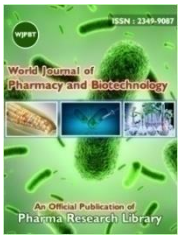

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Formulation and Evaluation of Enteric Coated Tablet of Dexlansoprazole

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A B S T R A C T

Dexlansoprazole is a proton pump inhibitor requiring precise quantification and optimized formulation for effective therapeutic outcomes. This study aimed to develop a reliable analytical method and formulate enteric-coated capsules with enhanced dissolution and controlled release profiles. A UV-Visible spectrophotometric method was developed and validated using 6.8 phosphate buffer, measuring absorbance at 238 nm across 2 to 10 µg/ml concentrations. Solid dispersions of Dexlansoprazole with HP-β-cyclodextrin were prepared to improve solubility. Powder blends were evaluated for flow and compressibility prior to direct compression of enteric-coated capsules. Post-compression parameters and in vitro dissolution profiles were assessed. The spectrophotometric method showed excellent linearity and precision. Solid dispersions significantly increased dissolution rates, with over 90% drug release within an hour. The powder blends exhibited consistent flow properties suitable for manufacturing. Capsules met pharmacopeial standards concerning weight variation, thickness, friability, drug content, and hardness. In vitro dissolution demonstrated sustained and nearly complete drug release over 12 hours. Kinetic analyses indicated a diffusion-controlled release mechanism involving anomalous transport. The study successfully formulated robust Dexlansoprazole enteric-coated capsules with enhanced dissolution and controlled release characteristics, indicating potential for improved therapeutic efficacy and patient compliance.

Keywords: Dexlansoprazole, enteric-coated capsules, UV-Visible spectrophotometry, HP-β-cyclodextrin, dissolution enhancement, sustained release.

A R T I C L E I N F O

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C O N T E N T S

1. Introduction

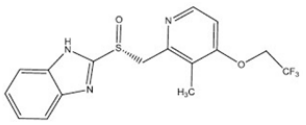

Fig.1: Dexlansoprazole

Molecular Formula: $C_{16}H_{14}F_3N_3O_2S$
Molecular Weight: 369.36g/mol
Chem Spider ID: 5293601

IUPAC Name: (+)-2-[(R)-{[3-methyl-4-(2,2,2-trifluoroethoxy)pyridin-2-yl]methyl}sulfinyl]-1H-benzimidazole
Density: ~1.5 ± 0.1 g/cm³
Boiling Point: ~555.8 ± 60.0 °C at 760 mmHg
Flash Point: ~289.9 ± 32.9 °C
Melting Point: 66–68 °C
Refractive Index: Not readily available
Polar Surface Area: Not specified

LogP (Octanol/Water): ~2.38
Generic Name: Dexlansoprazole
Brand Names: Dexilant, Kapidex
Drug Category: Proton pump inhibitor (PPI)
Indications: Treatment of GERD (gastroesophageal reflux disease), erosive esophagitis, and maintenance of healed erosive esophagitis
Pharmacology: It's a delayed-release PPI that inhibits the H^+/K^+-ATPase enzyme in gastric parietal cells, reducing acid secretion
Potency: More potent than lansoprazole due to its enantiomeric purity
Tolerability: Generally well tolerated; long-term use may require monitoring
Contraindications: Known hypersensitivity to dexlansoprazole or other PPIs
Adverse Effects: Diarrhea, abdominal pain, nausea, flatulence, and headache are common; rare risks include hypomagnesemia and C. difficile infection
Availability: Widely available in oral delayed-release capsule form

2. Materials and Methods

Table 1: List of Materials Used

S.No.	Materials	Source
1	Dexlansoprazole	Supplied By Qualychrome Research Labs Pvt. Ltd.
2	HP-β-Cyclodextrin	S.D. Fine Chemicals Limited, Mumbai
3	Crospovidone	S.D. Fine Chemicals Limited, Mumbai
4	Purified Talc	S.D. Fine Chemicals Limited, Mumbai
5	Magnesium Stearate	S.D. Fine Chemicals Limited, Mumbai
6	Micro crystalline cellulose	S.D. Fine Chemicals Limited, Mumbai

Table 2: List of Equipment's used

S.No	Equipment	Model/ source
1	UV-spectrophotometer	Labindia Uv 3000+
2	Digital Balance	Scale-Tec
3	Digital pH meter	Systronic Electronics, Mumbai
4	Dissolution apparatus	Electrolab TDT-08L
5	Hot air oven	Tempo Instruments & Equipments, Mumbai
6	Hardness tester	Monsanto Hardness Tester
7	Friability test apparatus	Roche Friabilator Electrolab, Mumbai
8	Tablet punching machine	Cadmach, Ahmedabad

Analytical Method Development
Preparation of 6.8 phosphate bufffer
6.8gms of potassium di hydrogen ortho phosphate was taken in a 1000ml volumetric flask and dissolved with distilled water and make up to 1000 ml with distilled water and adjust pH up to 6.8 with Sodium hydroxide solution.
Determination of Dexlansoprazole λ_{max} in 6.8 phosphate bufffer
Working standard: 100mg of Dexlansoprazole was weighed and dissolved in 10ml methanol and then make up to the volume with 6.8 phosphate buffer, it give 1000µg/ml concentrated stock solution.
Dilution 1: From the working standard, 10ml solution was diluted to 100ml with 6.8 phosphate buffer, it will give 100µg/ml concentrated solution.
Dilution 2: From the dilution1, 10ml solution was diluted to 100ml with 6.8 phosphate buffer, it will give 10µg/ml concentrated solutions.
This solutions 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 Dexlansoprazole in 6.8 phosphate buffer
Working standard: 100mg of Dexlansoprazole was weighed and dissolved in 10ml water and then make up to the volume with 6.8 phosphate buffer, it give 1000µg/ml concentrated stock solution.
Dilution 1: From the working standard, 10ml solution was diluted to 100ml with 6.8 phosphate buffer, it will give 100µg/ml concentrated solution.
Dilution 2: From dilution 1, take 0.2, 0.4, 0.6, 0.8, and 1ml of solution was diluted up to the mark with 6.8 phosphate buffer in 10ml volumetric flask to obtain 2, 4, 6, 8 and 10µg/ml concentrated solutions. This solutions absorbance was noted at 238nm.
Preparation of the Solid Dispersions

1. **Physical mixture method:** Drug with polymers in different molar ratios (1:1 and 1:2) were mixed in a mortar for about one hour with constant trituration, passed through sieve No. 80 and stored in desiccators over fused calcium chloride.
2. **Kneading method:** Drug with polymers in different molar ratios (1:1 and 1:2) was taken. First cyclodextrin is added to the mortar, small quantity of 50% ethanol is added while triturating to get slurry like consistency. Then slowly drug is incorporated into the slurry and trituration is further continued for one hour. Slurry is then air dried at 25°C for 24 hours, pulverized and passed through sieve No. 80 and stored in desiccators over fused calciumchloride.
3. **Co-precipitate method:** Drug was dissolved in ethanol at room temperature and polymer was dissolved in distilled water. Different molar ratios of Drug with polymers (1:1 and 1:2) were taken. The mixture was stirred at room temperature, for one hour and then slowly evaporated on a boiling water bath. The inclusion complex precipitated as a crystalline powder was pulverized and passed through sieve No. 80 and stored in a desiccator till free from any traces of the organic solvent.

Evaluation Studies on Solid Dispersions
Drug Content Estimation: Cyclodextrin inclusion complex, a quantity of powder equivalent to 100 mg of

Dexlansoprazole was weighed transferred to a 100 ml volumetric flask. The drug is dissolved in methanol by vigorously shaking for 15 minutes. Then the volume is adjusted to the mark with water and the solution is filtered. From prepared solution take 0.1ml in 10ml volumetric flask and make up to mark with water. The Dexlansoprazole content was determined by measuring the absorbance at 238nm after appropriate dilution. The drug content was calculated using the standard calibration curve. The mean percent drug content was calculated as an average of three determinations. Calculate the quantity in mg of Dexlansoprazole in the portion taken by the formula.

***In vitro* dissolution studies for solid dispersions**

Dissolution Profile:

Apparatus: USP - type II (Paddle)
Medium: 900 ml of 6.8 phosphate buffer
Speed: 50 rpm
Temperature of Medium : 37°C ±1°C
Sampling time points: 5,10,15, 20, 30 , 40, 50 and 60 min
Withdrawn the 5 ml samples through a 0.45µ filter at different intervals of time, suitably diluted and assayed for Dexlansoprazole at 238nm using a UV spectrophotometer & replace with same volume of buffer. The dissolution experiments were conducted in triplicate

Table 3: Formulae of Dexlansoprazole EC Capsule

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

Table 4: Angle of Repose Limits

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

Table 5: Compressibility Index Limits

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

Table 6: Dissolution Parameters

Parameter	Details
Dissolution apparatus	USP -Type II (paddle)
Medium	6.8 Phosphate buffer and
Volume	900 ml
Speed	50rpm
Temperature	37± 0.5 ºC
Sample volume withdrawn	5ml
Time points	1, 2, 4, 6, 8, 10, 12hours
Analytical method	Ultraviolet Visible Spectroscopy
λ_{max}	238nm

Table 7: Weight Variation Tolerance for Uncoated Tablets

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

3. Results and Discussion

Construction of Standard calibration curve of Dexlansoprazole in 6.8 phosphate buffer: The absorbance of the solution was measured at 238nm, using UV spectrometer with 6.8 phospphate bufffer 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 Dexlansoprazole 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

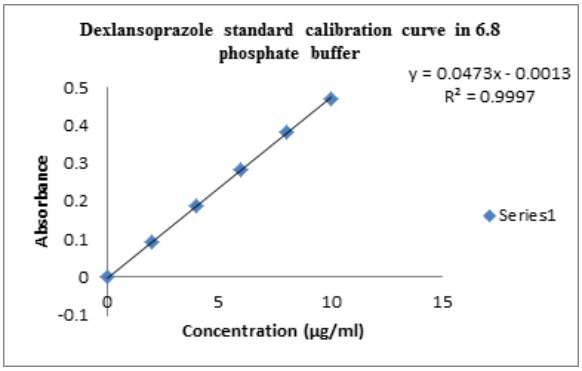

Fig.2: Standard calibration curve of Dexlansoprazole

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

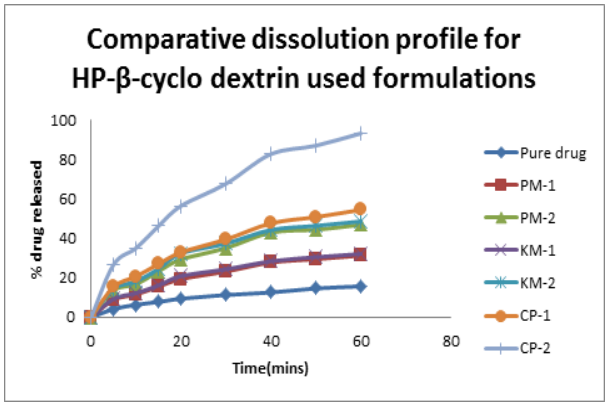

Fig.3: Comparative dissolution profile for pure drug and HP-β-cyclodextrin used formulations

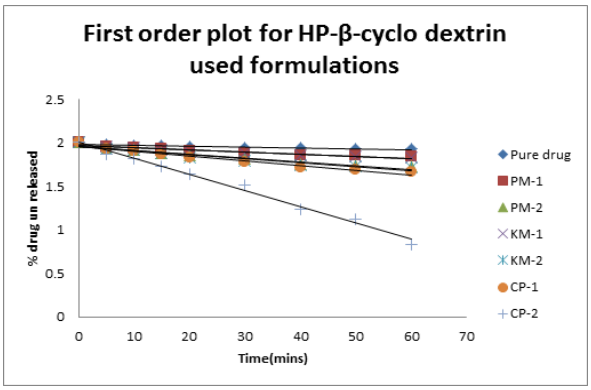

Fig.4: First order plot for pure drug and HP-β-cyclodextrin used formulations

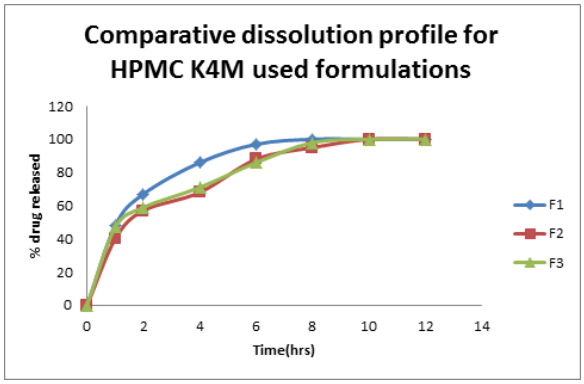

Fig.5: Dissolution profiles of Dexlansoprazole Enteric coated capsules for F1, F2 and F3 formulations

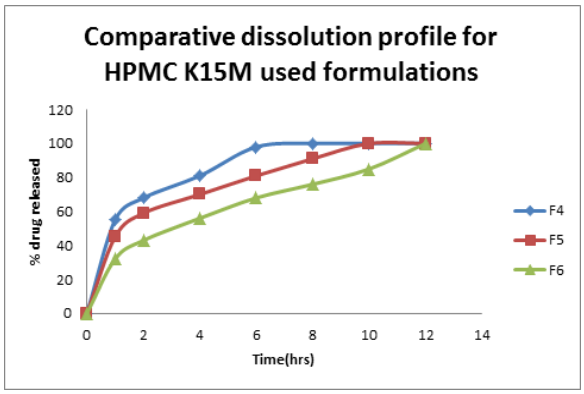

Fig.6: Dissolution profiles of Dexlansoprazole sustained release capsules for F4, F5 and F6 formulations

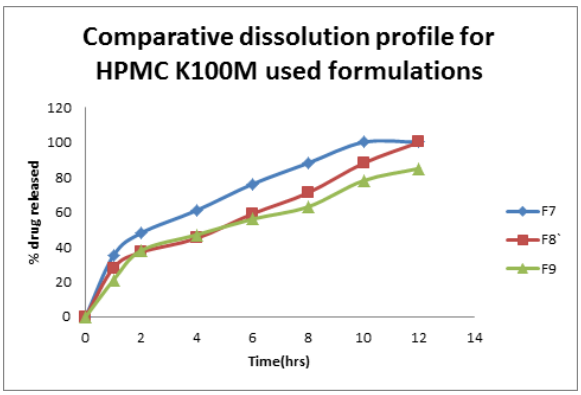

Fig.7: Dissolution profiles of Dexlansoprazole sustained release capsules for F7, F8 and F9 formulations

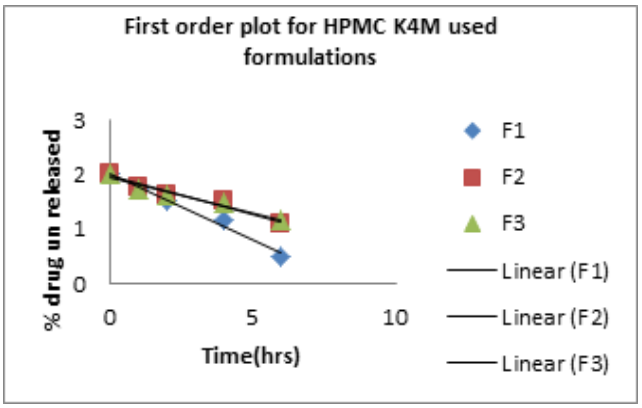

Fig.8: First order plot forF1, F2 and F3 formulations

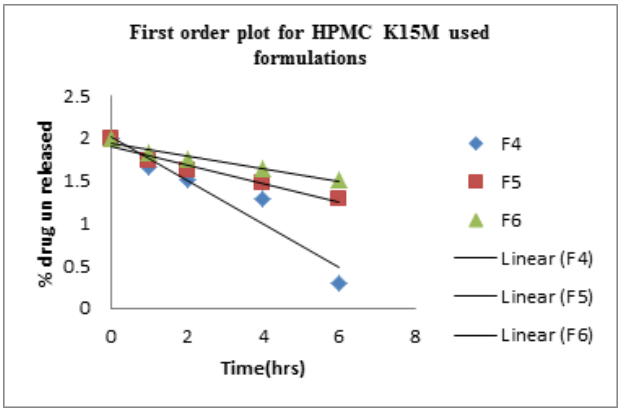

Fig.9: First order plot forF4, F5 and F6 formulations

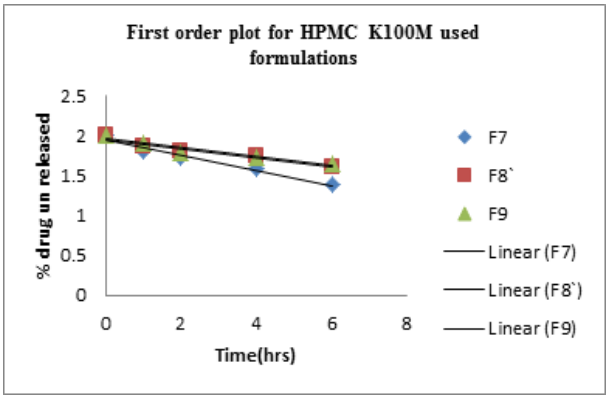

Fig.10: First order plot for F7, F8 and F9 formulations

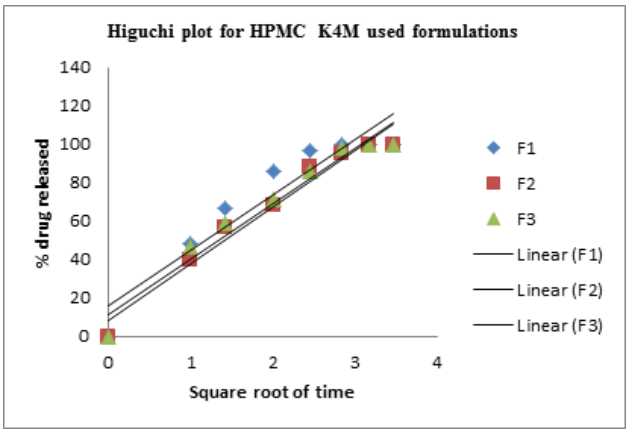

Fig.11: Higuchi plot for F1, F2 and F3 formulations

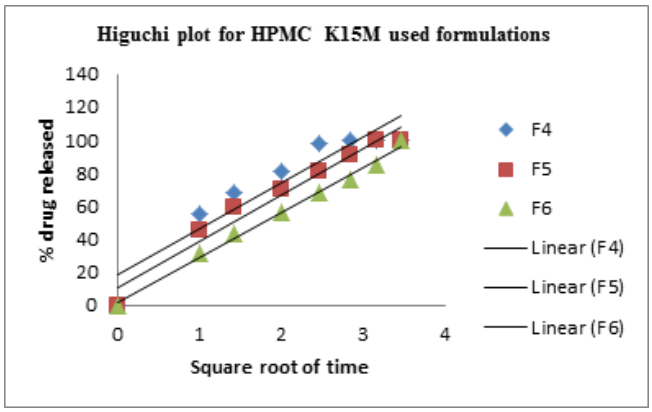

Fig.12: Higuchi plot for F4, F5 and F6 formulations

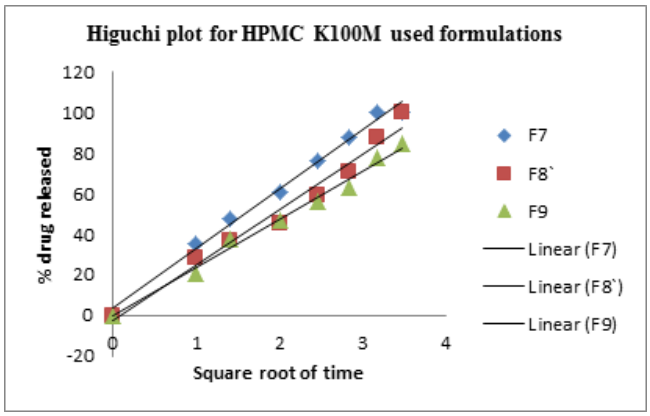

Fig.13: Higuchi plot for F7, F8 and F9 formulations

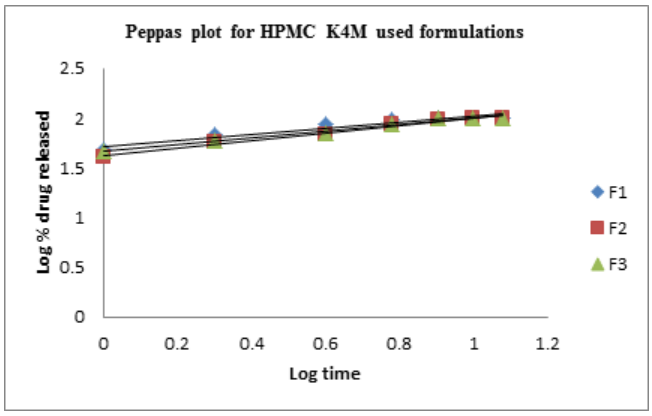

Fig.14: Peppas plot for F1, F2 and F3 formulations

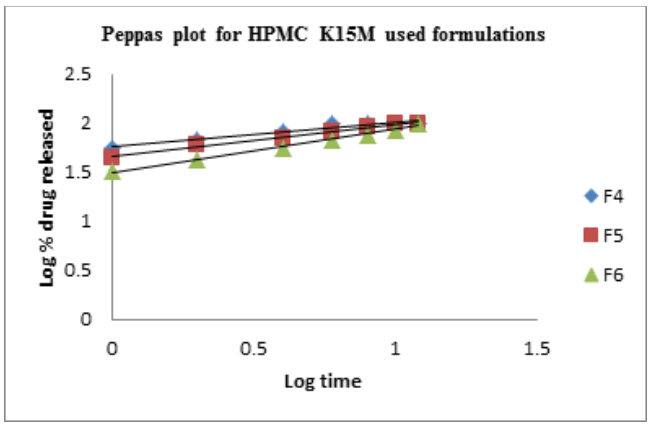

Fig.15: Peppas plot for F4, F5 and F6 formulations

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

Table 10: Pre compression studies of Dexlansoprazole Enteric coated capsules

Formulations	Bulk density (Kg/cm^3)	Tapped density (Kg/cm^3)	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

Table 11: Post compression studies of Dexlansoprazole Enteric coated tablets

Formulation Code	% weight variation	Thickness	% friability	%Drug Content	Hardness (Kg/cm^2)
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

Table 12: Dissolution data of various enteric coated capsules of Dexlansoprazole

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

Table 13: R2 and N result table for Dexlansoprazole EC capsules

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

4. Conclusion

UV-Visible spectrophotometric method was developed and validated for the quantification of Dexlansoprazole in 6.8 phosphate buffer, measuring absorbance at 238 nm. The calibration curve showed excellent linearity within a concentration range of 2 to 10 µg/ml, demonstrating compliance with Beer's law and confirming the method's precision and reliability for routine drug analysis. Solid dispersions of Dexlansoprazole complexed with HP-β-cyclodextrin significantly enhanced dissolution rates compared to the pure drug, with cumulative release reaching over 90% within 60 minutes. Pre-compression studies of powder blends for the formulation of enteric coated capsules showed consistent bulk and tapped densities, Carr's index, Hausner ratio, and acceptable angles of repose indicating good flow and compressibility suitable for direct compression processes. Post-compression evaluations confirmed that all capsule formulations conformed to pharmacopoeial standards in parameters such as weight variation, thickness, friability, drug content, and hardness, ensuring mechanical strength and uniformity. In vitro dissolution studies demonstrated sustained and nearly complete drug release within 12 hours, with kinetics fitting zero-order, first-order, Higuchi, and Korsmeyer-Peppas models. The release mechanism for the best-performing formulations appears to be diffusion-controlled with anomalous transport characteristics. Overall, the study successfully developed robust enteric coated Dexlansoprazole capsules with enhanced dissolution, stability, and controlled release profiles, offering promise for improved therapeutic efficacy and patient compliance.

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