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DESIGN AND OPTIMIZATION OF GASTRO RETENTIVE BILAYER FLOATING TABLETS OF LEVODOPA

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Abstract

According to this perspective, the gradation of the available medication delivery technologies is the main obstacle faced by healthcare providers. Effective disease/disorder management, fewer side effects, and more patient compliance in an economical way are the ultimate goals of any medication delivery system. By controlling the drug release in the body in a well-defined, regulated manner, the therapeutic indices of the medicine could be maximised while the indices of unfavourable reactions or side effects might be minimised. Parkinsonism diseases are treated with levodopa, an immediate precursor of dopamine. The goal of the current study is to create levodopa floating matrix tablets that will increase the drug's stomach residence time and improve absorption. The goal of the current study was to create levodopa floating tablets using the direct compression method. For a number of post-compression evaluation criteria, including tablet thickness, hardness, weight variation, floating lag time, total floating time, content homogeneity, and in vitro drug release, the formulated tablets demonstrated satisfactory results. Compared to the other formulations, Formulation F2 provided more regulated drug release and floating characteristics. The Korsmeyer-Peppas model, Higuchi model, and first-order model fit the release pattern of the F2 formulations the best. In conclusion, the proposed levodopa floating matrix tablet may be considered a promising formulation that could provide better management of Parkinsonism disorders by releasing the medication in the stomach at a controlled rate.

Keywords: *Levodopa, floating drug delivery system, Anti-Parkinson's, direct compression method, Korsmeyer-Peppas model.*

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INTRODUCTION

The need for health care services is growing in nations like India due to the country's constantly growing population. Due to shifting lifestyles and the so-called "fast culture," good health is becoming increasingly scarce. It is challenging to achieve the World Health Organization's (WHO) definition of health in our fast-paced world. The notions and intensity of illness, diseases, and disorders are evolving along with lifestyle improvements. According to this perspective, the gradation of the available medication delivery technologies is the main obstacle faced by healthcare providers [1,2]. Because of their flexibility in formulation, ease of administration, and high patient compliance, oral dosage forms are widely used to deliver medications. Conventional drug administration has several drawbacks, including inadequate bioavailability. The therapeutic efficacy and drug bioavailability of oral dosage forms have been the subject of numerous initiatives in recent years.In this context, various gastroretentive drug delivery systems (GRDDS) have been used to improve the therapeutic efficacy of drugs that have a narrow absorption window, are unstable at alkaline pH, are soluble in acidic conditions, and are active locally in the stomach [3-5].

Levodopa is chemically (2S)-2-amino-3-(3,4-dihydroxyphenyl)propanoic acid. It is used in Anti-Parkinson's therapy. It will cause Nausea, vomiting,

dizziness, dyskinesia, hallucinations, confusion, orthostatic hypotension as adverse effects.Levodopa, the naturally occurring form of di hydroxy phenylalanine and the direct precursor of dopamine, is utilised in clinical settings to treat parkinsonism disorders. Dopamine's metabolic precursor is levodopa. In extrapyramidal areas that atrophy in parkinsonism, it replenishes dopamine levels. The brain easily absorbs levodopa and transforms it into dopamine.Large doses of levodopa are required, because much of the drug is decarboxylated by dopamine decarboxylase to dopamine in the periphery [6-8].

By creating floating matrix tablets, the most palatable solid unit dose form, the current investigation aims to increase the bioavailability and gastrointestinal residence duration of levodopa in order to improve patient compliance in Parkinsonism patients.

MATERIALS AND METHODS

Materials

Levodopa was a gift sample procured from Hetero Pharma Ltd., Hyderabad, Telangana. Other polymers were received as the gift sample from Sura Labs, Hyderabad, Telangana. All the reagents and chemicals from SD Fine Chemicals Pvt. Ltd, Mumbai, India.

Analytical Method Development

Determination of λ_{max} of levodopa:

Working standard: 100mg of Levodopa was weighed and dissolved in 10ml methanol and then make up to a volume of 100ml with solvent it gives 1000µg/ml concentrated stock solution.

Dilution 1: From the working standard solution 10ml was diluted to 100ml with it will give 100µg/ml concentrated solution.

Dilution 2: From the dilution-1, 10ml was diluted to 100ml with solvent it will give 10µg/ml concentrated solution.This solution was scanned at range of 200-400nm wavelength light corresponding scan spectrum curve was noted. The corresponding wavelength having highest absorbance is noted as λ_{max}.

Construction of calibration curve of levodopa:

Working standard: 100mg of Levodopa was weighed and dissolved in 10ml methanol and then made up to a volume of 100ml with solvent it gives 1000µg/ml concentrated stock solution.

Dilution 1: From the working standard solution 10ml was diluted to 100ml with solvent it will give 100µg/ml concentrated solution.From dilution-1, take 0.2, 0.4, 0.6, 0.8 and 1ml of solution and was diluted up to mark in 10ml volumetric flask to obtain 2, 4, 6, 8 and 10µg/ml concentrated solutions. This solutions absorbance was noted at λ_{max}=280 [9-12].

Formulation of gastro retentive floating tablets by direct compression method

The matrix tablets were prepared by following the general methodology as given below:

1. All ingredients (except magnesium stearate and talc) were weighed accurately and co sifted by passing through #40 Sieve, blended in a Poly Bag for 5 min.
2. The above blend was lubricated with # 60 Sieve passed magnesium stearate & talc.
3. The final blend was then compressed into tablets using 16 station tablet compression machines with an average hardness of 5.0 -6.0kg/cm^2, by using 8mm to 10mm.

Table 1: Formulation of levodopa floating tablets by direct compression method

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
Levodopa	40	40	40	40	40	40	40	40	40
HPMC K 100	10	30	50	-	-	-	-	-	-
Chitosan	-	-	-	10	30	50	-	-	-
Eudragit	-	-	-	-	-	-	10	30	50
MCC	6	6	6	6	6	6	6	6	6
Xanthan gum	30	30	30	30	30	30	30	30	30
Lactose	80	60	40	80	60	40	80	60	40
Adipic acid	2	2	2	2	2	2	2	2	2
Talc	2	2	2	2	2	2	2	2	2
Mg.Stearate	30	30	30	30	30	30	30	30	30
Total weight	200	200	200	200	200	200	200	200	200

The formulated tablets were evaluated for the following pre, post compression quality control studies &*in vitro* Buoyancy studies and dissolution studies as per standard protocol [13-16].

***In vitro* Buoyancy studies**

Floating Lag Time (FLT): A tablet was placed in a 100 ml beaker containing solvent. The time required for the tablet to rise to the surface and float was determined as the Floating Lag Time (FLT).

Total Floating Time (TFT): A tablet was placed in a 100 ml beaker containing solvent. The duration of time up to which the tablet constantly floats on the dissolution medium was noted as the Total Floating Time (TFT).

Matrix integrity: During the period of TFT the swelled matrix tablets were observed for integrity. For 12 h.

***In vitro* Dissolution Study**

900 ml of was placed in the vessel and the USP-II apparatus (Paddle method) was assembled. The medium was allowed to equilibrate to temperature of $37^0C \pm 0.5^0C$. A tablet was placed in the vessel and was covered; the apparatus was operated up to 12 hat 50 rpm. At definite time intervals, 5 ml of dissolution medium was withdrawn; filtered and again replaced with 5 ml of fresh medium to maintain sink conditions. Suitable dilutions were done with dissolution medium and were analyzed spectrophotometrically at λ_{max} =280 nm using a UV-spectrophotometer [17-20].

Table 2: Dissolution parameters

Parameter	Details
Dissolution apparatus	USP -Type II (paddle)
Medium	0.1N HCl
Volume	900 ml
Speed	50rpm
Temperature	37± 0.5 °C
Sample volume withdrawn	5ml
Time points	1,2, 3, 4,6,8,10,12 h
Analytical method	Ultraviolet Visible Spectroscopy
λ_{max}	280 nm

RESULTS AND DISCUSSION

The physical attributes of the Levodopa floating tablet were found to be satisfactory. The absorbance of the solution was measured at 280nm, using UV spectrometer with distilled water as blank.

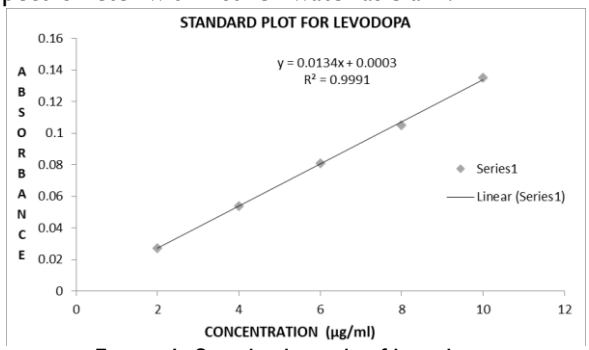

Figure 1: Standard graph of levodopa

Table 3: Precompression studies of levodopa floating tablets

Formulation Code	Bulk density(Kg/cm³)	Tappedd ensity(Kg/cm³)	Cars index	Hausner' sratio	Angle ofrepose (°)
F1	0.30	0.34	11.76	1..13	11.73
F2	0.31	0.40	16.22	1.29	10.29
F3	0.40	0.48	16.67	1.20	10.58
F4	0.29	0.32	9.38	1.10	11.23
F5	0.27	0.31	12.90	1.15	11.35
F6	0.33	0.42	13.16	1.27	10.62
F7	0.34	0.40	15	1.18	8.92
F8	0.31	0.35	11.43	1.13	10.85
F9	0.29	0.38	17.14	1.31	10.96

Table 4: Post compression studies of levodopa floating tablets

Formulation Code	% Weight variation	Thickness (mm)	% Friability	% Drug Content	Hardness (Kg/cm²)
F1	Pass	4.06±0.11	0.122	101.3 ±1.2	4.56 ±0.057
F2	Pass	4.06±0.15	0.141	102.3 ±1.7	4.03 ±0.115
F3	Pass	4.03±0.057	0.52	100.1 ±1.2	4.01 ±0.1
F4	Pass	4.1±0.1	0.144	100.7 ±1.1	4.63 ±0.05
F5	Pass	4.03±0.05	0.122	99.6±1.5	4.63 ±0.03
F6	Pass	4.03±0.15	0.133	98.9 ±2.3	4.5 ±0.05
F7	Pass	3.93±0.05	0.110	100.2± 1.7	4.7 ±0.1
F8	Pass	4.1±0.1	0.123	100.5± 1.4	4.53 ±0.04
F9	Pass	4.02±0.2	0.12	99.2±1.1	4.69 ±0.05

**Test for Friability was performed on single batch of 20 tablets.*

Table 5: In vitrobuoyancy studies of levodopa floating tablets

Formulation Code	Floating lag time(sec) n = 3	Total floating timen = 3	Matrixintegrity upto 12 hn = 3
F1	20 ± 0.51	Up to 12	+
F2	40 ± 0.21	Up to 12	+
F3	80 ± 0.61	Up to 12	+
F4	20 ± 0.71	Up to 10	-
F5	30 ± 0.81	Up to 12	+
F6	35 ± 0.51	Up to 12	+
F7	24 ± 0.31	Up to 10	-
F8	20 ± 0.81	Up to 12	+
F9	36 ± 0.71	Up to 12	+

Table 6: Invitro dissolution results for formulation trails

Time (h)	% Drug released								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	**0**	0	0	0	0	0	0	0
1	35	**28**	21	48	40	47	55	45	32
2	48	**37**	38	67	57	59	68	59	43
4	61	**45**	4	86	68	71	81	70	56

			7						
6	76	**59**	56	97	88	86	98	81	68
8	88	**71**	63	100	95	98	100	91	76
10	100	**88**	78	100	100	100	100	100	85
12	100	**100**	85	100	100	100	100	100	100

Table 7: R^2 value

Formulation code	R^2 value				"n" value
	Zero Order	First Order	Higuchi	Peppas	
F2	0.957	0.923	0.974	0.962	0.503

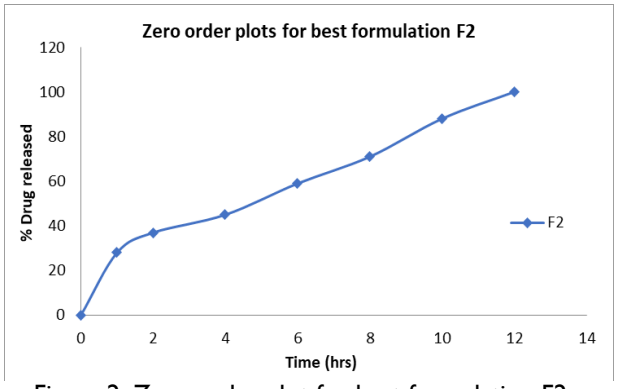

Figure 2: Zero order plot for best formulation F2

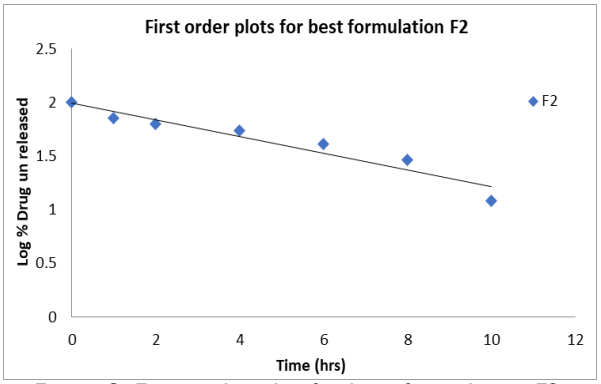

Figure 3: First order plot for best formulation F2

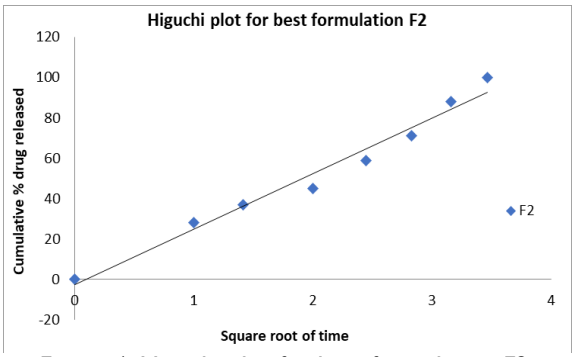

Figure 4: Higuchi plot for best formulation F2

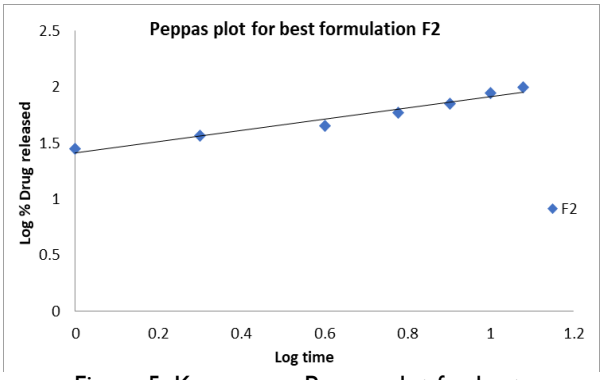

Figure 5: Korsmeyer-Peppas plot for best formulation F2

HPMC K100M had the greatest drug release retarding capacity among the various control release polymers. F2 was displaying results that were satisfactory. The diffusion exponent n value for the F2 formulation falls between 0.45 and 0.89, indicating that they are using a non-Fickian anomalous diffusion model. The drug is releasing through a diffusion mechanism because the Higuchi plots for the F2 formulation have good correlation values.

CONCLUSION

One promising method for extending the levodopa's stomach residence period was floating medication delivery. Levodopa floating tablets are designed to prolong the drug's stomach residence duration and enhance its therapeutic effectiveness. HPMC K100M demonstrated superior levodopa sustained drug release. Because the diffusion path length increases with increasing polymer concentration, the release rate decreases as drug polymer concentration rises. For a number of post-compression evaluation criteria, including tablet thickness, hardness, weight variation, floating lag time, total floating time, content homogeneity, and in vitro drug release, the formulated tablets demonstrated satisfactory results.Compared to the other formulations, Formulation F2 provided more regulated drug release and floating characteristics. The Korsmeyer-Peppas model, Higuchi model, and first-order model fit the release pattern of the F2 formulations the best. Non-Fickian diffusion, also known as anomalous diffusion, was the most likely mechanism for the drug release pattern from the formulation. As a result, the current study's findings amply demonstrate the levodopa floating system's intriguing potential as a substitute for the traditional dosage form. Once the safety and effectiveness of the produced formulations have been established in healthy human volunteers, they can be effectively commercialised.

CONFLICT OF INTERESTS

The authors declare that there are no conflicts of interest regarding the publication of this paper.

ETHICS STATEMENT

None.

FUNDING

None.

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