International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 30, Issue 12, December 2024 **ijppr.humanjournals.com** ISSN: 2349-7203

Effect of 1% SLS on Fast Release Buffer Tablet of Lansoprazole and Domperidone Tablet

Rizwana Fatima, Shahid Mohammad

Deccan School Of Pharmacy, Dar-Us-Salam. Aghapura, Hyderabad, 500001, India

Received: 2024-12-07 Revised: 2024-12-18 Accepted: 2024-12-24

ABSTRACT

Lansoprazole is an acid labile drug and is an proton pump inhibitor and commonly given as enteric coated tablet for peptic ulcer. Alkalizing stomach pH using buffering agent like sodium bicarbonate prevents degradation of lansoprazole in acidic environment. One of the major symptom of GERD is nausea and vomiting. Combination with domperidone helps in reducing this side effect. SLS helps in faster dissolution of lansoprazole and domperidone. Six formulation of Lansoprazole and domperidone tablets were prepared using sodium bicarbonate as buffering agent , Sodium starch glycolate, Cross povidone, Cross Carmellose sodium as super disintegrant, and sodium lauryl sulphate as dissolution enhancer and magnesium stearate as lubricant. The physiochemical evaluation results for the granules and tablets of all trials pass the official limits All formulations showed disintegration time of 180 secs. All other parameters viz: hardness, thickness, weight variation and drug content were also found to be within limits. The *in-vitro* drug release profiles of Lansoprazole and domperidone showed F6 formulation as optimized for its better dissolution rate and other physiochemical properties. Stability studies were performed for 6 months and found to be satisfactory.

KEY WORDS: Lansoprazole, Domperidone, Buffering agents, Sodium lauryl sulphate

INTRODUCTION

Tablets are defined as solid preparations each containing a single dose of one or more active ingredients and obtained by compressing uniform volumes of particle. One of the major drawback of proton pump inhibitor are degradation in stomach due to acidic environment. Enteric coating of PPI leads to delay onset of action. This can be overcome using buffer tablets. Buffer Tablets are pharmaceutical formulations designed to enhance the stability and effectiveness of acid labile drugs (proton pump inhibitors) in acidic environment. These tablets can incorporate buffering agents like sodium bicarbonate, citric acid and tartaric acid which help neutralize stomach acid, creating an optimal environment for the acid labile drugs to be stable in acidic environment. Superdisentigrant like sodium starch glycolate, cross carmellose and cross povidone helps in faster disintegration of tablet. Non-ionic surfactants like sodium lauryl sulphate helps in better dissolution of poorly soluble drugs.

The aim and objective of the present work is to prevent degradation of acid labile drug from acidic environment using buffering agent and help faster release from acidic environment using superdisentigrant and surfactant and thereby faster onset of action.

METHODOLOGY

PRE FORMULATION STUDIES – LANSOPRAZOLE AND DOMPERIDONE

Preformulation is defined as the science of investigation of physio-chemical properties of a drug. Based on the physio- chemical properties, the drug delivery system can be designed. A thorough understanding of these properties may ultimately provide a rationale for the formulation design, or support the need for molecular modification.

1. Organoleptic Properties:

The colour, odour and Appearance of the drug are evaluated using descriptive terminology.

2. Melting Point:

- The melting point of the drug is found by using the Melting/Boiling Point Apparatus.
- The drug can be transferred to the melting point apparatus using a capillary tube and the temperature can be gradually increased until the mixture melts.
- The melting point can be determined by observing the changes in the physical state of the drug and recording the temperature range at which the melting occurs.

3. Solubility Analysis:

The solubility of the drug was determined by an equilibrium method using the following solvents

- Distilled Water,
- Methanol,
- Ethanol,
- Phosphate Buffer 6.8

➢ Prepare a series of solutions containing 5ml of solvents in test tubes.

➢ Place 5mg of the API in each solution and dissolve using the handshake method until it is completely dissolved.

➢ Then keep on increasing until saturation is achieved.

4. Standard Curve For Lansoprazole And Domperidone:

Determination Of λ Max

Preparation Of Standard Stock Solution, Working Standard And Dilutions:

- 50 mg of Drug was dissolved in 50 ml of 6.8 pH phosphate buffer to give a concentration of 1000 µg/ml
- From the above solution 1 ml was withdrawn and made to 10 ml with 6.8 pH phosphate buffer to give a concentration of 100 µg/ml
- From the above solution concentration of 5,20,15,20,25 was prepared.

Scanning:

The UV scan was taken between 200 to 400 nm.

5. FTIR Studies:

FTIR studies are performed on drug alone and drug-excipient mixture. About 0.1-1.0% sample was well mixed with KBr powder which was put into a pellet-forming die and by applying a force of 8 tons under vacuum, transparent pellets were obtained. Analysis was done on 4000-400 cm -1 wave number range samples.

International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 30, Issue 12, December 2024 **ijppr.humanjournals.com** ISSN: 2349-7203

6. PRE-COMPRESSION EVALUATION FOR BOTH DRUGS

(i) Drug Powder Characterization: Angle Of Repose:

The angle of repose is the maximum angle of a stable slope determined by friction, cohesion and the shapes of the particles. The internal angle between the surface of the pile and the horizontal surface is known as the angle of repose and is related to the density, surface area and coefficient of friction of the raw material:

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

Where, **h** = height of heap,

r = radius of heap,

Θ = angle of repose.

Table 1: Limits

Angle of flow property	
<25°	Excellent
25-30°	Good
30-40°	Passable
>40°	Very poor

(ii) Bulk Density:

Bulk density is defined as the mass of the powder divided by the bulk volume. Bulk density largely depends on particle shape, as the particle becomes more spherical, bulk density is increased. In addition, as the granule size increases bulk density decreases.

A quantity of 5 gm of powder was weighed and transferred to a measuring cylinder and observed the volume occupied by the sample. The initial volume was calculated. Bulk density was calculated using the formula.

Bulk density = Bulk mass / Bulk volume

(iii) Tapped Density:

Tapped density is achieved by mechanically tapping a measuring cylinder containing a powder sample. After observing the initial volume, the cylinder is mechanically tapped and volume readings are taken until little further volume changes are observed the mechanical tapping is achieved by raising the cylinder and allowing it to drop under its weight a specific distance device that rotates the device during tapping may be preferred to minimize any possible separation of the mass during tapping down.

The powder in the measuring cylinder was tapped for specific times at a height of 2.5 cm at an interval of 2 seconds. The powder in the graduated cylinder was tapped for specific times at a height of 2.5 cm at an interval of 2 seconds. The final volume occupied by the sample was noted and tapped density was calculated by using the formula:

$$\textbf{Tapped density} = m/ v_f$$

Where**, m =** initial weight of material in gm,

V_f **=** volume of material after tapping.

Generally, replicate determinations are desirable for the determination of this Property.

(iv) Measurement Of Powder Compressibility:

Carr's Index

Based on the apparent bulk and the tapped density, the percentage compressibility of bulk was determined by the following formula.

Carr's index: =100 (V_0-V_f) /V_0

Where, **V_f** = final tapped volume,

V_o = initial un-tapped volume

Table 2: Limits

SNO	Compressibility index	Flow
1	5-12	Free flow
2	13-16	Good flow
3	17-22	Fair
4	22-25	Poor
5	26-39	Very poor
6	>40	Extremely poor

(v) Hausner Ratio

Based on the apparent bulk and the tapped density, the percentage compressibility of bulk was determined by the following formula.

Hausner Ratio: =V_0/ V_f

Where, **V_f** = final tapped volume,

V_o = initial un-tapped volume.

Table 3: Limits:

SNO	Hausner's ratio	Flow
1	1-1.2	Free-flowing
2	1.2-1.61	Cohesive powder

(vi) Formulation of Lansoprazole and Domperidone buffer tablet:

Direct compression was used to develop Lansoprazole and Domperidone immediate release tablets. Sodium bicarbonate and API were combined, and the mixture was tested using super disintegrants such as sodium starch glycolate, cross povidone, and cross carmellose sodium. As lubricant, magnesium stearate is added to this. A rotary machine with eight stations and punch size DS was then used to compress the mixture into tablets weighing 1200 mg. The formula ratios are listed in the table below.

Addition of 1% SLS:

1% SLS was introduced to the optimized formulation to observe and assess its dissolution behaviour.

Table 4 : Formulation of immediate release buffer tablet -Total 1200 mg

S.NO.	Ingredients (mg)	F1	F2	F3	F4	F5	F6
1.	Lansoprazole	15	15	15	15	15	15
2.	Domperidone	10	10	10	10	10	10
3.	Sodium bicarbonate	1100	1100	1100	1100	1100	1100
4.	Sodium starch glycolate	60	-	-	-	-	-
5.	Cross povidone	-	60	-	30	90	60
6.	Cross carmellose sodium	-	-	60	-	-	-
7.	Sodium lauryl sulphate	-	-	-	-	-	12
8.	Magnesium stearate	15	15	15	15	15	15
	Average weight of tablet	1200	1200	1200	1170	1230	1212

(viii) POST-COMPRESSION STUDIES-EVALUATION OF BUFFER TABLET

All the prepared buffer tablets were evaluated for the following parameters.

(i) Appearance:

The buffer tablets were identified visually by checking the colour difference.

(ii) Thickness:

Thickness was measured using a vernier calliper. Five tablets of the formulation were picked randomly and thickness was measured individually.

(iii) Hardness:

Hardness was measured using a Monsanto hardness tester. For each batch, three tablets were tested.

(iv) Friability:

Twenty tablets were weighed and placed in the Roche friability and the apparatus was rotated at 25 rpm for 4 minutes. After revolutions, the tablets were weighed again. The percentage friability was measured using the formula,

$$\% F = \{1-(W_t/W)\} \times 100$$

Where, **% F** = Friability in percentage

W = Initial weight of tablets

W_t = Weight of tablets after the revolution

(v) Weight Variation:

Ten tablets were randomly selected from each batch and individually weighed. The average weight and standard deviation of 20 tablets were calculated. The batch passes the test for weight variation test if not more than two of the individual tablet weights deviate from the average weight.

(vi) Disintegration Test:

For a drug to be absorbed from a solid dosage form after oral administration, it must be in solution, and the first important step toward this condition is usually the break-up of the tablet; a process known as disintegration. The disintegration test is a measure of the time required under a given set of conditions for a group of tablets to disintegrate into particles which will pass through a 10 mesh screen. Generally, the test is useful as a quality assurance tool for conventional dosage forms.

(vii) In-Vitro Dissolution Studies:

In vitro drug release studies were conducted using 900 mL of pH 6.8 phosphate buffer for the first 2 hours with a USP type 2 dissolution apparatus (Electro lab TDT-08L) at 75 rpm and 37 ± 0.5°C. During the dissolution process, samples (5 mL) were taken at specified time points for analysis and replaced with an equal volume of fresh medium to maintain consistent conditions. The samples were then filtered, appropriately diluted, and analysed spectrophotometrically (Systronics, India) at 260nm, 207nm for the determination of Lansoprazole and domperidone.

DETAILS OF DISSOLUTION TEST:

Dissolution test apparatus : USP type II

Speed : 75 rpm

Stirrer : Paddle type

Volume of medium : 900 ml

Volume withdrawn : 5 ml

Medium used : Phosphate buffer 6.8 pH

Buffer temperature : 37 ± 0.5°C

10. STABILITY STUDIES OF THE OPTIMIZED FORMULATION:

The stability of a pharmaceutical preparation can be defined as "the capability of a particular formulation in a specific container/closure system to remain within its physical, chemical, microbiological, therapeutic and toxicological specifications throughout its shelf life." The purpose of stability testing is to provide evidence on how the quality of a drug substance or drug product varies with time under the influence of a variety of environmental factors such as temperature, humidity and light, and enables recommended storage conditions, re-test periods and shelf-lives to be established. ICH specifications for stability study.

Procedure:

In the present study, the formulations F2 were selected and the stability studies were carried out at 25 ± 2 ºC, 60 ± 5 % RH (Long-term stability condition), 30 ± 2º C, 65 ± 5 % RH (intermediate condition) and 40 ± 2º C, 75 ± 5 % RH (accelerated conditions), the tablets were packed in amber colour screwcap container and kept in above said condition for a period of three months. The tablets were analysed periodically for their physical appearance and in-vitro drug release.

Evaluation of samples:

The samples were analysed for the following parameters:

I. Physical evaluation:

Appearance: The samples were checked for any change in colour at an interval of 1 month up to 6 months.

Hardness: The samples were tested for hardness at an interval of 1 month up to 6 months.

II. Chemical evaluation:

Drug content: The samples were checked for drug content at an interval of 1 month up to 6 months.

Drug release: The samples were subjected to drug release studies at an interval of 1 month up to 6 months.

RESULTS AND DISCUSSION:

1. Organoleptic properties

Table 5

S.NO.	Parameter	Lansoprazole	Domperidone
1.	State	Solid	Solid
2.	Colour	White to brownish-white	White
3.	Odour	Odourless	Odourless
4.	Appearance	White crystalline powder	White crystalline powder
5.	Taste	Bitter	Bitter

All values expressed as mean ± SD, (n=3)

2. Solubility

Table 6

Solvent	Lansoprazole	Domperidone
Distilled water	0.020mg/ml±0.76	0.25mg/ml±0.34
Ethanol	0.047mg/ml±0.21	0.32mg/ml±0.17
6.8 pH phosphate buffer	0.061mg/ml±0.64	0.58mg/ml±0.32
DMSO	0.050mg/ml±0.32	0.52mg/ml±0.54
Methanol	0.062mg/ml±0.12	0.69mg/ml±0.31

All values expressed as mean ± SD, (n=3)

3. Melting point

Table 7

DRUG	Reported melting point	Observed melting point
Lansoprazole	178-182°C	180 ±0.23 °C
Domperidone	242-245°C	242.5 ±0.34°C

All values expressed as mean ± SD, (n=3)

4. Standard Curve For Lansoprazole And Domperidone

Determination of λ Max (Lansoprazole)

Table 8

Drug	Observed range
Lansoprazole	260 nm

All values expressed as mean ± SD, (n=3)

International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 30, Issue 12, December 2024 ijppr.humanjournals.com ISSN: 2349-7203

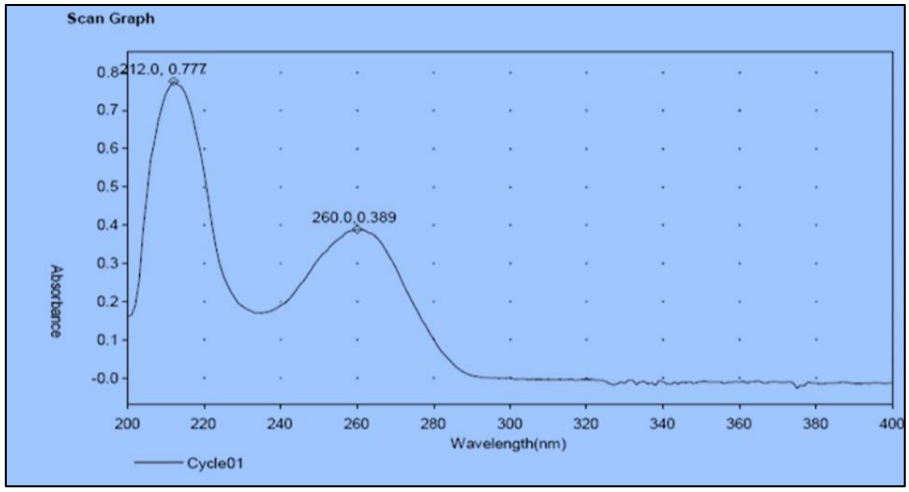

Fig 1. The Standard Lansoprazole Graph Demonstrated Strong Linearity with an R2=0.9985 , Signifying Its Adherence To The "BEER-LAMBERT'S LAW"

Table 9

Concentration(µg/ml)	Absorbance
5	0.094 ± 0.016
10	0.198±0.014
15	0.316±0.012
20	0.428±0.010
25	0.547±0.013
30	0.645±0.014
35	0.777±0.015
40	0.876±0.001
45	0.987±0.012

All values expressed as mean ± SD, (n=3)

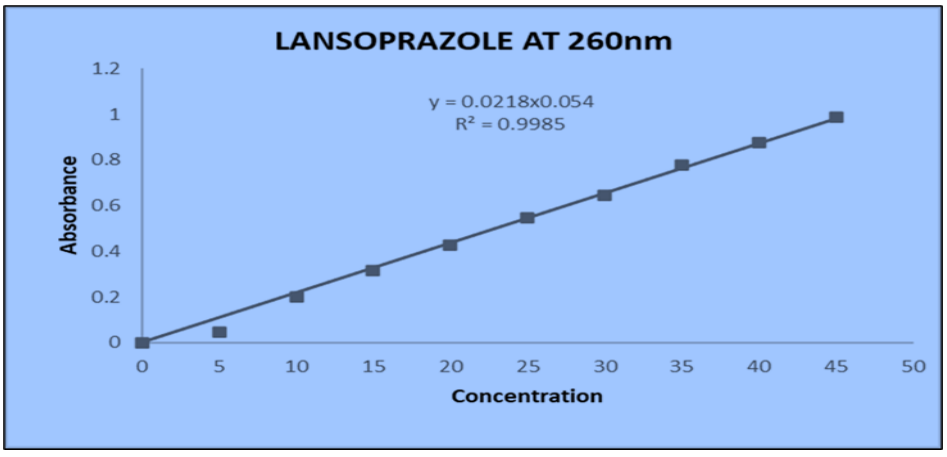

Fig 2. Calibration curve of Lansoprazole in 6.8 pH phosphate buffer

Domperidone

Table 10

Drug	Observed range
Domperidone	207 nm

All values expressed as mean ± SD, (n=3).

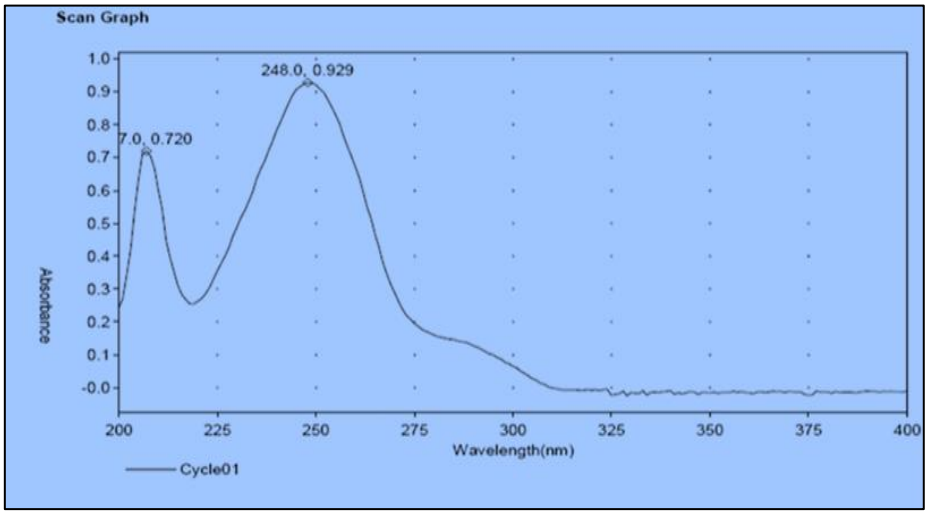

Fig 3. The Standard Deferiprone Graph Demonstrated Strong Linearity with an R2= 0.9979 , Signifying Its Adherence To The "BEER-LAMBERT'S LAW"

Table 11

Concentration(µg/ml)	Absorbance
5	0.087 ±0.011
10	0.156±0.012
15	0.356±0.015
20	0.412±0.013
25	0.543±0.018
30	0.654±0.014
35	0.723±0.016
40	0.885±0.020
45	0.976±0.019

All values expressed as mean ± SD, (n=3).

International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 30, Issue 12, December 2024 ijppr.humanjournals.com ISSN: 2349-7203

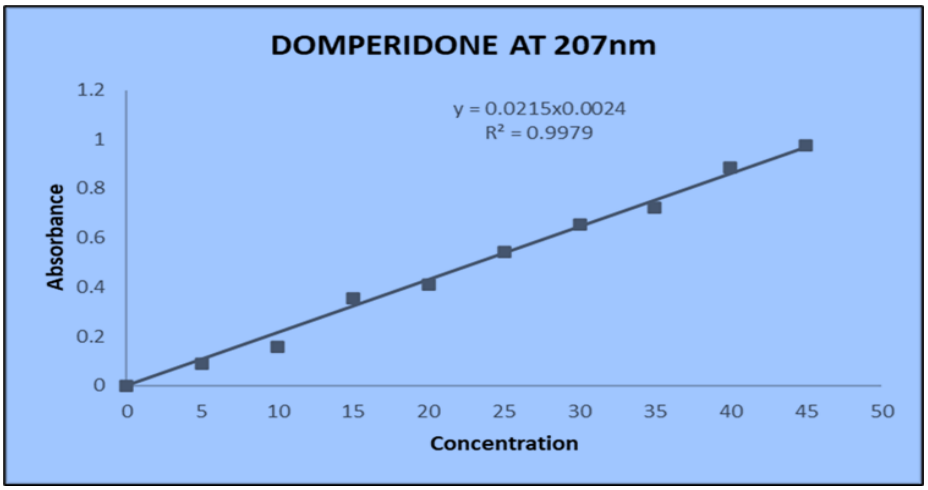

Fig 4. Calibration curve of Domperidone in 6.8 pH phosphate buffer

5. FTIR STUDIES

Lansoprazole

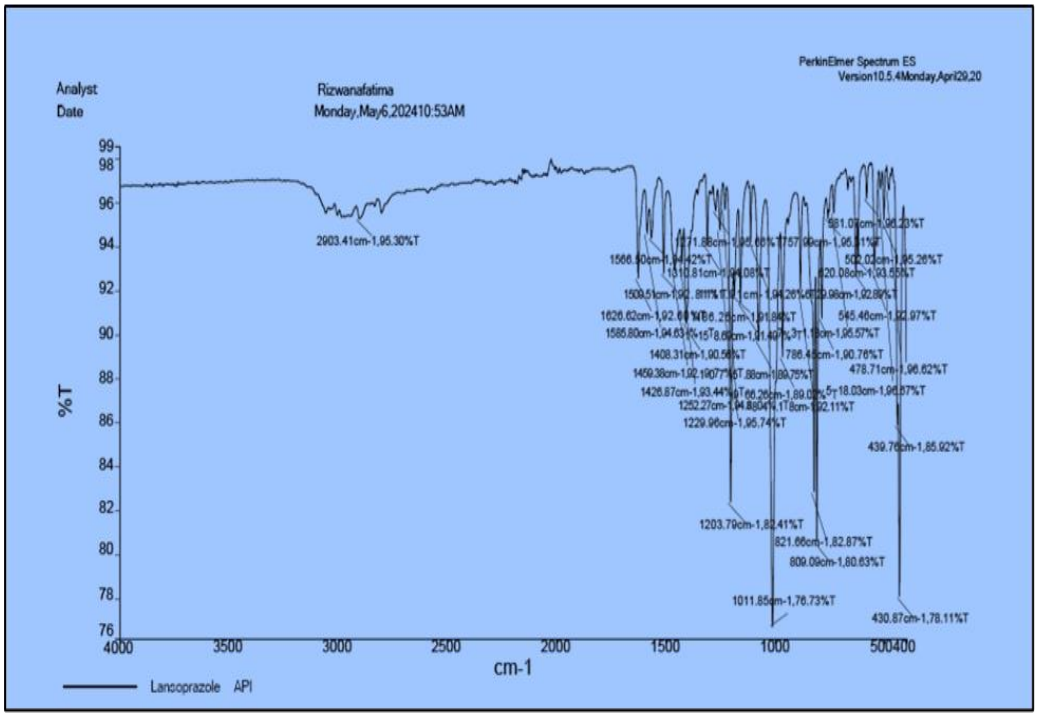

Fig 5: FTIR spectra of Lansoprazole pure drug

International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 30, Issue 12, December 2024 ijppr.humanjournals.com ISSN: 2349-7203

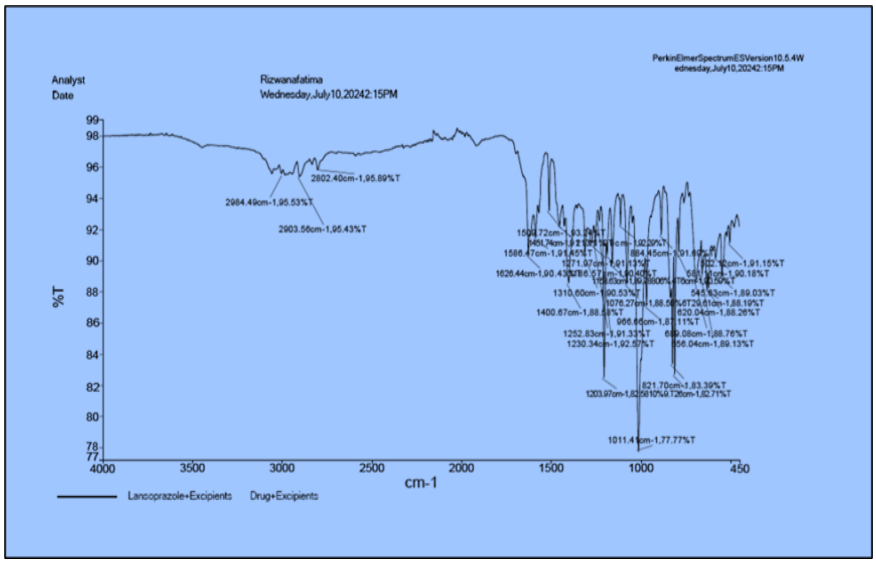

Fig 6. FTIR spectra of Lansoprazole pure drug + Excipients

Table 12

Group	Standard values	Pure drug Lansoprazole	Drug + Excipients
N-H	3300-2800	2903.41	2984.49
C=O	1870-1540	1509.51	2903.56

Domperidone

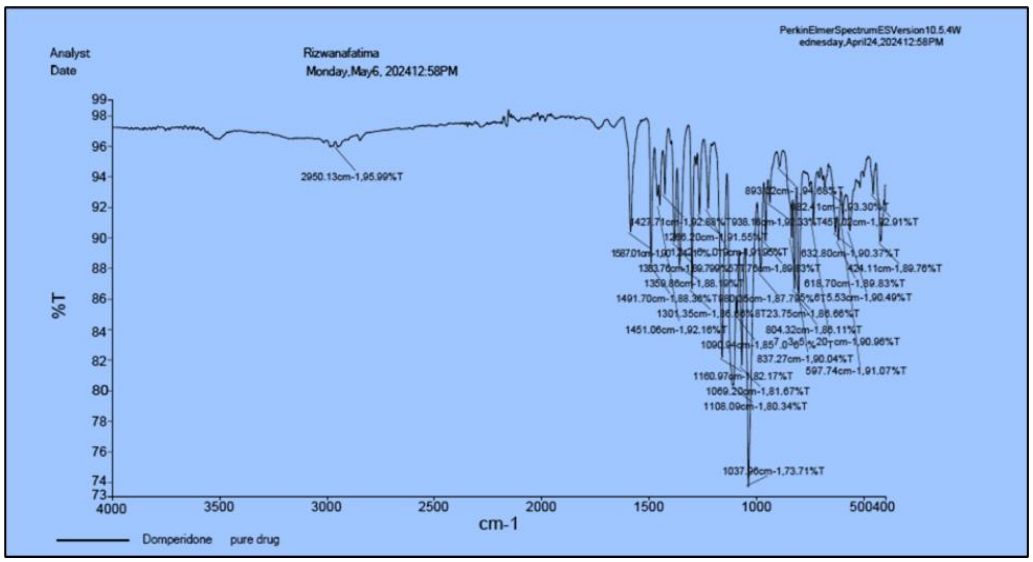

Fig 7. FTIR spectra of Domperidone pure drug

International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 30, Issue 12, December 2024 ijppr.humanjournals.com ISSN: 2349-7203

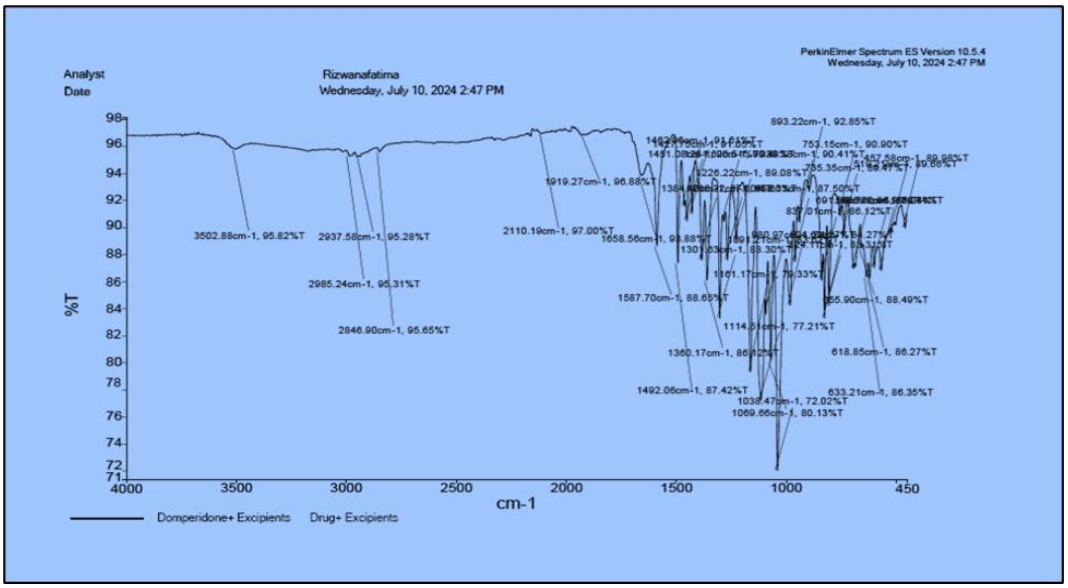

Fig 8. FTIR spectra of Domperidone pure drug + excipients

Table 13

Group	Standard values	Pure drug Domperidone	Drug + Excipients
N-H	3300-2800	2950.13	3502.88
C=O	1870-1540	1587.01	2937.58

EVALUATION OF PRE AND POST COMPRESSION PARAMETERS

Pre-compression parameters for blend

Table 14 : Pre compression parameters for powdered blend

Formulation	Angle of repose (θ)	Bulk density (g/ml)	Tapped density(g/ml)	% compressibility	Hausner's ratio
F1	27.30±0.03	0.35±0.007	0.41±0.12	14.60±0.01	1.14±0.001
F2	25.00±0.06	0.29±0.013	0.33±0.15	12.12±0.11	1.13±0.005
F3	28.70±0.04	0.30±0.006	0.34±0.03	11.76±0.07	1.13±0.003
F4	26.40±0.02	0.31±0.011	0.30±0.10	13.14±0.09	1.12±0.002
F5	25.34±0.05	0.33±0.005	0.40±0.06	11.34±0.03	1.18±0.004
F6	28.45±0.01	0.28±0.004	0.36±0.05	11.56±0.08	1.15±0.007

All values expressed as mean ± SD, (n=3)

Post compression parameters

Tablet 15 -Post Compression Parameters For Immediate Release Tablets

S.no	Hardness ± S.D. (KP)	Thickness ± S.D. (mm)	Friability (%)	Drug content (Lansoprazole) (%) n = 3	Drug content (Domperidone) (%) n = 3	Average weight variation (mg) n = 10	Disintegration time ± S.D. n = 3 (mins)
F1	6.8±1.5	6.2±0.05	0.6	97.5±0.85	98.5±0.25	1200±0.60	190secs
F2	6.7±1.4	6.9±0.01	0.5	98.6±0.72	98.7±0.46	1200±0.45	180 secs
F3	6.9±1.3	6.2±0.07	0.4	98.2±0.41	98.7±0.72	1200±0.10	200 secs
F4	6.5±1.2	6.3±0.03	0.5	96.3±0.32	98.4±0.45	1170±0.23	220 secs
F5	6.6±1.1	6.5±0.02	0.4	97.2±0.23	98.2±0.34	1230±0.56	180 secs
F6	6.9±1.6	6.4±0.04	0.4	97.4±0.22	98.6±0.12	1200±0.41	180 secs

All values expressed as mean ± SD, (n=3)

***IN VITRO* DISSOLUTION STUDIES FOR IR TABLETS -**

***In-Vitro* Drug Release Studies for Lansoprazole & Domperidone (IR) buffer tablets**

RESULTS OF *IN-VITRO* RELEASE PROFILE OF LANSOPRAZOLE

Table 15. *In-Vitro* Release Profile of Lansoprazole from formulations F1-F6

Time (Min)	F1	F2	F3	F4	F5	F6
0	0	0	0	0	0	0
5	21.96±0.11	48.27±0.12	35.35±0.11	30.33±0.11	40.21±0.16	49.32±0.15
10	52.48±0.18	80.52±0.11	56.94±0.25	42.89±0.21	51.65±0.12	85.56±0.17
15	70.92±0.15	91.25±0.10	77.56±0.41	56.45±0.14	67.78±0.32	96.23±0.21
30	75.45±0.11	97.25±0.05	81.02±0.29	61.77±0.16	72.98±0.34	98.42±0.24

All values expressed as mean ± SD, (n=3)

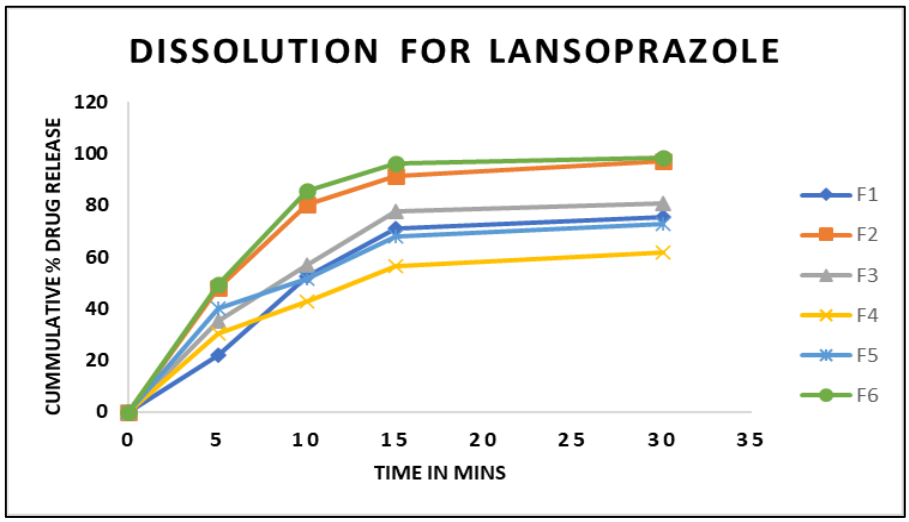

Fig 9 - Dissolution Graph For Lansoprazole Formulations

International Journal of Pharmacy and Pharmaceutical Research (IJPPR)
Volume 30, Issue 12, December 2024 ijppr.humanjournals.com ISSN: 2349-7203

***IN-VITRO* RELEASE PROFILE OF DOMPERIDONE**

Table.17 *In-vitro* release profile of Domperidone from formulations F1-F6

Time (mins)	F1	F2	F3	F4	F5	F6
0	0	0	0	0	0	0
5	37.91±0.15	41.25±0.24	34.32±0.12	33.41±0.32	39.43±0.23	48.52±0.14
10	51.42±0.18	68.22±0.10	66.57±0.21	43.34±015	57.45±0.28	78.22±0.11
15	62.51±0.12	85.87±0.12	75.21±0.18	51.45±0.34	76.25±0.17	92.78±0.21
30	76.46±0.10	95.87±0.07	76.12±0.04	65.23±0.12	77.34±0.23	97.87±0.41

All values expressed as mean ± SD, (n=3)

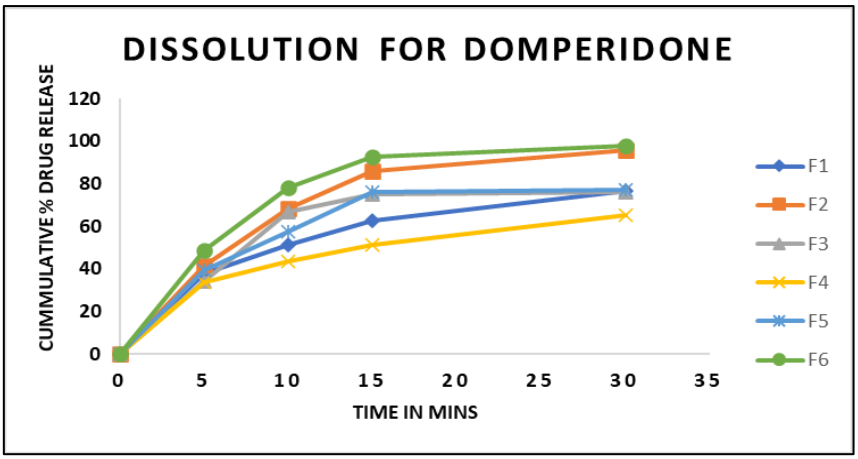

Fig 10. Dissolution Graph For Domperidone Formulations

STABILITY STUDIES:

Table.18 Stability studies of optimized formulation post compression parameters (F6)

S. no	Parameters	Initial	Optimized parameters								
			25±2°C,60±5%RH			30±2°C,65±5°C%RH			40±2°C,75±5%RH		
			1st Month	2nd Month	3rd Month	1st Month	2nd Month	3rd Month	1st Month	2nd Month	3rd Month
1	Average weight (mg)	1200	1200	1199	1198	1200	1200	1199	1200	1199	1200
2	Thickness (mm)	6.9	6.9	6.9	6.9	6.9	6.9	6.9	6.9	6.9	6.9
3	Hardness (Kp)	6.7	6.7	6.7	6.7	6.7	6.7	6.7	6.7	6.7	6.7
4	Friability	0.5	0.5	0.5	0.4	0.5	0.5	0.4	0.5	0.4	0.5
5	Disintegration time (sec)	32	32	30	32	32	29	30	32	31	32
6	Drug release in 30 mins	98.25	98.25	97.25	96.23	97.25	97.25	96.24	97.25	96.23	95.25

Table.19 Stability studies of optimized formulation cumulative % drug release Lansoprazole (F6)

S.no	Time in hrs	Initial	Cumulative % drug release (mean SD) (n=3)								
			25±2ºC,60±5%RH			30±2ºC,65±5ºC%RH			40±2ºC,75±5%RH		
			1st Month	2nd Month	3rd Month	1st Month	2nd Month	3rd Month	1st Month	2nd Month	3rd Month
1	0.5	34.25	34.25	34.24	34.23	34.25	34.25	34.24	34.25	34.24	34.22
2	1	48.21	48.21	48.20	48.19	48.21	48.19	48.20	48.21	48.20	48.20
3	2	52.10	52.10	52.10	52.09	52.10	52.09	52.08	52.10	52.08	52.07
4	3	60.45	60.45	60.44	60.43	60.45	60.45	60.44	60.45	60.42	60.44
5	4	65.61	65.61	65.60	65.59	65.61	65.60	65.60	65.61	65.61	65.60
6	6	71.87	71.87	71.86	71.85	71.87	71.83	71.81	71.87	71.86	71.86
7	8	98.42	98.42	98.42	98.41	98.42	98.42	98.41	98.42	98.41	98.40
8	10	91.23	91.23	91.23	91.21	91.23	91.22	91.21	91.23	91.22	91.21
9	12	97.87	97.87	97.86	97.85	97.87	97.87	97.85	97.87	97.85	97.84

Table.20 Stability studies of optimized formulation cumulative % drug release Domperidone (F6)

S.no	Time in hrs	Initial	Cumulative % drug release (mean SD) (n=3)								
			25±2ºC,60±5%RH			30±2ºC,65±5ºC%RH			40±2ºC,75±5%RH		
			1st Month	2nd Month	3rd Month	1st Month	2nd Month	3rd Month	1st Month	2nd Month	3rd Month
1	0.5	34.25	34.25	34.24	34.23	34.25	34.25	34.24	34.25	34.24	34.22
2	1	48.21	48.21	48.20	48.19	48.21	48.19	48.20	48.21	48.20	48.20
3	2	52.10	52.10	52.10	52.09	52.10	52.09	52.08	52.10	52.08	52.07
4	3	60.45	60.45	60.44	60.43	60.45	60.45	60.44	60.45	60.42	60.44
5	4	65.61	65.61	65.60	65.59	65.61	65.60	65.60	65.61	65.61	65.60
6	6	71.87	71.87	71.86	71.85	71.87	71.83	71.81	71.87	71.86	71.86
7	8	82.40	82.40	82.40	82.40	82.40	82.39	82.39	82.40	82.40	82.39
8	10	91.23	91.23	91.23	91.21	91.23	91.22	91.21	91.23	91.22	91.21
9	12	99.87	99.87	99.86	99.85	99.87	99.87	99.85	99.87	99.85	99.84

CONCLUSION

The aim of the study was to develop and analyse a buffer formulation for lansoprazole and domperidone. Preformulation studies showed were performed. Absorption maxima was 260 nm for lansoprazole and 207 nm for domperidone. FTIR studies confirming no interaction between the drugs and excipients. Upon optimization, the F6 formulation of lansoprazole and domperidone demonstrated acceptable physical characteristics, including weight variation of 1200, thickness of 6.9 mm, hardness of 6.7 kg/cm², friability of less than 0.5%, and a disintegration time of 180 seconds. The drug content was determined to be 99.5%. The drug release rates were found to be 98.4% for lansoprazole and 99.84% for domperidone in 30 minutes, indicating good content uniformity. The dissolution study of the optimized formulation revealed better dissolution rates compared to formulations without SLS. The formulation demonstrated good stability, with all values falling within acceptable ranges. Consequently, it was concluded that the buffer tablets containing lansoprazole and domperidone are suitable for generating stable, immediate-release dosage forms.

REFERENCES

1. Aulton EM, Pharmaceutics: The Science of Dosage Form Design: Principles of dosage form. 2nd edition; pg. 1.
2. Allen LV, Popovich NG, Ansel CH (2011): Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems. 9th ed, pg. 185.
3. Al-Achi A (2019) Tablets: A Brief Overview. Journal of Pharm Practice and Pharmaceutical Science. 2019(1): 49-52.
4. Nagashree K. Solid dosage forms: Tablets. Research and Reviews: Journal of Pharmaceutical Analysis. 2015.
5. Kohn and T. F. Dunlap Calculation of the Buffering Capacity of Bicarbonate in the Rumen and In Vitro R. A. J. Anim. Sci. 1998. 76:1702–1709.
6. Principles of Anatomy and Physiology / Edition 15 by Gerard J. Tortora, Bryan H. Derrickson pg. no 645.
7. Talia F. Malik; Karthik Gnanapandithan; Kevin Singh Peptic Ulcer Disease Stat Pearls June 5, 2023.
8. Narayanan M, Reddy KM, Marsicano E. Peptic Ulcer Disease and Helicobacter pylori infection. Mo Med. 2018 May-Jun;115(3):219-224. [PMC free article] [PubMed]

9. Lanas Á, Carrera-Lasfuentes P, Arguedas Y, García S, Bujanda L, Calvet X, Ponce J, Perez-Aísa Á, Castro M, Muñoz M, Sostres C, García-Rodríguez LA. Risk of upper and lower gastrointestinal bleeding in patients taking nonsteroidal anti-inflammatory drugs, antiplatelet agents, or anticoagulants. Clin Gastroenterol Hepatol. 2015 May;13(5):906-12.e2. [PubMed]
10. Huang JQ, Sridhar S, Hunt RH. Role of Helicobacter pylori infection and non-steroidal anti-inflammatory drugs in peptic-ulcer disease: a meta-analysis. Lancet. 2002 Jan 05;359(9300):14-22. [PubMed]
11. Fass R, Frazier R. The role of dexlansoprazole modified-release in the management of gastroesophageal reflux disease. Therap Adv Gastroenterol. 2017 Feb;10(2):243-251. [PMC free article] [PubMed]
12. El-Serag HB, Sweet S, Winchester CC, Dent J. Update on the epidemiology of gastro-oesophageal reflux disease: a systematic review. Gut. 2014 Jun;63(6):871-80. [PMC free article] [PubMed]
13. Hom C, Vaezi MF. Extraoesophageal manifestations of gastroesophageal reflux disease. Gastroenterol Clin North Am. 2013 Mar;42(1):71-91. [PubMed]
14. Ahmed SS, Gupta RC, Brancato RR. Significance of nausea and vomiting during acute myocardial infarction. Am Heart J. 1978;95:671–72. [PubMed]
15. Barnes JH. The physiology and pharmacology of emesis. Molecular Aspects of Medicine. 1984;7:397–508. [PubMed]
16. Feldman M. Nausea and vomiting. In: Sleisenger MH, Fordtran JS, eds. Gastrointestinal disease. Philadelphia: W. B. Saunders, 1983;160–77.
17. Gibbs D. Nausea and vomiting. Br Med J. 1976;2:1489–92. [PMC free article] [PubMed]
18. Malagelada J-R, Camilleri M. Unexplained vomiting: a diagnostic challenge. Ann Intern Med. 1984;101:211–18. [PubMed]
19. Stoudemire A, Cotanch P, Laszlo J. Recent advances in the pharmacologic and behavioral management of chemotherapy-induced emesis. Arch Intern Med. 1984;144:1029–33. [PubMed]
20. Swanson DW, Swenson WM, Huizenga KA. et al. Persistant nausea without organic cause. Mayo Clin Proc. 1976;51:257–62. [PubMed]
21. Sanjesh Kumar Gotam Rathi, Dhaval J. Patel, Shrenik K. Shah and Bhagyashree Y. Joshi Formulation and Evaluation of Lansoprazole and Domperidone Mouth Dissolving Tablets IJPSR, 2020; Vol. 11(12): 6402-6412.
22. Subhash Chandra Bose PENJURI, et.al Formulation and Evaluation of Lansoprazole Loaded Nano sponges December 2016Turkish Journal of Pharmaceutical Sciences 13(3):304-310.
23. Fabio Baldi, Peter Malfertheiner, Lansoprazole fast disintegrating tablet: a new formulation for an established proton pump inhibitor "Digestion"[jour] 2003 67(1-2):1-5.
24. Alsu lays BB, et. al, Preparation and evaluation of enteric coated tablets of hot-melt extruded lansoprazole Drug Dev Ind Pharm. 2017 May;43(5):789-796. Epub 2016 Aug 21.
25. Prasanthi D, Prashanti S., Meghana G, Formulation And Evaluation Of Press Coated Tablets Of Lansoprazole, Int J App Pharm, Vol 11, Issue 4, 2019, 49-56.
26. Sumio Chono, Megumi Matsui, Katsuki Nakamura, and Ryoya Kasai, Ingestibility and Formulation Quality of Lansoprazole Orally Disintegrating Tablets, Journal of Pharmaceutics Volume 2016.
27. Geeta P. Darekar et al., Formulation, Development and Evaluation of Oro dispersible Tablets of Lansoprazole Asian Journal of Pharmaceutical Technology & Innovation, 04 (16); 2016; 31 – 38.
28. Ravi Subhashini, and D. Ramesh Reddy, Formulation And Evaluation Of Domperidone Fast Dissolving Tablets Using Plantago Ovata Mucilage, IJPSR, 2013; Vol. 4(9): 3489-3493.
29. Shailesh Prajapati, et. al, Floating matrix tablets of domperidone formulation and optimization using simplex lattice, Iranian Journal of Pharmaceutical Research (2011), 10 (3): 447-455
30. S. T. Prajapati, L. D. Patel, and D. M. Patel Studies on Formulation and In Vitro Evaluation of Floating Matrix Tablets of Domperidone Indian J Pharm Sci. 2009 Jan-Feb; 71(1): 19–23.
31. S. Patra, R. Sahoo, R. K. Panda, K. Himasankar, and B. B. Barik, In Vitro Evaluation of Domperidone Mouth Dissolving Tablets, Indian J Pharm Sci, 2010 Nov-Dec; 72(6): 822–825.
32. Wasim Khan, Noor Fatima Siddique, Javed Siddiqui, Dr. Zeeshan Hussain, Sana Farooqui, Formulation and Evaluation of Domperidone Sustained Release Tablet, Research J. Pharm. And Tech. 11(12): December 2018.
33. Ashiqul Islam, Syed Shabbir Haider and Md. Selim Reza, Formulation and Evaluation of Oro dispersible Tablet of Domperidone, Dhaka Univ. J. Pharm. Sci. 10(2): 117-122, 2011 December.
34. Sajan Maharjan, Rupesh Tiwari, Kripa Regmi, Sarbani Neupane, Formulation and Evaluation of Domperidone Lozenges, Asian Journal of Pharmacy and Technology, Volume - 14, Issue - 1, Year – 2024.
35. Lee, S.-H.; Kim, J.-E. Quality by Design Applied Development of Immediate-Release Rabeprazole Sodium Dry-Coated Tablet. Pharmaceutics 2021, 13, 259.
36. Colin W. Howden, 2006, Immediate-Release Omeprazole/Sodium Bicarbonate Gastroenterology & Hepatology Volume 2, Issue 5 May 2006.
37. Shailendra Kumar Singh, et.al, Fast Disintegrating Combination Tablets of Omeprazole and Domperidone Asian Journal of Pharmaceutical and Clinical Research Vol.2 Issue 3, July-September 2009.
38. Kumari M, Jain NP, Formulation Development & Evaluation of Buffered Tablet of Proton Pump Inhibitors Drug Rabeprazole Sodium , Journal of Drug Delivery and Therapeutics. 2019; 9(4-s):315-321.

39. Darshna Mishra, Tripti Shukla, Neha Jain, Neeraj Upamanyu, 2016, Formulation, Development and Evaluation of an Immediate Release Buffer Tablet of Omeprazole, Pharma Science Monitor an International Journal of Pharmaceutical Sciences 7(2), Apr-Jun 2016, 270-281.
40. Parag das, debajyoti das, 2014, Formulation, Development and Evaluation of buffer esomeprazole tablet in tablet preparation International Journal of Pharmaceutics and Drug Research 2014; 1(2): 7-35.
41. XIAMEN ENCHENG 2014 Method for producing omeprazole sodium bicarbonate capsule CN103860584A.
42. 3Camillo Benetti, et.al, Esomeprazole immediate release tablets: Gastric mucosa ex vivo permeation, absorption and antisecretory activity in conscious rats, Journal of Controlled Release 239 (2016) 203–210.
43. Mukesh P. Ratnaparkhi, Pravin S. Pongale and Shilpa P. Chaudhari, 2013, Formulation & Evaluation of Buffered Pantoprazole Sodium Tablet, International Journal of Pharmaceutical Sciences and Research 4708, 2013; Vol. 4(12): 4708-4714.
44. Francis Moore, Geoffrey Okelo, Ivelisse Colón, Joseph Kushner IV, 2010, Improving the hardness of dry granulated tablets containing sodium lauryl sulphate, International Journal of Pharmaceutics 400 (2010) 37–41.

How to cite this article:
Rizwana Fatima. Ijppr.Human, 2024; Vol. 30 (12): 63-79

Conflict of Interest Statement: All authors have nothing else to disclose.

This is an open access article under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited, the use is non-commercial and no modifications or adaptations are made.