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FORMULATION AND ASSESSMENT OF TRANDOLAPRIL TABLETS FOR IMMEDIATE RELEASE USING VARIOUS SUPER DISINTEGRATING AGENTS

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ABSTRACT

Recent developments in research are more focused on oral, innovative, site-specific controlled drug delivery technologies with the objective of minimizing drug wastage and preventing off-target adverse effects. These technologies are used to maintain control of active pharmacological agents in predetermined locations of action. Even pre-modulated release kinetics of controlled-release formulations do not guarantee sufficient absorption of drugs in human subjects due to physiological parameters like gastrointestinal transit and gastric residence time (GRT) of dosage administration. The absorptive limitation mentioned above can be overcome through the gastro-retentive technology; this is the (GRDDS), which prolongs time of presence of pharmaceuticals in the gastrointestinal tract of the host by making the formulation to be buoyant in gastric fluid due to its low bulk density as compared to gastric medium. To extend period of gastric residence, the current study designed & evaluated floating pills comprising of trandolapril &acebutol hydrochloride, respectively, with assistance of both natural & synthetic polymeric excipients.

KEYWORDS: Method Validation, Pharmaceutical Analysis, Stability Study.

INTRODUCTION

The primary sites of drug absorption in humans are stomach & proximal portion of small intestine; however, gastric emptying time is relatively short, about two to three hours; this short time can result in reduced drug release from traditional drug delivery systems, leading to suboptimal drug efficacy; therefore, controlling the location of (DDS) in a localized area

within GI tract would be advantageous for drugs that exhibit instability in the GI tract or have a narrow absorption window; Many efficient medication delivery methods, including oral, topical, nasal, rectal, vaginal, and ophthalmic routes, have been developed within the last 10 years [1]. increased contact between the DDS and the absorptive mucosa will improve drug absorption and therefore novel drug delivery systems exhibiting oral controlled-release properties and gastro-retentive characteristics can be formulated; drugs with primarily local pharmacological activity or are rapidly absorbed need a longer gastric residence time in the stomach to optimize the pharmacologic effectiveness of the medication; unfortunately, providing such an extended gastric residence time is extremely difficult to accomplish using traditional drug delivery systems; the majority of these traditional formulations necessitate multiple doses to both obtain and maintain therapeutic plasma drug concentrations; developing oral Developing efficient oral controlled-release drug delivery devices is therefore a major technological challenge. Sustained-release or controlled-release drug delivery systems that can maintain effective systemic drug concentrations for prolonged periods of time and deliver the drug slowly into the GI tract is an extraordinary complex and challenging task; Because only the portion of the dose released during or just prior to the absorption window is efficiently absorbed, When a medication exhibits a specific absorption window at a certain GI tract region, (CRDDS) are particularly useful; The medication released from the CRDDS may not be absorbed well or may be completely eliminated if the drug administration is postponed beyond the absorption window, which would lower the medication's therapeutic efficacy; A type of CRDDS called a (GRDDS) is designed to remain in stomach for an extended period of time. This duration boosts the medicine's bioavailability by enabling the drug to be released at the proper location in GI tract just prior to the absorption window.[6].

MATERIALS AND METHODS

MATERIALS

A pH 1.2 hydrochloric acid buffer solution was prepared by dissolving 2.0 g of sodium chloride in a small quantity of purified water, followed by the addition of 70 mL of concentrated hydrochloric acid. The resulting solution was transferred into a 1000 mL volumetric flask and the volume was made up to the mark with distilled water. The pH of the prepared buffer was adjusted and maintained at 1.2.For the determination of the maximum absorption wavelength (λmax), a standard solution of Acebutolol Hydrochloride was prepared using the pH 1.2 hydrochloric acid buffer as the solvent. The solution was scanned

in the ultraviolet region between 200 and 400 nm using a UV–Visible spectrophotometer. The wavelength corresponding to the maximum absorbance was recorded as the λmax of Acebutolol Hydrochloride.

Methodology

Preparing a pH 12 simulated gastric fluid (SGF):-

A tiny amount of purified water got employed to dissolve spherical 2Zero g of sodium chloride with 70 ml of powerful hydrochloric acid The combination get sooner or later multiplied up to a thousand cc with distilled water whose pH ought to be 12412 Calculating λ max for acebutolol hydrochloride in pH 12.

Simulated stomach fluid:

A a hundred ml volumetric flask changed into packed with precisely weighed one hundred mg of acebutolol hydrochloride, which modified into then dissolved in a hint amount of SGF pH 12 Next, it became prepared the usage of SGF pH 12 as much as one hundred ml SGF pH 12 have become used to dilute 10 ml of this approach to one hundred ml in a volumetric flask One millilitre changed into taken out of this answer, constructed up to ten millilitres with SGF pH 12, and scanned within the two hundred–4 hundred nm variety the usage of a UV spectrophotometer and SGF pH 12 as a easy The obtained spectra confirmed that 234 nm changed into the λ max for acebutolol hydrochloride in SGF pH 12.

Acebutolol hydrochloride in SGF pH 12 modern graph:

Acebutolol hydrochloride (one hundred mg) end up precisely weighed and taken to a a hundred ml volumetric flask. After that, a tiny amount of SGF pH 12 changed into introduced to dissolve it, and the quantity became expanded to a hundred milliliters This have become used to make as much as a hundred ml with SGF pH 12 after 10 ml have become taken out Using SGF pH 12 (2 to twenty µg/ml), zero2, zeroFour, zero6, 0Eight, 1, 12, 1Four, 16, 1Eight, and a couple of ml have been extracted from this answer and built up to 10 ml separately. Their absorbance were determined at λ max of 234nm using a UV spectro-photometer with SGF pH 12 as a clean Table 1 and Fig Display the drug's big graph with absorbance at 234 nm because the y-axis and attention (µg/ml) due to the fact the x-axis.

Preparation of Standard Solution

Dissolution of 10 mg Hydrochlorothiazide and 50 mg Metoprolol in 80 mL methanol was prepared as a standard solution. The volume was made up to 100 mL with methanol and sonicated for 10 minutes to ensure that all of the sample is dissolved. Thus, to prepare stock solutions in the concentration range of 2.5–25 µg mL−1 of Hydrochlorothiazide and 12.5–

125 µg mL−1 of Metoprolol, 10 mL of standard solution made up to 10 mL of the same solvent. Further after the prepared solutions were filtered through a 0.45 µm Millipore membrane filter to remove any particulate matter they were analysed [7, 8].

Sample Solution Preparation

Accurate weighing of twenty tablets comprising of Hydrochlorothiazide and Metoprolol, and finely grinding. A mobile phase (1 mL) was added into a 100 mL volumetric flask, in which 10 mg of Hydrochlorothiazide and 50 mg of Metoprolol were dissolved, then a quantity equivalent to 10 mg of Hydrochlorothiazide and 50 mg of Metoprolol was transferred to this sample. It was sonicated for complete dissolution of the powdered sample. The volume was made up to 100 mL by addition of mobile phase after dissolution. The resulting solution was filtered through a 0.45 µm membrane filter to remove any particulate, before being analyzed in for dichloromethane to calculate the amount of silicic acid based [9].

Table 1: Acebutolol hydrochloride fashionable curve at pH 12 in SGF

SNo	Concentration (µg/ml)	Absorbance at 234 nm
1	0	0
2	2	0081
3	4	0185
4	6	0269
5	8	0370
6	10	0440
7	12	0583
8	14	0621
9	16	0750
10	18	0863
11	20	0921

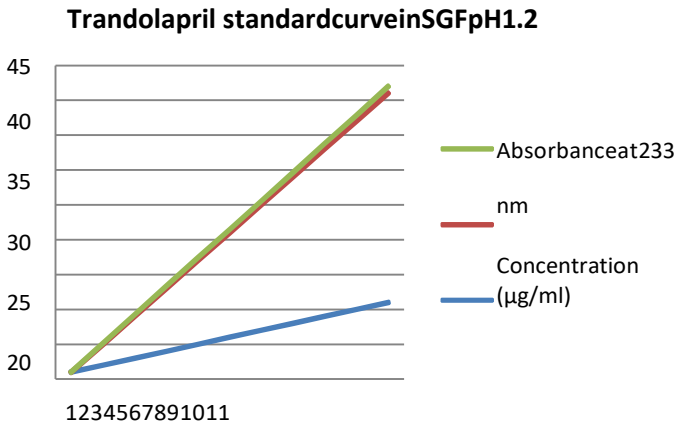
Trandolapril'sλmaxinsimulatedgastricfluidwithapHof12:

One hundred ml volumetric flasks have become packed with exactly 10 mg of Trandolapril,whichbecomethendissolvedinatouchamountofSGFpH12Afterthat, it changed into dissolved in 10 milliliters of methanol and brought to 100 milliliters ofSGF pH 12 Using SGF pH 12 as a easy, 1 ml have become taken out of this answer, constructed up to 10 ml, and scanned in thehundred–400 nm variety the use of a UV spectrophotometer. The λ max for Trandolapril in SGF pH 12 became decided to be 233 nm primarily based on the

measured spectra.

TrandolaprilmoderngraphinSGFpH12:

In a one hundred ml volumetric flask, 10 mg of Trandolapril became exactly weighed After dissolving it in 10 milliliters of methanol, SGF pH 12 turn out to be introduced to make up to a hundred milliliters Using SGF pH 12 (3 to 30 µg/ml), zero3, zero6, 0Nine, 12, 15, 18, 21, 2Four, 27, and three ml have been extracted from this answer and constructedupto10mlevery.Theirabsorbancehavebeenmeasuredatλmaxof233 nm the usage of a UV spectrophotometer with SGF pH 12 as a smooth Table 2 and Fig Show a famous graph of the drugs with absorbance at 233 nm as the y-axis and attention (µg/ml) as the x-axis.



Post-Compression parameters:

All the medication from one among a type formulations were checked for its desired appear to be length, form, colour, odor, floor texture, bodily flaws & consistency.

Hardness:

Tablets require a precise degree of hardness and mechanical strength to endure shocks and stresses occurring during production, packaging, and shipping. Tablet hardness was measured using a Monsanto hardness tester. For each batch, the hardness of 6 tablets was tested using the Monsanto tablet hardness tester & mean value was determined[81]

Limit: Generally speaking, tablets with a hardness of 3–5 kg/cm2 are considered suitable. Tables 15, 16, and 18 provide the hardness results for the floating tablets of acebutolol hydrochloride and trendolapril, respectively.

Friability:

The capacity of the tablets to withstand mechanical stress during handling and transportation was evaluated using a Roche friabilator. In this test, tablets were placed within a rotating plastic drum spinning at 25 rpm and exposed to combined abrasion and impact stresses. The

tablets were allowed to drop from a height of about 6 inches with each rotation. A sample of undamaged tablets with a total weight as close to 65 g as possible was selected for the test for tablets weighing 650 mg or less. After being weighed and dedusted, the tablets were placed in the friabilator and rotated 100 times. To determine the percentage weight loss, the tablets were taken out, dedusted again, and weighed after the test was finished.

Limit: Conventional compressed pills that lose lots far less than 05-1% of their wt. had been normally viewed into account correct. The repercussions for friability for floating pill of Trandolapril and Acebutolol hydrochloride one after the other are confirmed in desk 15, sixteen and 18 correspondingly.

Preformulation look at:

Investigation of drug excipient compatibility using Fourier transforms infrared (FTIR) analysis:

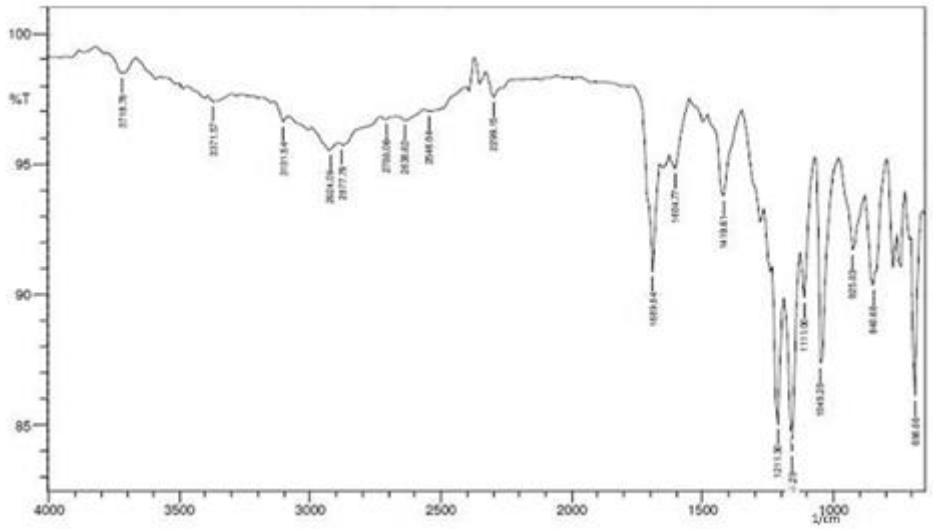


Fig 2: FTIR evaluation of trandolapril.

The exceptional floating tablets of trandolapril and acebutolol hydrochloride in addition to their character Fourier rework infrared spectra were recorded and tested for chemical interactions.

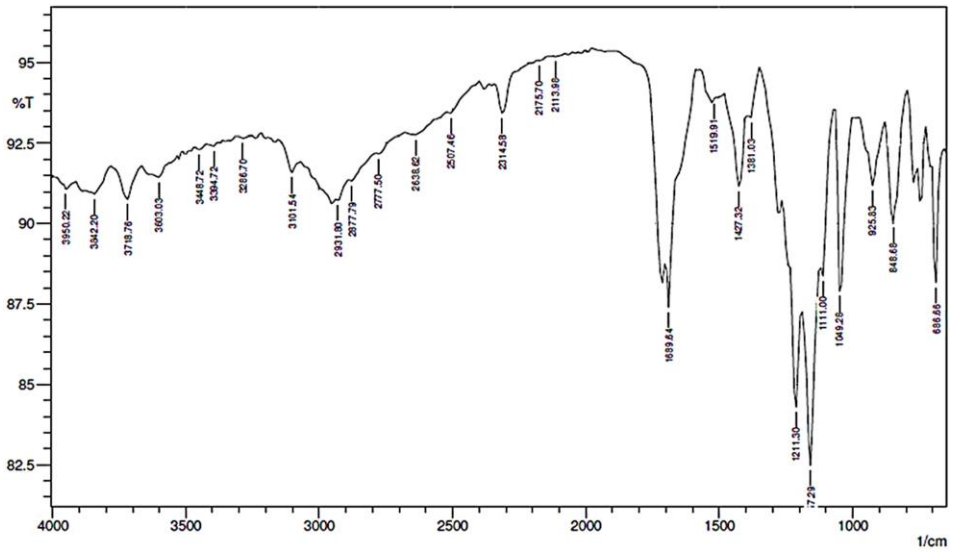


Fig2: FTIR spectra of the most suitable trandolapril system.

Discussion:-

The FTIR spectrum of trandolapril exhibited characteristic absorption peaks corresponding to N–H stretching at 3371 cm^{-1}, aromatic C–H stretching at 3101 cm^{-1}, carboxylic acid C–H stretching at 2924 cm^{-1}, aromatic C=C stretching at 1639 cm^{-1}, S=O stretching at 1111 cm^{-1}, and C–N stretching vibrations at 1049 cm^{-1}, as shown in the spectrum presented in the figure. When compared with the FTIR spectrum of pure trandolapril (Figure 30), no significant alterations or loss of these distinctive peaks were found in the formulation spectra. The retention of all main functional group peaks demonstrates the lack of any chemical interaction between trandolapril and the excipients utilized in the improved formulation.

Description of a powder combination of trandolapril and acebutolol hydrochloride:

Pre-compression traits of the trandolapril powder mixture:

Table 3: Pre-compression parameters of powder combination of Trandolapril.

Formulation Code	Bulk Density (g/ml)	Tapped density (g/ml)	Carr's Compressibility index (%)	Hausner's ratio
F 1	066	072	859	109
F 2	042	045	701	108
F 3	068	072	559	106
F 4	072	079	898	110
F 5	069	079	1012	112
F 6	044	049	10	111
F 7	067	071	549	106
F 8	074	082	1009	111
F 9	045	049	8	109
F10	047	051	799	109

F11	071	079	950	111
F12	047	051	799	109
F13	068	075	920	110
F14	044	049	999	111
F15	074	081	914	110
E1	069	073	912	106
E2	044	048	765	108
E3	072	079	897	110
E4	047	051	8	109
E5	073	081	914	110
E6	046	050	8	109
E7	072	082	1185	113
E8	043	047	999	111

Pre-compression parameters for the acebutolol hydrochloride powder combination:

Pre-compression traits of the acebutolol hydrochloride powder mixture

Formulation Code	**Bulk Density (g/ml)**	**Tapped density (g/ml)**	**Carr's Compressibility index (%)**	**Hausner's ratio**
A1	068	072	559	106
A2	074	081	914	110
A3	072	079	897	110
A4	047	051	799	109
A5	044	048	765	108
A6	067	071	549	106
A7	071	079	950	111
A8	045	049	79	109

Bulk density, tapped density, compressibility index, and Hausner ratio had been used to physically have a study the mixture of floating pills containing acebutolol hydrochloride and trandolapril According to the findings, all formulations using artificial and natural polymers (F1–F15, E1–E8, and A1 and A8) had super go together with the flow houses for each trandolapril and acebutolol hydrochloride.

Studies of stability:

CONCLUSION

In the current work, an attempt was made to promote stomach retention and consequently improve the bioavailability of trandolapril and acebutolol hydrochloride by synthesizing gastroretentive floating tablets utilizing an effervescent technique. The compositions were created using the direct compression approach combining both synthetic and natural polymers. Sodium bicarbonate and citric acid were utilized as effervescent agents, and the main idea of the gastroretentive system was to lower the density of the dose form below that

of stomach fluid, hence lengthening gastric residence duration.Initially, Fourier Transform Infrared (FTIR) spectroscopy was applied to authenticate the identification of the obtained pharmaceuticals and to verify drug–excipient compatibility. To assess the effects of various polymers on swelling behavior and the effect of effervescent agents on in vitro buoyancy, trandolapril floating tablets were produced in three successive phases.In the third stage of formulation development, the ideal concentration and ratio of effervescent agents necessary for the creation of floating tablets were identified based on the findings of the prior stages. These findings were also utilized to exclude inappropriate polymers from both synthetic and natural sources. The optimized parameters gained from this step were later utilized to the manufacture of floating tablets of acebutolol hydrochloride.Based on the swelling index data acquired during the initial stage of formulation development, ethyl cellulose (synthetic polymer) and sodium alginate (natural polymer) were removed from future investigations. The poor swelling behavior of ethyl cellulose may be ascribed to its hydrophobic character, which inhibits water absorption, whereas sodium alginate demonstrated decreased hydration and swelling owing to its lower viscosity. In contrast, polymers with greater hydrophilicity and viscosity displayed improved swelling properties, making them more appropriate for the production of gastroretentive floating tablet formulations.

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Conflict of Interest

The authors announce that there is no disagreement of interest associated with this research work.

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