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DEVELOPMENT AND INVITRO CHARACTERISATION OF PANTAPROZOLE SODIUM TABLETS BY USING NATURAL DISINTEGRANTS

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Abstract:

The present study was aimed at the formulation and evaluation of Pantoprazole sodium tablets using natural polymers such as Tragacanth and Guar gum by the direct compression method. Pantoprazole sodium is a proton pump inhibitor widely used in the treatment of gastric and duodenal ulcers, gastroesophageal reflux disease, and other acid-related disorders. The objective of the study was to develop a stable tablet formulation with satisfactory physicochemical characteristics and drug release profile.Preformulation studies including organoleptic evaluation, melting point determination, solubility studies, calibration curve preparation, and FTIR compatibility studies were carried out. Pantoprazole sodium was found to be compatible with the selected excipients, as confirmed by FTIR analysis. The powder blends were evaluated for bulk density, tapped density, compressibility index, Hausner ratio, and angle of repose, and all formulations exhibited satisfactory flow properties suitable for direct compression.Four formulations (F1–F4) were prepared using varying concentrations of Tragacanth and Guar gum. The prepared tablets were evaluated for weight variation, thickness, hardness, friability, drug content, disintegration time, and in vitro drug release. All formulations complied with pharmacopoeial specifications. The cumulative drug release after 8 hours ranged from 93.22% to 98.12%. Among the formulations, F4 showed the highest drug release of 98.12% and was selected as the optimized formulation.The optimized formulation was subjected to accelerated stability studies at different storage conditions for a period of 90 days. The formulation remained stable without any significant changes in physical appearance or drug release profile.The study concluded that Pantoprazole sodium tablets prepared using Tragacanth and Guar gum exhibited satisfactory physicochemical properties, good drug release characteristics, and acceptable stability. The optimized formulation may serve as a promising oral dosage form for effective drug delivery.

Keywords: *Pantoprazole Sodium, Direct Compression, , FTIR, Dissolution Study, Stability Studies.*

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INTRODUCTION:

Oral drug delivery remains the most preferred and widely accepted route of administration due to its convenience, safety, cost-effectiveness, and high patient compliance. Among oral dosage forms, tablets are the most commonly used because of their stability, ease of manufacturing, accurate dosing, and suitability for large-scale production. However, conventional immediate-release tablets often require frequent dosing to maintain therapeutic drug levels, which can lead to fluctuations in plasma drug concentration, reduced patient adherence, and increased incidence of side effects.

A solid dosage form is a delivery system that includes tablets, capsules, sachets and bulk or unit dosage powders and granules. The most commonly used pharmaceutical solid dosage forms today include granules, pellets, tablets and capsules. A simplified flow-chart of the relationship of pharmaceutical dosage forms. These dosage forms are designed either for improving the physical and mechanical properties of materials during manufacture and/or for providing a desired drug delivery system. The tablets and capsules can be made directly from powders or from granules and pellets, or from film-coated multiple units.

Oral dosage form is the most popular route for drug therapy and over 80% of the drugs formulated to produce systemic effects are produced as oral dosage forms. The tablet dosage form accounts for approximately 50% of all dosage forms on the market. Tablets and capsules are currently accounted for the highest proportion of all drug dosage forms. Tablets are defined by the European Pharmacopeia 2001, as "solid preparations each containing a single dose of one or more active substances and usually obtained by compressing uniform volumes of particles. Tablets are intended for oral administration. Some are swallowed whole, some after being chewed, some are dissolved or dispersed in water before being administered and some are retained in the mouth where the active substance is liberated". When a new drug is discovered the pharmaceutical company makes all possible efforts to ensure that the drug can be so formulated that it is competent of being administered orally.

MATERIALS:

Pantaprozole sodium was procured from Synpharma Research Labs, Hyd, Guargum, Tragacanth ,Magnesium stearate, Talc and Micro crystalline cellulose were obtained from Synpharma Research Labs, Hyderabad. Other chemicals and the reagents used were of analytical grade.

METHODOLOGY:

Drug and excipient compatibility studies

Drug–excipient compatibility studies were carried out using Fourier Transform Infrared (FTIR) spectroscopy to investigate any possible interaction between Pantoprazole sodium and the excipients used in the formulation. The FTIR spectra of the pure drug and the physical mixture of drug and excipients were recorded over the range of 4000–400 cm^{-1}. The obtained spectra were compared for any significant changes in the characteristic peaks of Pantoprazole sodium. The absence of major shifts, disappearance, or appearance of new peaks indicated the compatibility of the drug with the selected excipients and confirmed the stability of the formulation components.

Pre compression parameters

Bulk density

Bulk density, also known as apparent density, is the ratio of the mass of a powder sample to its volume, including the volume of the spaces between the particles. It's a measure of the powder's apparent density, or how it appears in a large volume.

D = M / V,

where:

D: Bulk density (g/l) M: Weight of the full container (g) V: Container volume

Tapped density

The tapped density is an increased bulk density attained after mechanically tapping a container containing the powder sample. The tapped density is obtained by mechanically tapping a graduated measuring cylinder or vessel containing the powder sample.

Tapped density= m/Vf

Which

M= Mass

Vf is the final tapped volume.

Hausner Ratio

Hausner ratio = Hausner ratio was related to inter-particle friction: Tapped density Poured or bulk density

Angle of repose

The sample is poured onto the horizontal surface and the angle of the resulting pyramid is measured.

The user normally selects the funnel orifice through which the powder flows slowly and reasonably constantly.

Angle of repose=Tan ø=h/r Ø=tan-1 (h/r)

Carr's compressibility index

A volume of powder is filled into a graduated glass cylinder and repeatedly tapped for a known duration. The volume of powder after tapping is measure.

Carr's index (%) = $100\left(\frac{Tappeddensity-Bulkdensity}{Tappeddensity}\right)$

Formulation Table

Table-1: Preparation Of Pantoprazole Tablets

Ingredients(mg)	F1	F2	F3	F4
Pantoprazole sodium	40	40	40	40
Tragacanth	10	20	30	40
Guargum	10	20	30	40
Microcrystalline cellulose	135	115	95	75
Talc	2	2	2	2
Magnesium Stearate	3	3	3	3
Total wt	200	200	200	200

Preparation of tablets by direct compression method:

Different matrix embedded formulations of Pantoprazole were prepared by direct compression method using varying proportion of polymers. The ingredients were passed through a 60 mesh sieve. Calculated amount of the drug and various natural polymers and filler (MCC) was mixed thoroughly. Magnesium stearate was added as lubricant, the appropriate amount of the mixture was weighed and then compressed using a 8 station rotary press at a constant compression force equipped with a 8-mm flat-faced punches at a compression force required to produce tablets of about 2.5–5 kg/cm^2 hardness. All the tablets were stored in airtight containers for further study. Prior to compression, the powder blend was evaluated for flow and compressibility properties.

Evaluation studies

Thickness

The thickness of tablets was measured using a Vernier caliper. Three tablets from each formulation were selected randomly, and the average thickness was calculated. Tablet thickness was maintained within ±5% of the standard value.

Hardness

Tablet requires a certain amount of strength or hardness and resistance to friability to withstand mechanical shakes of handling in manufacture, packaging and shipping. Hardness generally measures the tablet crushing strength.

Friability

Friability of a tablet can determine in laboratory by Roche friabilator. This consist of a plastic chamber that revolves at 25 rpm, dropping the tablets through a Distance of six inches in the friabilator, which is then operate for 100 revolutions. The tablets are reweighed. Compress tablet that lose less than 0.5 to 1.0 % of the Tablet weigh are consider acceptable.

Weight Variation test (U.S.P.)

Take 20 tablet and weighed individually. Calculate average weight and compare the individual tablet weight to the average. The tablet pass the U.S.P. test if no more that 2 tablets are outside the percentage limit and if no tablet differs by more than 2 times the percentage limit.

Content Uniformity Test

Randomly select 30 tablets. 10 of these assayed individually. The Tablet pass the test if 9 of the 10 tablets must contain not less than 85% and not more than 115% of the labeled drug content and the 10th tablet may not contain less than 75% and more than 125% of the labeled content. If these conditions are not met, remaining 20 tablet assayed individually and none may fall outside of the 85 to 115% range.

Disintegration Test (U.S.P.)

The disintegration test was performed using a USP disintegration test apparatus. Six tablets were placed individually in the six tubes of the basket rack assembly, and a perforated disc was placed over each tablet. The basket rack assembly was suspended in a 1000 mL beaker containing distilled water maintained at 37 ± 0.5°C. The apparatus was operated at a frequency of 28–32 cycles per minute. The time required for complete disintegration of each tablet, with no palpable mass remaining on the screen, was recorded as the disintegration time. The test was considered satisfactory when all tablets disintegrated completely within the specified pharmacopoeial limits.

Dissolution Test (U.S.P.)

The in vitro dissolution study of Pantoprazole tablets was carried out using USP Dissolution Apparatus II (Paddle Method). The dissolution medium consisted of 900 mL of pH 6.8 phosphate buffer maintained at 37 ± 0.5°C. The paddle was rotated at 50 rpm. At predetermined time intervals, 5 mL samples were

withdrawn and replaced with an equal volume of fresh dissolution medium maintained at the same temperature to maintain sink conditions. The withdrawn samples were filtered, suitably diluted, and analyzed using a UV-visible spectrophotometer at 289 nm. The cumulative percentage drug release was calculated and plotted against time.

Stability studies:

The optimized formulation of Pantoprazole tablets was subjected to accelerated stability studies as per ICH guidelines. The tablets were packed in aluminum foil and stored in a stability chamber maintained at 40 ± 2°C and 75 ± 5% RH for a period of 3 months. Samples were withdrawn at intervals of 0, 1, 2, and 3 months and evaluated for physical appearance, drug content, and in vitro drug release. The results obtained were compared with the initial values to assess the stability of the formulation.

RESULTS & DISCUSSIONS:

Fourier Transformation Infra-red (FTIR) analysis

Fourier Transformation Infra-red Spectrophotometer Alpha Brooker FTIR (Tokyo, Japan) was used for Infra-red spectroscopy analysis.

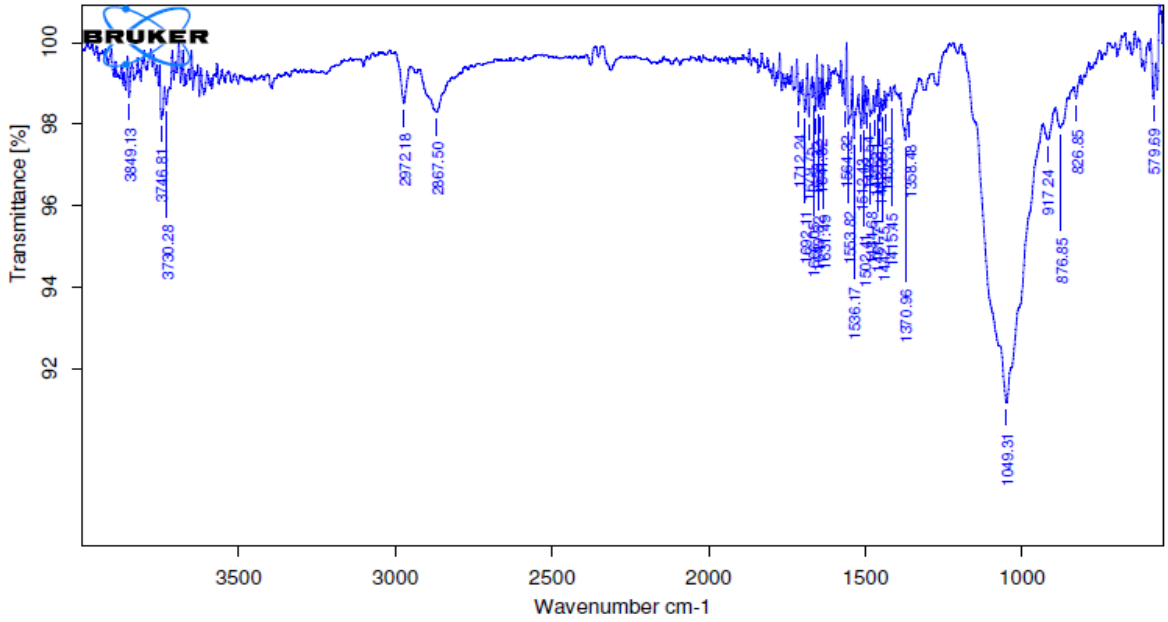


Fig-1: FTIR Studies of Pantoprazole

Table-2: Characteristic Peaks for Pantoprazole

S.No.	Characteristic Peaks	Frequency range (cm-1)	Frequency (cm-1)
1	OH stretching	3500-3000	2972.18
2	OH Bending	1000-1500	1049.31
3	C-H stretching	3000-2500	2867.50
4	C=O stretching	2000-1500	1692.11

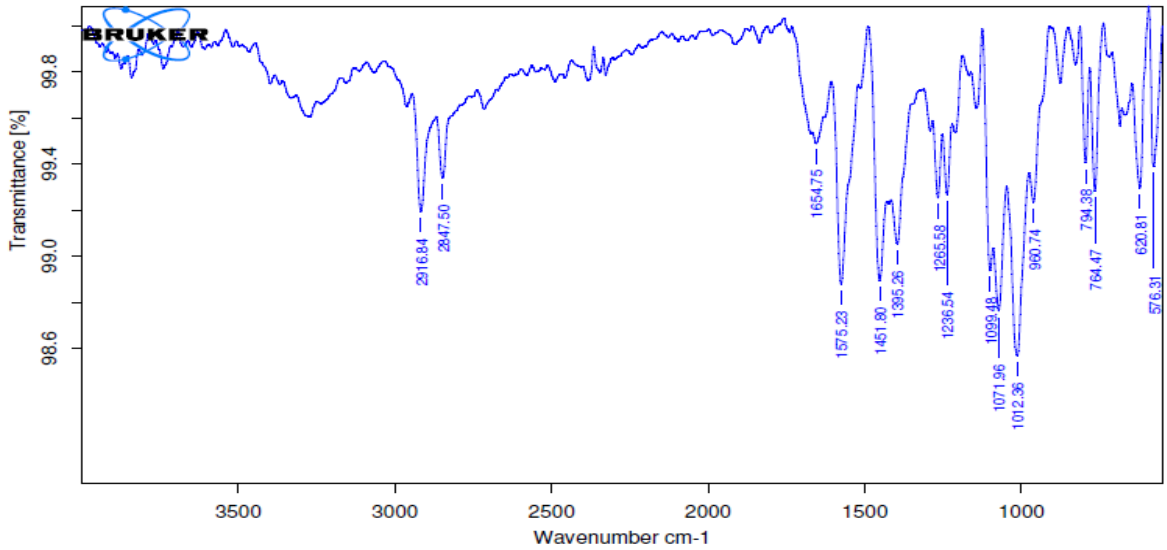


Fig-2: FTIR Studies of Physical mixture of drug and excipients

Table-3: Characteristic Peaks for drug and excipients

S.No.	Characteristic Peaks	Frequency range (cm-1)	Frequency (cm-1)
1	OH stretching	3500-3000	2916.84
2	OH Bending	1000-1500	1071.96
3	C-H stretching	3000-2500	2647.50
4	C=O stretching	2000-1500	1572.23

In the present investigation, no chemical interaction between Pantoprazole sodium and the selected polymers was observed. The characteristic peaks of the pure drug were retained in the physical mixture, indicating compatibility of the drug with the excipients.

EVALUATION STUDIES

Pre compression Parameters

Bulk Density and Tapped Density:

Bulk density values ranged from 0.605 to 0.619 g/mL, while tapped density ranged from 0.709 to 0.719 g/mL across all formulations.

The small difference between bulk and tapped densities indicates good packing and minimal interparticle voids, suggesting a homogeneous powder blend suitable for compression.

Compressibility Index (Carr's Index):

Values ranged from 13.22% to 14.78%, which falls within the range of 10–15%, indicating good flow properties.Lower compressibility index indicates that the powder will flow easily, reducing the risk of weight variation in tablets.

Hausner Ratio:

The Hausner ratio ranged from 1.15 to 1.17, which is below 1.25, indicating good to fair flowability.A Hausner ratio closer to 1.0 signifies excellent flow, and values below 1.25 are generally acceptable for direct compression.

Angle of Repose:

The angle of repose varied from 28° to 31° (except one value possibly mistyped as "28 0"), indicating excellent to good flow.An angle of repose <30° is considered excellent, while 30–40° indicates good flow properties suitable for tablet compression.

Table-4: Pre compression Parameters

S. no	Bulk density	Tapped density	Compressibility index	Hausner ratio	Angle of repose(0)
F1	0.617	0.711	13.22	1.15	28^0
F2	0.615	0.719	14.46	1.16	31^0
F3	0.612	0.716	14.52	1.16	29^0
F4	0.609	0.709	14.1	1.16	27^0

Post compression parameters

Weight Variation:
The weight of tablets ranged from 199 to 202 mg, which is very close to the theoretical weight of 200 mg. This indicates that the tablets are uniform in weight, reflecting good flow and compressibility of the powder blends, and ensuring consistent drug dosing.

Thickness:
Thickness of all formulations ranged from 1.3 to 1.7 mm, indicating uniform die filling and compression.

Hardness:
Hardness values ranged from 3.1 to 3.8 kg/cm², which is within the acceptable range for immediate-release tablets. Adequate hardness ensures mechanical stability during handling and packaging, but is not too high to delay disintegration.

Friability:
Friability values were between 0.22% and 0.31%, well below the 1% limit set by pharmacopoeial standards. This indicates that the tablets are mechanically strong and resistant to abrasion, suitable for transport and storage.

Drug Content (%):
Drug content ranged from 89.33% to 94.28%, indicating acceptable uniformity. Slight variations may be due to mixing efficiency or the presence of different concentrations of polymers. All values are within the pharmacopoeial limit of 85–115%, confirming content uniformity.

Disintegration Time: The disintegration time of all formulations ranged from 12 to 14 minutes, indicating acceptable disintegration characteristics.

Table-5: Evaluation parameters of Tablets

F. No.	Weight variation (mg)	Thickness (mm)	Hardness (kg/cm^2)	Friability (%)	Drug Content (%)	Disintegration time(min)
F1	199	1.4	3.6	0.29	92.46	13
F2	202	1.7	3.7	0.31	93.47	13
F3	201	1.5	3.5	0.31	90.85	14
F4	200	1.3	3.2	0.30	94.28	12

In-vitro Dissolution Study

All the four formulations (F1–F4) of Pantoprazole sodium tablets were subjected to in vitro dissolution studies using USP Dissolution Apparatus II. The dissolution medium consisted of 900 mL of pH 6.8 phosphate buffer maintained at 37 ± 0.5°C.

Table-6: Dissolution Profile of F1 to F4

Time (hrs.)	F1	F2	F3	F4
0	0	0	0	0
1	24.59	25.19	26.93	28.30
2	31.22	32.56	33.22	32.42
3	35.65	42.39	43.59	41.18
4	55.98	56.39	52.36	50.90
5	66.49	65.81	65.24	63.82
6	75.82	76.83	75.66	73.86
7	84.69	85.10	83.65	84.82
8	94.56	93.22	97.81	98.12

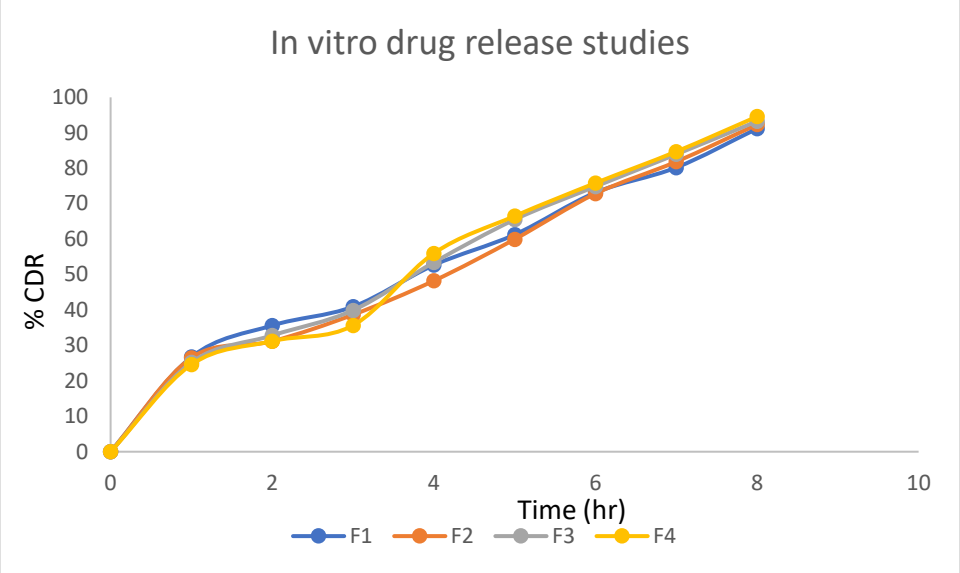


Fig-3: In vitro drug release studies of F1-F4 formulations

Among all formulations, F4 showed the highest cumulative drug release of 98.12% at the end of 8 hours and was selected as the optimized formulation.

Stability studies

Tablets formulated in the present study were subjected to accelerated stability studies. Stability studies were performed at 25°C/60% RH, 30°C/75% RH and 40°C/75% RH for a period of 90 days.

Table-7: Results of stability studies of optimized formulation F-4

F. Code	Parameters	Initial	1st Month	2nd Month	3rd Month	Limits as per Specifications
F-4	25^{0}C/60%RH % Release	98.12	97.86	96.17	96.55	Not less than 85 %
F-4	30^{0}C/75% RH % Release	98.12	97.52	96.18	96.28	Not less than 85 %
F-4	40^{0}C/75% RH % Release	98.12	97.16	96.33	96.20	Not less than 85 %

SUMMARY AND CONCLUSION:

Summary

The present study was undertaken to formulate and evaluate Pantoprazole sodium tablets using natural polymers such as Tragacanth and Guar gum by direct compression method. Preformulation studies including organoleptic evaluation, melting point determination, solubility studies, calibration curve preparation, and FTIR compatibility studies were carried out. The drug was found to be a white to off-white crystalline powder with a melting point range of 139–145°C and exhibited good solubility in water, methanol, and ethanol. The calibration curve of Pantoprazole sodium obeyed Beer-Lambert's law with an R^2 value of 0.997. FTIR studies confirmed the compatibility of the drug with the selected excipients.

The prepared powder blends were evaluated for pre-compression parameters such as bulk density, tapped density, compressibility index, Hausner ratio, and angle of repose. The results indicated satisfactory flow properties suitable for direct compression.The compressed tablets were evaluated for post-compression parameters including weight variation, thickness, hardness, friability, drug content, and disintegration time. All formulations complied with pharmacopoeial specifications. In vitro dissolution studies demonstrated satisfactory drug release from all formulations. Among the formulations, F4 exhibited the highest cumulative drug release of 98.12% at the end of 8 hours.The optimized formulation (F4) was subjected to accelerated stability studies for a period of 90 days at different storage conditions. The formulation

remained stable throughout the study period without significant changes in drug release characteristics.

CONCLUSION:

Pantoprazole sodium tablets were successfully formulated by the direct compression method using natural polymers such as Tragacanth and Guar gum. The pre-compression and post-compression evaluation parameters indicated that all formulations possessed acceptable flow properties, mechanical strength, content uniformity, and disintegration characteristics.FTIR studies confirmed the absence of any significant interaction between Pantoprazole sodium and the selected excipients. In vitro dissolution studies revealed that formulation F4 showed the highest cumulative drug release (98.12%) at the end of 8 hours and was identified as the optimized formulation.Stability studies demonstrated that the optimized formulation remained stable under accelerated storage conditions for 90 days without significant changes in drug release behavior. Therefore, the developed Pantoprazole sodium tablet formulation can be considered stable, effective, and suitable for oral drug delivery.

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