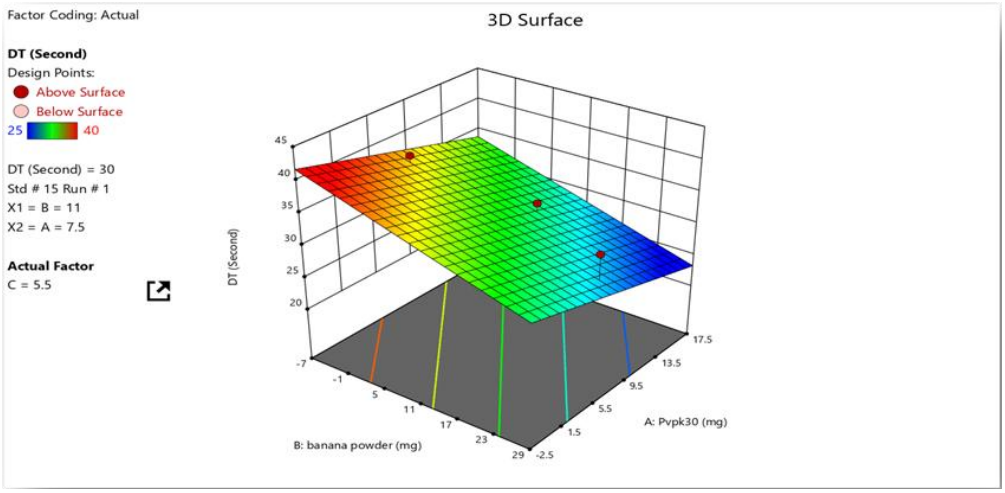

Fig No 8: Response Surface 3D Graph Showing the Influence of PVPK30 (A) and Banana Powder (B) on DT (Y2)

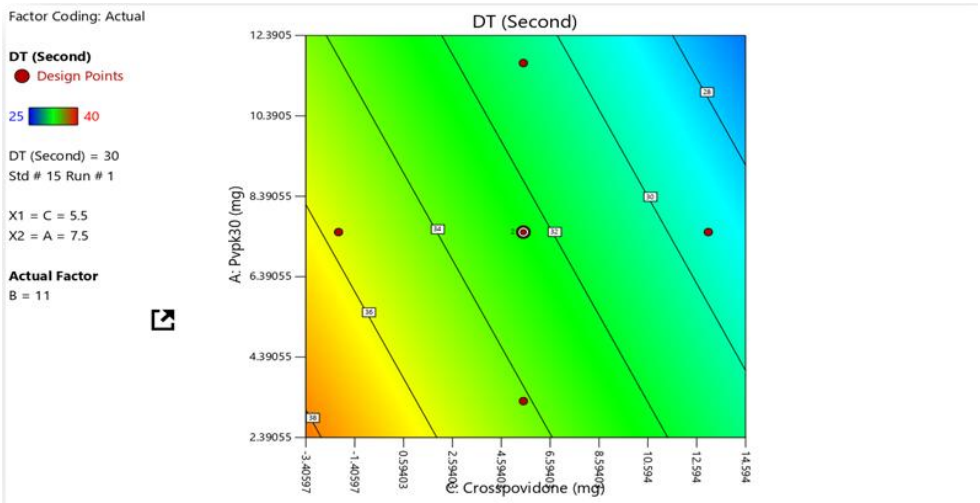

Fig No 9: Response Surface Contour Graph Showing the Influence of PVPK30 (A) and Cross Povidone (C) on DT (Y2)

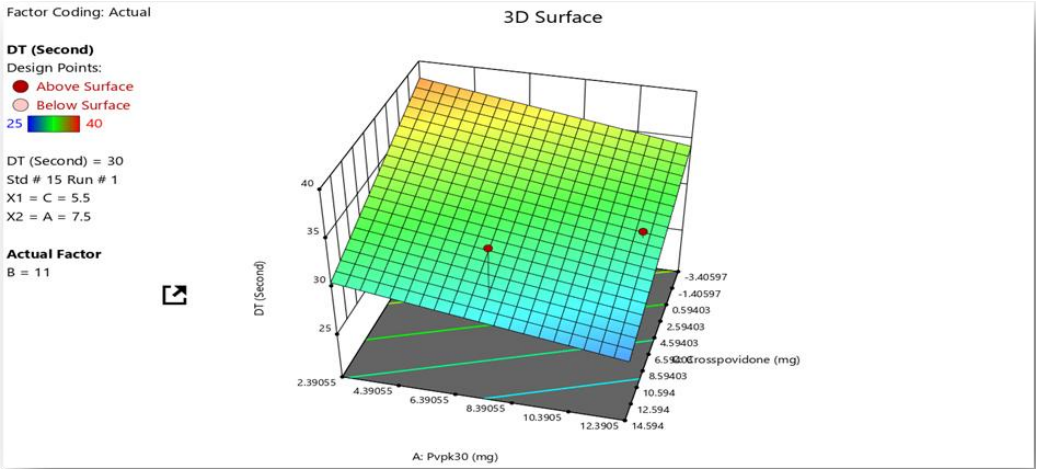

Fig No 10: Response Surface 3D Graph Showing the Influence of PVPK30 (A) and Cross Povidone (C) on DT (Y2)

Response (Y1) Dissolution

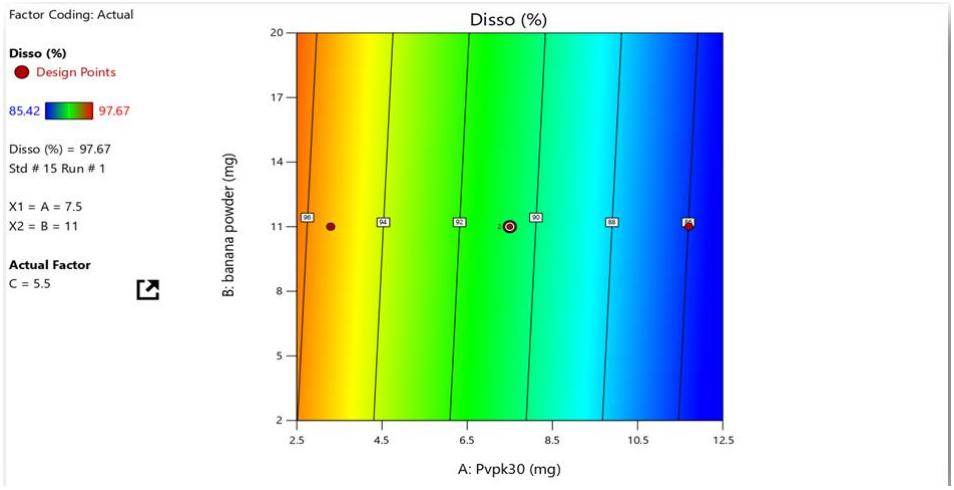

Fig No. 11: Response Surface Contour Graph Showing the Influence of PVPK30 (A) and Banan Powder (B) on Dissolution (Y1)

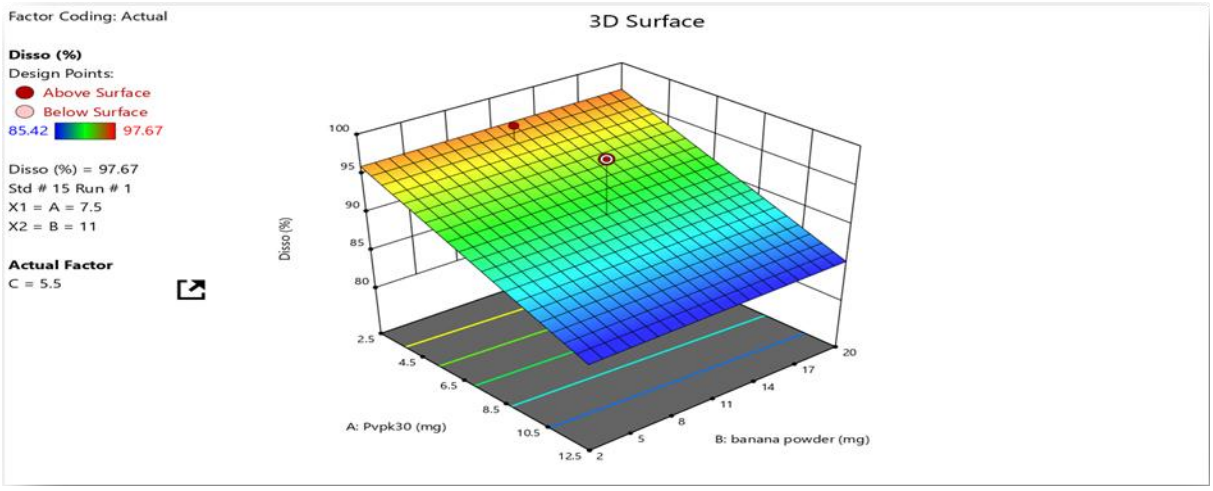

Fig No 12: Response Surface 3D Graph Showing the Influence of PVPK30 (A) and Banan Powder (B) on Dissolution (Y1)

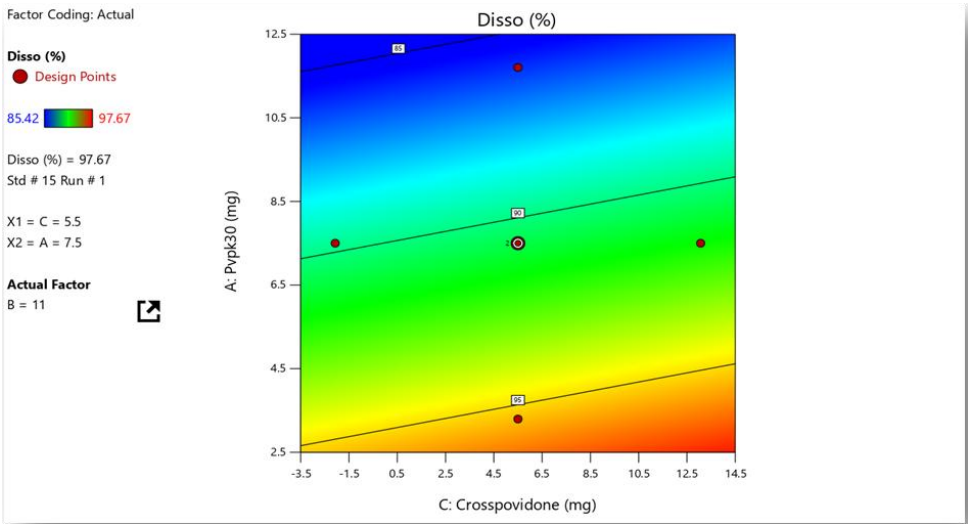

Fig No. 13: Response Surface Contour Graph Showing the Influence of PVPK30 (A) and Cross Povidone (C) on Dissolution (Y1)

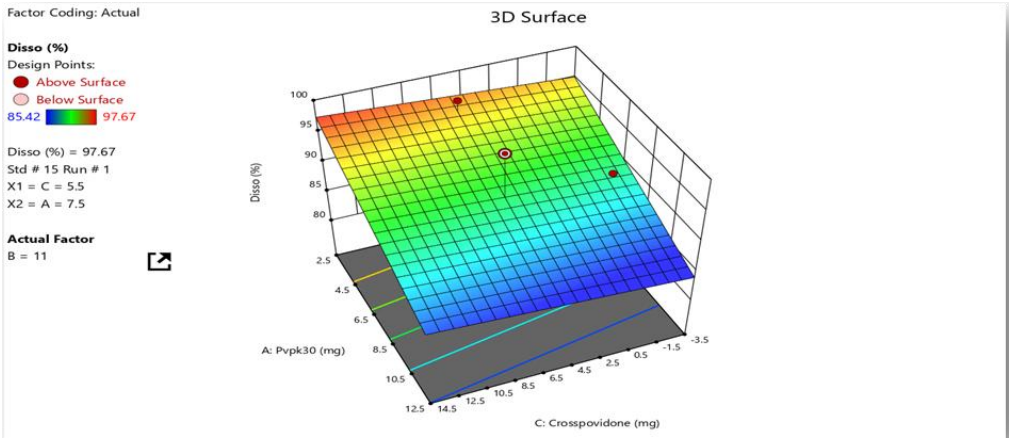

Fig No 14: Response Surface 3D Graph Showing the Influence of PVPK30 (A) and Cross Povidone (C) on Dissolution (Y1)

Table No.9: Comparison of Percentage Drug Released of Optimized Formulation (LB1) of Linagliptin IRT of Linagliptin and Marketed Tablet Trajenta

Sr. No.	Time (min)	%DR of LB1	%DR of Marketed Product
1	00	00	00
2	05	50.74	52.80
3	10	66.04	67.14
4	15	74.04	76.03
5	30	82.86	85.90
6	45	89.77	90.61
7	60	97.67	99.81

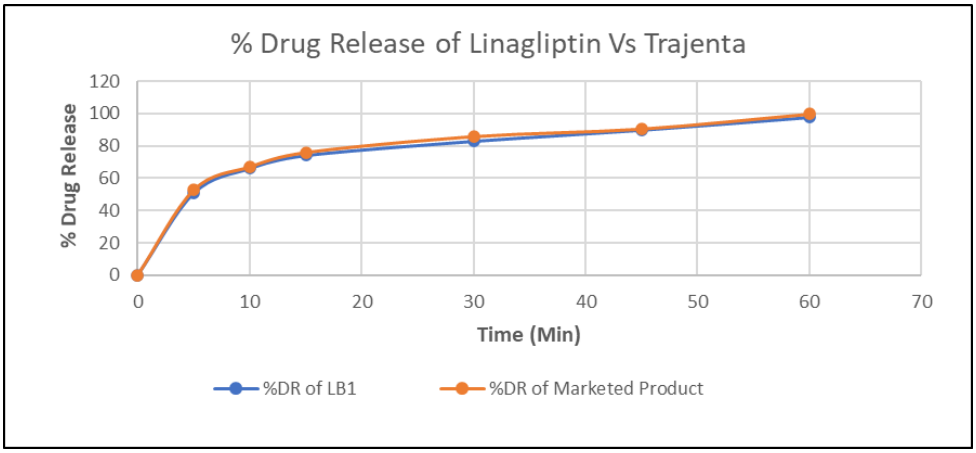

Fig No.15: Comparison of In-Vitro Drug Released of Optimized Batch LB1 and Marketed Formulation Trajenta

CONCLUSION:

The present study successfully developed and optimized an immediate release tablet formulation of Linagliptin using a Central Composite Design (CCD). Among the sixteen batches evaluated, batch LB1 demonstrated optimal performance with rapid disintegration (32.5 seconds) and high drug release (97.67% in 60 minutes), closely matching the marketed product (Trajenta). Preformulation and compatibility studies confirmed the stability of the drug and excipients,

including natural banana powder as a superdisintegrant and PVP K30 as a binder. The application of wet granulation and statistical design of experiments (DOE) proved effective for achieving the desired tablet characteristics. The optimized formulation is stable, cost-effective, and exhibits comparable efficacy to the commercial product, making it a promising candidate for further development and potential commercialization.

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