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Original Article

FORMULATION AND EVALUATION OF DELAYED RELEASE ENTERIC COATED LANSOPRAZOLE TABLETS

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ABSTRACT

Background: *Oral drug delivery remains highly favored due to its convenience and patient compliance, yet challenges persist with poor aqueous solubility affecting drug bioavailability. Lansoprazole, a proton pump inhibitor, exemplifies such issues despite its effectiveness in treating acid-related gastrointestinal disorders.*

Aim: *This study aimed to enhance the solubility and dissolution rate of Lansoprazole through solid dispersion formulations, employing different techniques such as physical mixture, kneading, and co-precipitate methods. Additionally, the development of sustained-release tablets using hydroxypropyl methylcellulose (HPMC) polymers aimed to prolong drug release.*

Objective: *Evaluate the effectiveness of various methods in enhancing Lansoprazole's solubility and dissolution rate, and characterize the performance of sustained-release tablets in controlled drug delivery.*

Conclusion: *Among the methods tested, the co-precipitate method using HP-β-cyclodextrin exhibited the highest enhancement in solubility for Lansoprazole. Sustained-release tablets formulated with HPMC polymers demonstrated controlled drug release profiles, with formulation F8 showing optimal release characteristics. The dissolution kinetics of the sustained-release tablets followed zero-order kinetics and were best described by the Higuchi model, indicating promising potential for controlled drug delivery.*

Keywords: *Lansoprazole, solid dispersion, Hydroxypropyl methylcellulose, sustained release, dissolution kinetics*

INTRODUCTION

Oral drug delivery is preferred due to its ease, patient compliance, and flexible dosage options, aiming for rapid and complete systemic absorption1,2. However, poor aqueous solubility often limits drug bioavailability, necessitating strategies such as physical modifications (micronization, nanocrystals), chemical alterations, and the use of surfactants, cyclodextrins, and lipid-based systems to enhance solubility and dissolution rates. Solid dispersions are effective in improving bioavailability by reducing particle size, enhancing wettability, and preventing drug aggregation. Various methods like melting, common solvent, melting-solvent, supercritical fluid processing, kneading, and co-grinding are employed, each with distinct advantages and drawbacks. Evaluation of solid dispersions involves thermal analysis, X-ray diffraction, and dissolution rate studies. Additionally, fast-disintegrating tablets are beneficial for dysphagic patients, ensuring rapid drug absorption and improved compliance through advanced technologies such as WOWTAB®, ORASOLV®, and ZYDIS®, utilizing techniques like tablet molding, freeze drying, spray drying, sublimation, and the addition of disintegrants or sugar-based excipients.

Lansoprazole[9], a proton pump inhibitor with the molecular formula C16H14F3N3O2S and molecular weight 369.36 g/mol, treats ulcers, erosive esophagitis, and conditions like Zollinger-Ellison syndrome by reducing gastric acid production. Available via prescription and over-the-counter, it may cause adverse effects including diarrhea, kidney issues, lupus-like syndrome, and increased fracture risk, contraindicated in those allergic to it

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or using Rilpivirine. Key excipients include β-cyclodextrin and HP-β-cyclodextrin11 for enhancing solubility, crospovidone as a disintegrant, purified talc as an anticaking agent, magnesium stearate10 as a lubricant, and microcrystalline cellulose12 (Avicel 102) for tablet formulation as filler, binder, and disintegrant.

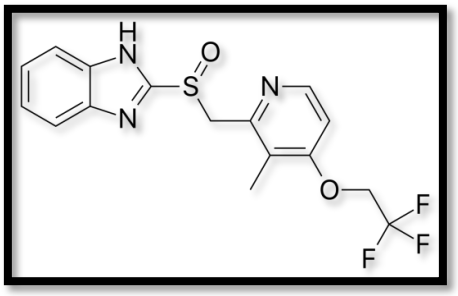

Fig 1: Structure of Lansoprazole

MATERIALS AND METHODS

MATERIALS:

Materials used in the study included Lansoprazole obtained from Qualychrome Research Labs Pvt. Ltd., HP-β-Cyclodextrin, Crospovidone, Purified Talc, Magnesium Stearate, and Microcrystalline Cellulose, all sourced from S.D. Fine Chemicals Limited, Mumbai. Equipment utilized for analysis comprised a UV-spectrophotometer (Labindia UV 3000+), Digital Balance (Scale-Tec), Digital pH meter (Systronic Electronics, Mumbai), Dissolution apparatus (Electrolab TDT-08L), Hot air oven (Tempo Instruments & Equipments, Mumbai), Hardness tester (Monsanto Hardness Tester), Friability test apparatus (Roche FriabilatorElectrolab, Mumbai), and Tablet punching machine (Cadmach, Ahmedabad).

METHODOLOGY:

Preparation of 6.8 Phosphate Buffer: Potassium dihydrogen orthophosphate (6.8 g) was dissolved in distilled water in a 1000 ml volumetric flask, adjusted to pH 6.8 with sodium hydroxide solution, and diluted to volume.

Determination of Lansoprazoleλmax in 6.8 Phosphate Buffer: A working standard of Lansoprazole (100 mg) was dissolved in 10 ml methanol and diluted with 6.8 phosphate buffer to prepare a 1000 µg/ml stock solution. From this, a 100 µg/ml solution was prepared by further dilution, followed by a 10 µg/ml solution in subsequent dilutions. The absorption spectrum was scanned from 200 to 400 nm to determine λmax.

Construction of Calibration Curve of Lansoprazole in 6.8 Phosphate Buffer: A working standard of Lansoprazole (100 mg) was dissolved in water and diluted with 6.8 phosphate buffer to prepare a 1000 µg/ml stock solution. From this, a 100 µg/ml solution was prepared by dilution, and then concentrations ranging from 2 to 10 µg/ml were prepared by diluting appropriate volumes with 6.8 phosphate buffer. Absorbance measurements were taken at 238 nm.

Preparation of Solid Dispersions:

1. Physical Mixture Method: Lansoprazole and polymers in ratios of 1:1 and 1:2 were mixed, triturated, sieved, and stored in a desiccator.
2. Kneading Method: Lansoprazole and polymers in ratios of 1:1 and 1:2 were kneaded with cyclodextrin and ethanol, air-dried, sieved, and stored in a desiccator.
3. Co-precipitate Method: Lansoprazole was dissolved in ethanol, polymer in water, mixed in ratios of 1:1 and 1:2, stirred, evaporated, precipitated, sieved, and stored in a desiccator.

Table 1: Formulation codes for the solid dispersions prepared by various methods

S.NO.	Composition	Method of Preparation of solid dispersions		
		Physical mixture	Kneading method	Co-precipitate method
1	API (Lansoprazole)			
2	API: HP-β –CD (1:1)	PM-1	KM-1	CP-1
3	API: HP- β – CD (1:2)	PM-2	KM-2	CP-2

EVALUATION STUDIES ON SOLID DISPERSIONS

1. Drug Content Estimation: Cyclodextrin inclusion complex equivalent to 100 mg of Lansoprazole was dissolved in methanol by shaking for 15 minutes in a 100 ml volumetric flask, then diluted to volume with water and filtered. A 0.1 ml aliquot was further diluted in a 10 ml volumetric flask with water. Lansoprazole content was determined by measuring absorbance at 238 nm and calculated using a standard calibration curve. Mean percent drug content was averaged from three determinations.

2. In vitro Dissolution Studies for Solid Dispersions: Dissolution Profile:

- Apparatus: USP Type II (Paddle)
- Medium: 900 ml 6.8 Phosphate Buffer
- Speed: 50 rpm
- Temperature: 37°C ± 1°C
- Sampling Time Points: 5, 10, 15, 20, 30, 40, 50, and 60 minutes
- Samples (5 ml) were withdrawn through a 0.45 µm filter at intervals, diluted, and assayed for Lansoprazole at 238 nm using a UV spectrophotometer. Dissolution experiments were conducted in triplicate.

Table 2: Formulae of Lansoprazole EC Tablet

Ingredients	Formulation code								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
Drug	30	30	30	30	30	30	30	30	30
HPMC K4M	8	16	24	-	-	-	-	-	-
HPMC K15M	-	-	-	8	12	24	-	-	-
HPMC K100M	-	-	-	-	-	-	8	12	24
DCP	136	128	120	136	128	120	136	128	120
Talc	2	2	2	2	2	2	2	2	2
Mg.Stearate	2	2	2	2	2	2	2	2	2
Total wt (mg)	160	160	160	160	160	160	160	160	160

EVALUATION OF ENTERIC COATED TABLETS of LANSOPRAZOLE

The formulated Tablets were evaluated for the following Pre, post compression quality control studies and dissolution studies

A) Pre Compression studies:

Pre formulation studies:

Angle of Repose:

The angle of repose is the maximum angle between the surface of a pile of powder and the horizontal plane. It was determined using the funnel method, where a accurately weighed powder blend was placed in a funnel. The funnel height was adjusted so that the tip just touched the apex of the powder blend. The blend was allowed to flow freely through the funnel onto a surface, forming a cone. The angle of repose (q) was calculated using the formula

$$q = \tan^{-1}(h/r)$$

where h is the height and r is the radius of the cone base. This angle is indicative of the flow properties of solids, reflecting inter-particle friction and resistance to movement.

Table 3: Angle of Repose Limits

Flow Properties and Corresponding Angles of Repose

Flow Property	Angle of Repose (degrees)
Excellent	25–30
Good	31–35
Fair—aid not needed	36–40
Passable—may hang up	41–45
Poor—must agitate, vibrate	46–55
Very poor	56–65
Very, very poor	>66

2. Density:

Bulk Density (BD): Measure the mass of powder and its bulk volume without compaction to calculate bulk density using the formula Db = M / V0.

Tapped Density (TD): Measure the mass of powder and its volume after tapping to minimum volume using a tap density tester. Calculate tapped density using Dt = M / Vf.

3. Carr's Index: Calculate compressibility index to assess powder blend compressibility using the formula: Compressibility index (%) = [(Tapped density - Bulk density) / Tapped density] x 100.

4. Hausner's Ratio: Calculate Hausner's Ratio to evaluate powder flowability using the formula: Hausner's Ratio = Tapped density / Bulk density.

Table 4: Compressibility Index Limits

Scale of Flow ability (USP29-NF34)

Compressibility Index (%)	Flow Character	Hausner's Ratio
≤ 10	Excellent	1.00-1.11
11-15	Good	1.12-1.18
16-20	Fair	1.19-1.25
21-25	Passable	1.26-1.34
26-31	Poor	1.35-1.45
32-37	Very Poor	1.46-1.59
> 38	Very, very Poor	> 1.60

Post compression Parameters:

1. General Appearance: Evaluate tablets for shape, color, texture, and odor.

2. Average Weight/Weight Variation: Weigh 20 tablets collectively and individually to calculate average weight. Check individual weights against average weight limits specified by USP 29-NF 34.

Average weight = weight of 20 tablets/20

$$\%\ \text{weightvariation} = \frac{\text{Averageweight} - \text{weightofeacttablet}}{\text{Averageweight}} * 100$$

Table 5: Weight variation tolerance for uncoated tablets

Acceptance criteria for tablet weight variation (USP 29-NF 34)

Average weight of tablet(mg)	% difference allowed
130 or Less than	± 10
130-324	± 7.5
More than 324	± 5

3. Thickness: Measure tablet thickness using a Vernier caliper (n=3).

4. Hardness Test: Measure tablet hardness using a Monsanto hardness tester (n=3) to assess tablet strength.

5. Friability Test: Determine friability by weighing 20 tablets before and after tumbling in a friabilator. Calculate friability as percentage loss in weight:

%Friability = [(W1 - W2) / W1] x 100.

6. Assay Procedure: Analyze drug content of tablets by preparing a solution, diluting, and filtering it. Calculate drug quantity using the formula provided.

$$\%\ \text{Assay} = \frac{\text{Test absorbance}}{\text{Standard absorbance}} * \frac{\text{Weight of standard}}{\text{Dilution of standard}} * \frac{\text{Dilution of test}}{\text{Weight of test}} * \frac{\text{Average weight}}{\text{lable claim}} * \frac{\%\ \text{purity of drug}}{100} * 100$$

7. In vitro Dissolution Study: Conduct dissolution testing using USP-II apparatus (Paddle method) in 6.8 phosphate buffer. Maintain sink conditions, withdraw samples at intervals, and analyze spectrophotometrically at λmax = 263 nm over 12 hours.

Table 6: Dissolution parameters

Parameter	Details
Dissolution apparatus	USP -Type II (paddle)
Medium	6.8 phosphate buffer
Volume	900 ml
Speed	50rpm
Temperature	37± 0.5 ºC
Sample volume withdrawn	5ml
Time points	1,2,4,6,8,10 and 12hr
Analytical method	Ultraviolet Visible Spectroscopy
λ_{max}	263 nm

C) In vitro Release Kinetics Studies: Drug release from the sustained-release (SR) tablets was analyzed using different kinetic models to understand the release mechanism:

Zero Order Release Kinetics: Describes a constant rate of drug release over time

(Q = k0t)

Where Q is the fraction of drug released at time t and k0 is the zero order release rate constant. A linear plot of drug released versus time indicates zero order kinetics.

First Order Release Kinetics: Assumes drug release is proportional to the remaining amount of drug .

(Log C = Log Co - kt/2.303)

where C is the amount of drug dissolved at time t, Co is the initial amount dissolved, and k is the first order rate constant. A linear plot of log cumulative drug remaining versus time suggests first order kinetics.

Higuchi Equation: Shows drug release as a square root of time dependence

(Q = K2t^1/2)

based on Fick's law of diffusion. A linear plot of drug released versus square root of time indicates Higuchi kinetics.

Peppas-Korsemeyer Equation (Power Law): Represents drug release as a power law function

(Mt/M∞ = Ktn)

where Mt is the amount of drug released at time t, M∞ is the total amount released, K is the kinetic constant, and n is the release exponent. A linear plot of log cumulative drug release versus log time shows the release mechanism governed by Peppas-Korsemeyer equation.

Regression analysis using MS Excel was performed to determine the correlation coefficients and assess the nature of drug release from the tablets according to these kinetic models.

Table 7: Drug release kinetics mechanism

Diffusion exponent(n)	Mechanism
0.45	Fickian diffusion
0.45 < n <0.89	Anomalous(Non- Fickian) diffusion
0.89	Case II transport
n > 0.89	Super Case II transport

RESULTS AND DISCUSSION

1. Construction of Standard calibration curve of Lansoprazole in 6.8 phosphate buffer:

The absorbance of the solution was measured at 238nm, using UV spectrometer with 6.8 phospphate buffer as blank. The values are shown in table no 10. A graph of absorbance Vs. Concentration was plotted which indicated in compliance to Beer's law in the concentration range 2 to 10 µg/ml.

Table 8: Standard Calibration graph values of Lansoprazole in 6.8 phosphate buffer

Concentration (µg/ml)	Absorbance
0	0
2	0.091
4	0.188
6	0.281
8	0.382
10	0.469

Standard plot of Lansoprazole by taking absorbance on Y – axis and concentration (µg/ml) on X – axis, the plot is shown fig.

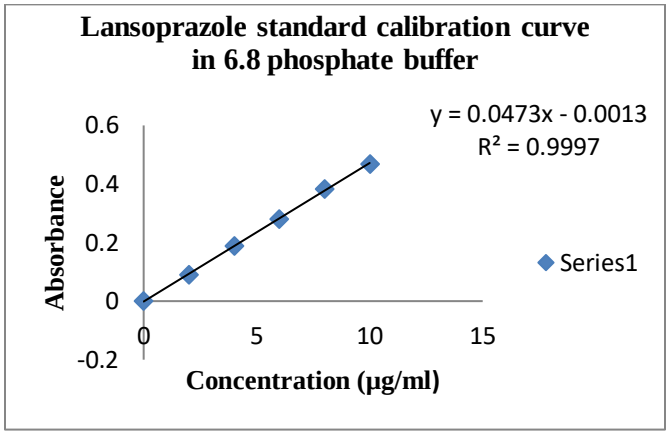

Fig 2: Standard calibration curve of Lansoprazole

Inference: The standard calibration curve of Lansoprazole in 6.8 phosphate buffer showed good correlation with regression value of 0.999

II. Evaluation of Solid dispersions:

Table 9: Dissolution data for Pure drug and HP-β-cyclodextrin used formulations

Time (min)	Cumulative % drug release						
	Pure drug	PM-1	PM-2	KM-1	KM-2	CP-1	CP-2
0	0	0	0	0	0	0	0
5	4.22	8.91	13.6	9.28	14.35	15.43	26.65
10	6.32	11.55	16.77	12.26	18.21	20.68	35.05
15	7.8	15.56	23.32	16.15	24.51	26.97	46.15
20	9.4	19.34	29.27	20.86	32.32	32.87	56.35
30	11.3	23.19	35.07	24.31	37.32	39.45	67.60
40	12.57	27.75	42.92	28.40	44.24	47.58	82.60
50	14.62	29.47	44.32	30.46	46.31	50.76	86.90
60	15.65	31.26	46.87	32.09	48.54	54.38	93.12

*Mean S.D, n=3

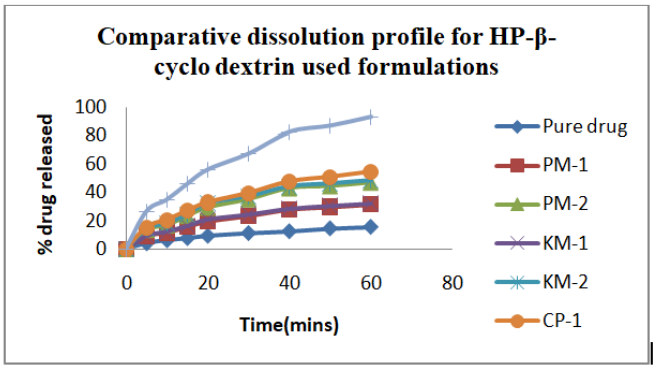

Fig 3: Comparative dissolution profile for pure drug and HP-β-cyclodextrin used formulations

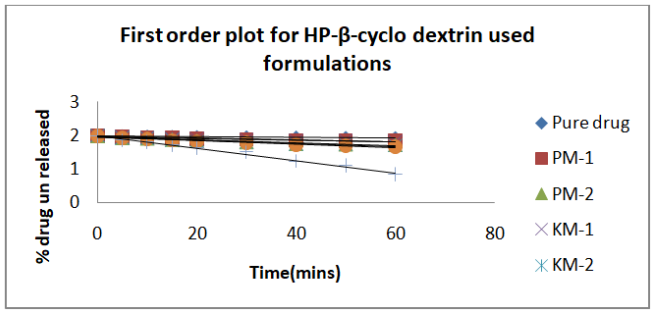

Fig 4: First order plot for pure drug and HP-β-cyclodextrin used formulations

III. EVALUATION TESTS FOR ENTERIC COATED TABLETS OF LANSOPRAZOLE

Table 10: Pre compression studies of Lansoprazole Enteric coated Tablets

Formulations	Bulk density (Kg/cm3)	Tapped density	Cars index	Hausners ratio	Angle of repose (°)
F1	0.37	0.41	9.75	1.1	21.61
F2	0.43	0.52	17.3	1.41	22.62
F3	0.40	0.46	13.0	1.50	22.29
F4	0.44	0.51	13.7	1.25	20.29
F5	0.39	0.47	17.0	1.56	28.23
F6	0.42	0.52	19.2	1.45	23.24
F7	0.41	0.50	18.0	1.50	27.4
F8	0.41	0.51	19.6	1.53	22.26
F9	0.44	0.52	15.3	1.40	23.62

Inference:

- The prepared tablets were evaluated for their flow properties; the results for the blends of compression Tablets were shown in Table
- The bulk density and the tapped density for all formulations were found to be almost similar.
- The Carr's index and Hausner's ratio were found to be in the range of ≤ 18 and 1.0 respectively, indicating good flow and compressibility of the blends.
- The angle of repose for all the formulations was found to be within range which indicating passable flow.

B) Post Compression Studies for Formulation of Enteric coated tablets of Lansoprazole:

Table 11: Post compression studies of Lansoprazole Enteric coated tablets

Formulation Code	% weight variation	Thickness	% friability	%Drug Content	Hardness (Kg/cm2)
F1	Pass	4.03	0.14	98.9	6.2
F2	Pass	3.93	0.11	100.2	5.7
F3	Pass	4.06	0.14	101.3	5.56
F4	Pass	4.06	0.15	101.5	6.03
F5	Pass	4.03	0.62	100.1	6.15
F6	Pass	4.1	0.15	100.7	6.63
F7	Pass	3.99	0.23	99.3	6.37

F8	Pass	4.15	0.19	100.2	6.23
F9	Pass	4.0	0.17	99.7	5.98

Inference:

- The variation in weight was within the range of ±7.5% complying with pharmacopoeia specifications of USP.
- The thickness of tablets was found to be between 3.93-4.15 mm.
- The hardness for different formulations was found to be between 5.56 to 6.63kg/cm2, indicating satisfactory mechanical strength
- The friability was < 1.0% W/W for all the formulations, which is an indication of good mechanical resistance of the tablet.
- The drug content was found to be within limits 98 to 102 %.

INVITRO DISSOLUTION STUDIES OF LANSOPRAZOLE TABLETS:

Table 12: Dissolution data of various enteric coated Tablets of Lansoprazole

Time (hrs)	% Drug released								
	F1	F2	F3	F4	F5	F6	F7	F8`	F9
0	0	0	0	0	0	0	0	0	0
1	48	40	47	55	45	32	35	28	21
2	67	57	59	68	59	43	48	37	38
4	86	68	71	81	70	56	61	45	47
6	97	88	86	98	81	68	76	59	56
8	100	95	98	100	91	76	88	71	63
10	100	100	100	100	100	85	100	88	78
12	100	100	100	100	100	100	100	100	85

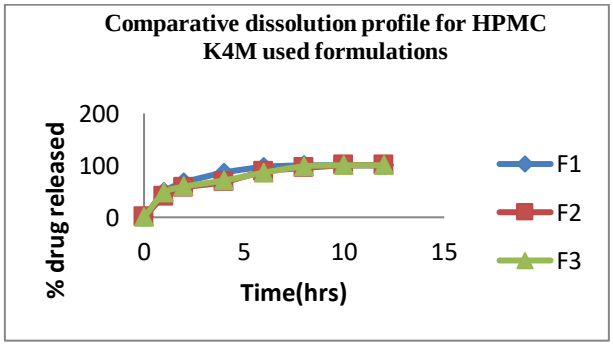

Fig 5: Dissolution profiles of Lansoprazole Enteric coated Tablets for F1, F2 and F3 formulations

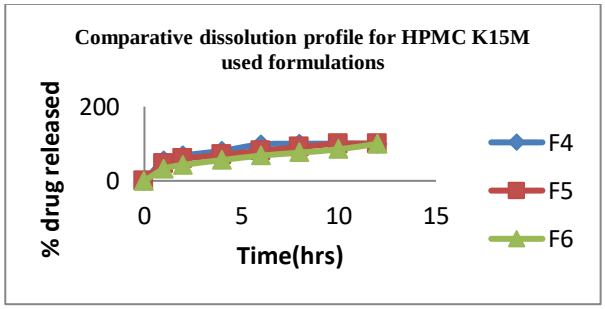

Fig 6: Dissolution profiles of Lansoprazole sustained release Tablets for F4, F5 and F6 formulations

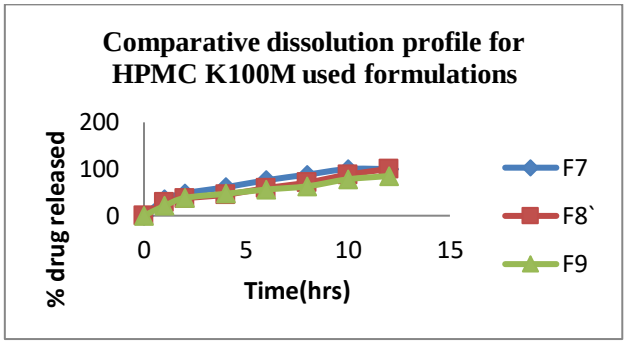

Fig 7: Dissolution profiles of Lansoprazole sustained release Tablets for F7, F8 and F9 formulations

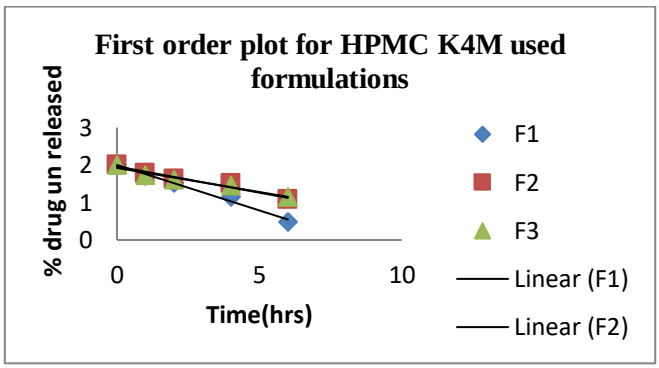

Fig 8: First order plot forF1, F2 and F3 formulations

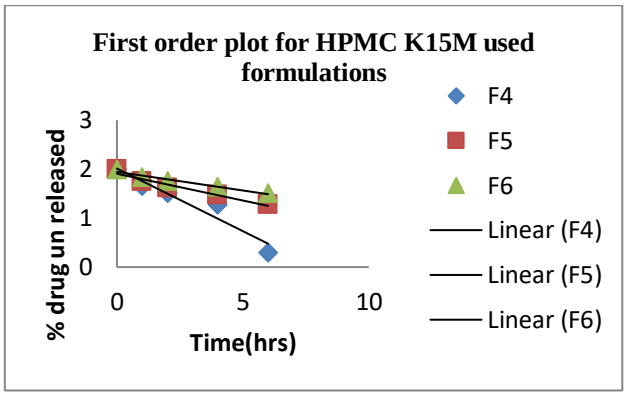

Fig 9: First order plot forF4, F5 and F6 formulations

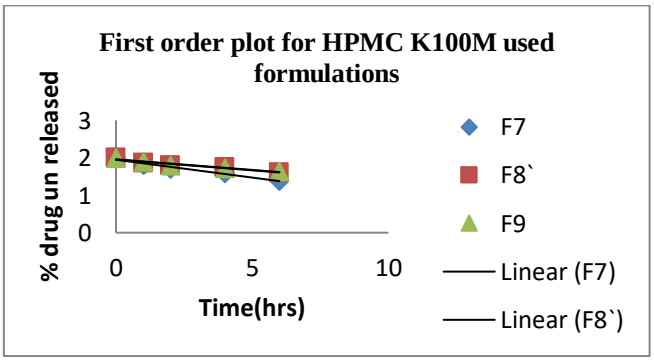

Fig 10: First order plot for F7, F8 and F9 formulations

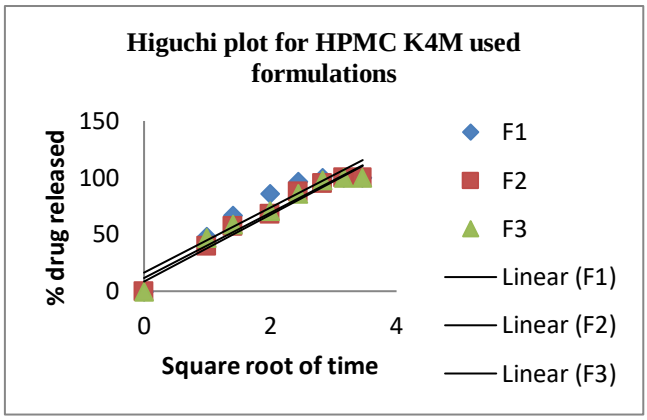

Fig 11: Higuchi plot for F1, F2 and F3 formulations

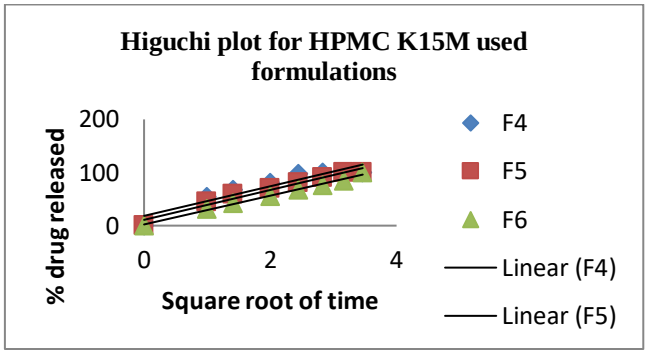

Fig 12: Higuchi plot for F4, F5 and F6 formulations

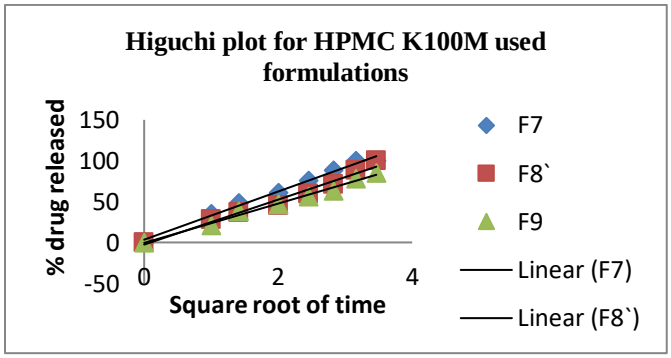

Fig 13: Higuchi plot for F7, F8 and F9 formulations

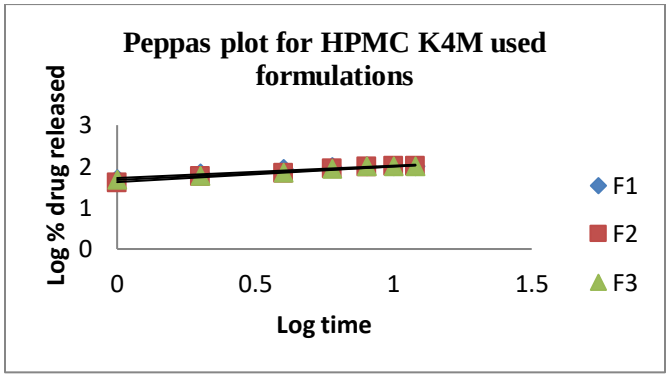

Fig 14: Peppas plot for F1, F2 and F3 formulations

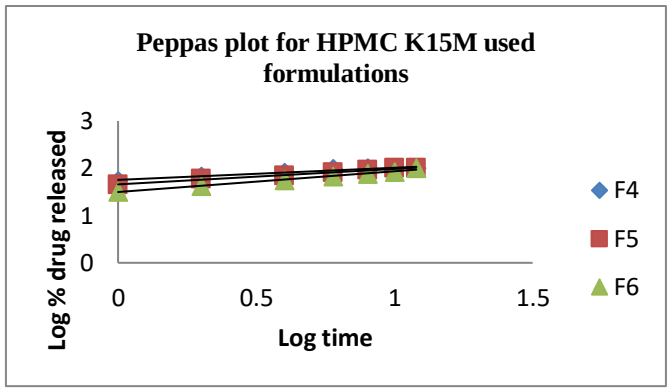

Fig 15: Peppas plot for F4, F5 and F6 formulations

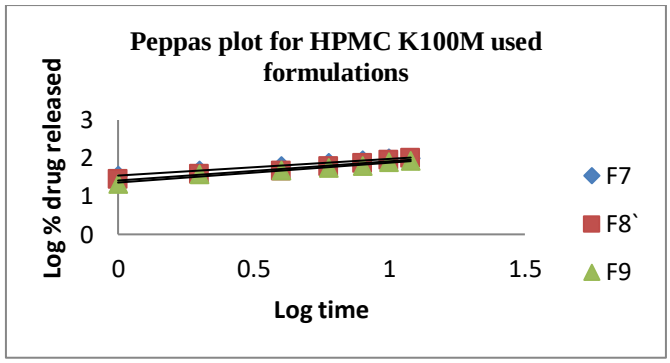

Fig 16: Peppas plot for F7, F8 and F9 formulations

Table 13: R2 and N result table for Lansoprazole EC Tablets:

Formulation code	R2 value				N value
	Zero order	First order	Higuchi	Peppas	
F1	0.819	0.993	0.946	0.964	0.299
F2	0.897	0.981	0.983	0.989	0.379
F3	0.881	0.979	0.976	0.992	0.324
F4	0.812	0.961	0.941	0.977	0.256
F5	0.892	0.968	0.981	0.996	0.327
F6	0.954	0.978	0.996	0.996	0.439
F7	0.941	0.985	0.996	0.997	0.437
F8	0.979	0.966	0.987	0.981	0.503
F9	0.962	0.967	0.994	0.987	0.520

SUMMARY AND CONCLUSION

The study investigated various methods for enhancing the solubility and dissolution rate of Lansoprazole through solid dispersion formulations, focusing on physical mixture, kneading, and co-precipitate techniques. Results indicated that among these methods, the solubility enhancement order was observed as Physical mixture < Kneading method < Co-precipitate method. In all cases, the drug-to-solid dispersion ratios favored 1:1 over 1:2. Specifically, formulations using HP-β-cyclodextrin in a 1:2 ratio via the co-precipitate method demonstrated the highest

solubility enhancement. Tablets containing Lansoprazole complexed with HP-β-cyclodextrin exhibited significantly superior dissolution rates compared to plain Lansoprazole capsules and tablets without cyclodextrin. Additionally, formulations for Lansoprazole sustained release were developed using HPMC polymers (K4M, K15M, K100M), which demonstrated suitable flow properties such as angle of repose, bulk density, tapped density, and compressibility index for direct compression. Increasing polymer concentration correlated with decreased drug release rates, with formulation F8 showing the most favorable release profile among all tested formulations. Overall, the sustained release capsules followed zero-order drug release kinetics, and their drug release mechanism was best described by the Higuchi model, highlighting their potential for controlled and efficient drug delivery.

BIBLIOGRAPHY

1. D.M.Brahmankar, Sunil B. Jaiswal, Biopharmaceutics and Pharmakokinetics, A Treatise, 1sted, VallabhPrakasan, Delhi, 2005; 27,5-6.
2. James Swarbrick., James C Boylan., Encyclopedia of Pharmaceutical Technology, 2nd edition, Vol-1:8.
3. Christian Leuner., Jennifer Dressmann., Improving drug solubility for oral delivery using solid dispersions. European Journal of Pharmaceutics and Biopharmaceutics, 2000, 50, 47-48.
4. Leon Shargel., Andrew B.C, Applied Biopharmaceutics and Pharmacokinetics, Appleton-Century-Crofts, 4th Ed, 1985. 134.
5. H.A. GareKani., F. Sadeghi., A. Badiee., S.A. Mostafa and A.R. Rajabisiahboomi., Crystal habit modifications of Ibuprofen and their Physicochemical Characteristics. Drug Development and Industrial Pharmacy, 2001, 27 (8), 803-809.
6. Leon Shargel., Andrew B.C, Applied Biopharmaceutics and Pharmacokinetics, Appleton-Century-Crofts, 4th Ed, 1985. 135.
7. D.M.Brahmankar, Sunil B. Jaiswal,Biopharmaceutics and Pharmakokinetics, A Treatise, 1sted, VallabhPrakasan, Delhi, 2005; 27,29-30.
8. Nandita G. Das and Sudip K. Das., Formulation of Poorly Soluble Drugs. Drug Delivery Report Spring/Summer, 2006, 52-55.
9. Lansoprazole drug profile: https://go.drugbank.com/drugs/ DB00448
10. Frominternetsource;https://en.wikipedia.org/wiki/Magnesium_stearate#:~:text=Magnesium%20stearate%20is%20a%20white,production%20of%20pharmaceuticals%20and%20cosmetics.
11. Excipient Profile :https://en.wikipedia.org/wiki/Cyclodextrin
12. ExcipientProfile: :https://en.wikipedia.org/wiki/Microcrystalline_cellulose#:~:text=Microcrystalline%20cellulose%20(MCC)%20is%20a,in%20vitamin%20supplements%20or%20tablets.
13. Kuchekar B S, Bhise S B, Armugam V. Design of fast dissolving tablets. Ind. J. Pharm. Edu. 2001; 35(4): 150-152.
14. Tetsuya O et al. Design of rapidly disintegrating oral tablets using acid-treated yeast cell wall: A Technical Note. AAPS PharmSciTech 2003; 4(4).
15. Beatrice P. Formulation design of carbamazepine fast-release tablets prepared by melt granulation technique. Int. J. Pharma 256 (2003) 53–63.
16. Abdelbary G et al. The preparation of orally disintegrating tablets using a hydrophilic waxy binder. Int. J. Pharma 278 (2004) 423–433.
17. Okuda Y et al. A new formulation for orally disintegrating tablets using a suspension spray-coating method. Int. J. of Pharma 382 (2009) 80–87.
18. Sastry SV, Nyshadham JR, Joseph AF. Recent technological advances in oral drug delivery – a review, PSTT 2000; 3(4).
19. Bandari S, Mittapalli RK, Gannu R, Rao YM. Orodispersible tablets: an overview. Asian J Pharm 2008 Jan [Cited 2008 Nov 9]. Available from URL: http://www.asiapharmaceutics.info.
20. Santosh Duddelli, Vedavathi T, Ajay Kumar, Zuheb Ur Rahman, R ShireeshKiran, Formulation And Evaluation Of Risperidone Sustained Release Tablets, Ijpbs, Volume 3, Issue 3, Jul-Sep 2013, 290-298.
21. Amir Badshah,FazalSubhan, Khalid Rauf, NadeemIrfanBukhari, Kifayatullah Shah, Samiullah Khan, Zia Ahmed, And Ihsanullah Khan, Development Of Controlled-Release Matrix Tablet Of Risperidone: Influence Of Methocel®- And Ethocel®-Based Novel Polymeric Blend On In Vitro Drug Release And Bioavailability,AapsPharmscitech. 2011 May 12; 12(2): 797.
22. GautamSinghvi, GauthamGampa, NileshYadav, Vipin Kumar And Ravi Ukawala, Design And Evaluation Of Rapidly Disintegrating Tablets Of Racecadotril With Enhanced In-Vitro Dissolution Achieved By Solid Dispersion Technique, Indian Journal Of Pharmaceutical Education And Research, Vol 47, Issue 3, Jul–Sep, 2013, 56-63.
23. Sanjay Jain, Sandeep Jain, Ankit Mishra, GopalGarg And Rahul Kumar Modi, Formulation And Characterization Of Fast Disintegrating Tablets Containing Cefdinir Solid Dispersion, International Journal Of Pharmacy & Life Sciences, Vol. 3, Issue 12: December: 2012, 2190-2199.
24. B.StephenRathinaraj, Ch. Rajveer, Prasanta Kumar Choudhury, Ganesh Sheshrao B And Gajanan V. Shinde, Studies On Dissolution Behaviour Of Sustained Release Solid Dispersions Of Nimodipine, International Journal Of Pharmaceutical Sciences Review And Research, Volume 3, Issue 1, July – August 2010; Article 018, 77-82.

25. Chiou WL and Riegelman SJ. JPharm Sci 1971; 60: 1283-1297.
26. James Swarbrick., James C. Boylan., Encyclopedia of Pharmaceutical Technology, 2nded, Vol: 1:641-647.
27. Christian Leuner., Jennifer Dressman., Improving Drug solubility for oral delivery using solid dispersions. European Journal of Pharmaceutics and Biopharmaceutics, 2000, 50, 48-51.
28. Modi A., Tayade P., Enhancement of dissolution profile of solid dispersion (Kneading) technique. AAPS Pharm Sci Tech., 2006, 7 (3), 1-13.

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