Comparative study of Ranitidine tablets of different pharmaceutical companies in bangladesh

A dissertation submitted to the Department of Pharmacy, Faculty of Allied Health Science, Daffodil International University

In the partial fulfilment of the requirements for the degree of Bachelor of Pharmacy (B. Pharm)

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APPROVAL

This is to certify that this project titled **"Comparative Study of Ranitidine Tables"** submitted for the partial fulfillment of the requirements for the degree of Bachelor of Pharmacy from the Department of Pharmacy at Daffodil International University constitutes my own work credit is given where I have used the language, ideas or writings.

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ECLARATION

I hereby declare that, this project report is done by me under supervision of **Tahmina Afroz,** Lecturer, Department of Pharmacy, Faculty of Allied Health Sciences, Daffodil International University, Dhaka, Bangladesh. Impartial fulfilment of the requirement for the degree of Bachelor of Pharmacy. I am declaring that this project my original work. I am also declaring that neither this project nor any part thereof has been submitted elsewhere for the award of Bachelor or any degree.

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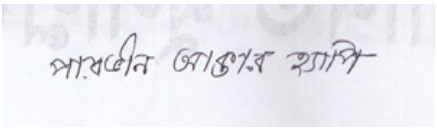

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DEDICATIONA

I Dedicate this work to my family especially my parents and to my respected teachers.

ABSTRACT

Ranitidine is a H2-receptor antagonist widely used in the treatment of a variety of gastrointestinal disorders. Since cimetidine--the predecessor drug of ranitidine--interacts with a variety of other agents and moreover ranitidine is often administered in combination with other drugs the interaction potential of ranitidine has been subject to extensive investigations. This review updates the information available from 1988 to present. Pharmacokinetic interactions of ranitidine with other drugs may occur at the site of absorption, metabolism and renal excretion. Most of the interactions reported at each of the three levels are minor and of low clinical significance. In view of some uncontrolled anecdotal reports, one cannot completely rule out the possibility that ranitidine might have some limited interaction potential in special patient populations under certain clinical conditions. However, it must be emphasized that numerous controlled studies have proven that ranitidine can be safely co administered with other drugs.

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Chapter one

Introduction

1.1 An overview

Pharmaceuticals sector is one of the fastest growing sectors in Bangladesh. With satisfactory annual growth rate of 34%, this sector is also fulfilling 97% of the total medicine requirement of the local market. Now more than 200 registered pharmaceutical manufacturers in Bangladesh. It is the largest employment sector in Bangladesh. Around 35,000 people work in the industry i.e.50% are pharmacists, chemists, biochemists and microbiologists. Government organization i.e. Directorate of Drug Administration and semi government Pharmacy Council of Bangladesh, control pharmacy practice in Bangladesh. Bangladesh medicine sales reached Tk. 7,000 crore in 2010. [1]

Export Prospect of Pharmaceuticals Sector in Bangladesh Bus 502: Managerial Communication than the regional average of 53.1. Globally, Bangladesh occupies 67th position in BMIs 83market-strong pharmaceutical universe. The experts forecast the growth trend would take the sales volume to Tk. 10,000 crore in 2011.At present Bangladesh is exporting more than 67 different countries of the world. There are about450 generics/substances registered in Bangladesh. [2]

1.2 Hypertension

Hypertension also known as high blood pressure (HBP), is a long-term medical condition in which the blood pressure in the arteries is persistently elevated. High blood pressure usually does not cause symptoms long-term high blood pressure, however, is a major risk factor for coronary artery disease, stroke, heart failure, peripheral vascular disease, vision loss, chronic kidney disease, and dementia. Blood pressure is expressed by two measurements, the systolic and diastolic pressures, which are the maximum and minimum pressures, respectively. For most adults, normal blood pressure at rest is within the range of 100–130 millimeters mercury (mmHg) systolic and 60–80 mmHg diastolic. For most adults, high blood pressure is present if the resting blood pressure is persistently at or above 130/90 or 140/90 mmHg. [3]

1.3 Ranitidine

Ranitidine is a type of medicine called an H2 receptor antagonist or H2 blocker. H2 receptors are found on the cells in the stomach lining. A natural body chemical called histamine normally acts on these receptors, causing them to produce stomach acid to help digest food. Ranitidine works by blocking the H2 receptors, which stops the cells from producing excessive stomach acid.

Ranitidine helps relieve indigestion symptoms that are caused by excess stomach acid. It also reduces the backflow of acid into the food pipe that can cause heartburn symptoms and damage to the food pipe (esophagitis)

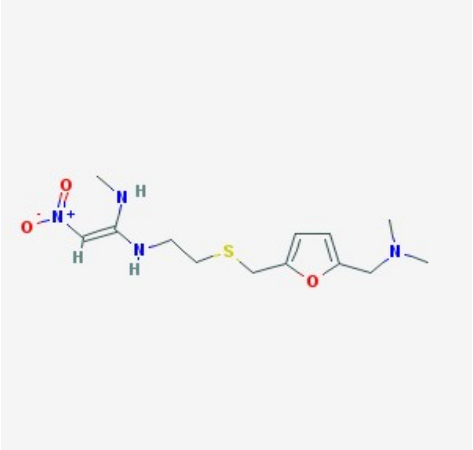

Fig: Ranitidine

By reducing the amount of acid in the stomach and duodenum, ranitidine allows peptic ulcers to heal. It can also help stop an ulcer developing if you're taking a non-steroidal anti-inflammatory drug such as diclofenac.

1.3.1 Mechanism of action

Ranitidine is a member of the class of histamine H2-receptor antagonists with antacid activity. An H2-receptor antagonist, often shortened to H2 antagonist, is a drug used to block the action of histamine on parietal cells in the stomach, decreasing acid production by these cells. These drugs are used in the treatment of dyspepsia, however their use has waned since the advent of the more effective proton pump inhibitors. Like the H1-antihistamines, the H2 antagonists are inverse agonists rather than true receptor antagon ists. Ranitidine is a competitive and reversible inhibitor of the action of histamine, released by enterochromaffin-like (ECL) cells, at the histamine H2-receptors on parietal cells in the stomach, thereby inhibiting the normal and meal-stimulated secretion of stomach acid. In addition, other substances that promote acid secretion have a reduced effect on parietal cells when the H2 receptors are blocked.

1.3.2 CLINICAL PHARMACOLOGY

Freshly isolated proximal tubular cells of the rat are used to study the uptake of a prototypical organic cation, tetraethyl ammonium, and the influence of other cationic drugs on tetraethyl ammonium uptake. The time dependency of 50 GM tetraethyl ammonium uptake was determined by incubating proximal tubular cells for time periods from 10 sec until 60 min. tetraethyl ammonium uptake was linear for at least 2 min and reached equilibrium after 30 min. The cell to medium ratio reached a value of 8 after 60 min, indicating marked accumulation of tetraethyl ammonium. Tetraethyl ammonium uptake was concentration dependent and saturable, with an apparent Km of 63 + or - 7 uM and V max of 0.57 + or - 0.02 nmol/mg protein. min. In comparison with cells cultured on filters, the overall transport characteristics of tetraethyl ammonium in PTC seem to resemble basolateral to apical flux. The concentration-dependent inhibition of some H2 antagonists and various cations on 32 uM tetraethyl ammonium uptake was investigated, as well as the interaction with probenecid. Analysis of the log-concentration inhibition curves showed that mepiperphenidol, trimethoprim, famotidine and cimetidine had a high and low IC50 value, whereas ranitidine, Niziatidine, cimetidine sulfoxide, Nl-methylnicotinamide and probenecid had only a low IC50 value. The data reported here are comparable with those from other preparations, and it is possible to extrapolate to the human in vivo situation. Moreover, the isolation procedure is relatively simple and quick and the yield is high.

1.3.3 Indication and usage:

- Ranitidine is used to treat intestinal and stomach ulcers, gastroesophageal reflux disease (GERD), and conditions where your stomach makes too much acid, including a rare condition called Zollinger-Ellison syndrome. This drug is also used to heal acid-related damage to the lining of the esophagus.
- Ranitidine used as part of a combination therapy. This means you may need to take it with other medications, especially for GERD. If you're taking this drug for other conditions, you may need long-term treatment. You may need to take it for several weeks or months.

1.3.4 Medical uses

Ranitidine is used to treat ulcers of the stomach and intestines and prevent them from returning after treatment. This medication is also used to treat and prevent certain stomach and throat (esophagus) problems caused by too much stomach acid (e.g., Hollinger-Ellison syndrome, erosive esophagitis) or a backward flow of stomach acid into the esophagus (gastroesophageal reflux disease-GERD).Ranitidine is known as an H2 histamine blocker. It works by reducing the amount of acid in your stomach. This helps heal and prevent ulcers and improves symptoms such as heartburn and stomach pain.This medication is also available without a prescription. It is used to prevent and treat heartburn and other symptoms caused by too much acid in the stomach (Acid indigestion). If you are taking this medication for self-treatment, it is important to read the manufacturer's package instructions carefully so you know when to consult your doctor or pharmacist.

1.3.5 Pharmacokinetics

The methods available for assaying ranitidine in plasma and both the drug and its metabolites in urine are high-performance liquid chromatography and radioimmunoassay. Following oral administration, the absorption of ranitidine in normal individuals has been found to be rapid, with peak plasma concentrations occurring at 1 to 3 hours. Peak plasma concentrations bear a constant relationship to dose, but vary widely between individuals. The bioavailability of ranitidine after oral administration is approximately 50% due to presystolic hepatic metabolism. Plasma protein binding of ranitidine is approximately 15% and the apparent volume of distribution is greater than body volume. Ranitidine penetrates very poorly into the cerebrospinal fluid but is concentrated into breast milk.

After intravenous administration, plasma concentrations decay in a exponential manner. The elimination half-life is almost 2 hours and is somewhat longer after oral administration. Plasma clearance is approximately 600 ml/min of which most is renal clearance. Elimination of ranitidine is not dose-dependent. Hepatic metabolism is the other major route of elimination and there may be some enterohepatic recycling of the drug. Food has no effect on the kinetics of ranitidine but concurrent administration of antacids reduces its absorption. Renal disease causes an increase in ranitidine plasma concentrations through reduced clearance and possibly increased bioavailability. Chronic liver disease causes an increase in the bioavailability of ranitidine and some reduction in clearance. In the elderly, there is a reduction in clearance and prolongation of the elimination half-life but little effect on bioavailability. There is a relationship between plasma

concentrations of ranitidine and suppression of gastric acid production but wide inter- individual variability.

1.3. 6 Adverse effects

Headaches, fatigue, vertigo and mild gastrointestinal pain are occasionally observed with ranitidine; these side-effects are at least as frequent as with a placebo. Less than 1% of the treated subjects (most likely those with complex medical problems) suffer from neuropsychiatric side-effects (confusion, hallucination, etc.). A rise of the hepatic enzymes can occur, but acute hepatitis is very rare. Other side-effects are even less frequent: isolated cases of dysrhythmias (bardycardia, heart block) have occurred following intravenous injections. In addition, there have been reports of occasional agranulocytosis and exanthema. The drug does not appear to cause any endocrine problems.

1.4 There are some test by which the comparative study of Ranitidine can be done,they are:

1.4.1 Hardness:

This test is conducted on 10 tablets of each brand to determine the strength of tablet when applied mechanical stress. A tablet must be hard enough to endure stress. Hardness of all the brands is checked on MH- 1, Hardness Tester of Galvano Scientific. The hardness value of each tablet was evaluated and average value was calculated and compared

1.4.2 Friability:

Friability test has been performed on 10 tablets of each brand of ranitidine by subjecting to a uniform tumbling motion for specified period of time i.e. 25 rotation/minute for 4minutes in FB–1004 CURIO Company and the weight loss is determined. Friability test is done to check if a tablet abrades during transportation by taking initial and final weight and determining the weight loss.

1.4.2 weight variation:

Variation in weight was checked on A.N.D Electronic Balance FX- 400. Weight variation between tablet with resp must be within BP limits. For which 20 tablets of each brand is selected randomly. In-process uniformity of weight which ensures evenness of dosage units through compression. The percentage weight variation from average tal calculated. In order to pass weight variation test, the tablet should be within the limits of the percentage deviation and lower control limit for weight variation is calculated as per following formula:

Upper control limit: Mean+ 3x Standard Deviation

Lower control limit: Mean- 3x Standard Deviation

And Maximum and minimum weight variation limit in percentage was calculated as per following formula:

Max wt. variation %=(Maximum weight–Average weight)/Average weight×100

Max wt. variation %=(Maximum weight–Average weight)/Average weight×100

1.4.3 Disintegration:

Disintegration Testing is one of the quality control test done to determine whether capsules or tablets are disintegrating within the approved time when placed in a fluid medium. Disintegration test for all brands s was done on CURRO MODEL NO DS-0702. A 900 ml beaker was filled with distilled water and temperature was maintained at 37 ± 2°C. From each brand, 6 tablets of each brand were selected randomly and placed into the basket rack assembly and connected to the disintegration apparatus. The disintegration time for each brand is compared with the Pharmacopoeial limit specified by BP.

1.4.4 Dissolution:

This test determines the amount of active ingredient released from oral solid dosage form, i.e. tablet or a capsule, using medium with known volume. Tablet dissolution was conducted on model no. GDT-7L of Galvano Scientific. It is carried out to determine the bioavailability of drug invitro dissolution tests were performed with the paddle apparatus I in 900 ml 0.1 N HCL dissolution media at 100 rpm for 60 minutes. The tablets were placed in the vessels at the beginning of each test and the stopwatch was started simultaneously. In order to minimize evaporation vessels are covered during the run with plastic covers. The temperature in the vessels was maintained at 37 ± 0.5°C throughout every dissolution run. Manually samples are removed using 5 ml syringes fitted with stainless tubing to make certain reproducibility of the sampling site.

1.5 Some market preparations available in Bangladesh:

Name of the company	Brands name	Dosage from available
Asiatic Laboratories Ltd.	**ACEPTIN-R**	Tab.150mg
Bio Pharma Laboratories Ltd.	**ACIN**	Tab.150mg
Rephco Laboratories Ltd.	**ALIN**	Tab.150mg
Ambee Pharmaceuticals Ltd..	**ANTAC**	Tab.150mg

1.6 Purpose of this work:

The main objectives of this presentation described below To evalualution of different brands of furosemide available in Bangladesh.

The major purpose of this project work is to find out the current status of the quality of the marketed furosemide preparations available in Bangladesh. This project work makes awareness among the people's health, health practitioners and drug control authority so that pharmaceutical manufacturers produce quality medicine and people may not waste their hard earning money by buying low quality product. This project work provides a comprehensive knowledge about the hardness, friability, weight variation, disintegration, dissolution, percentage of potencies of furosemide market preparations and compares these values with their specifications. This project work will help both health practitioners and consumers to select quality products. Also this work can provide some information for Drug Control Authority of Bangladesh to evaluate the overall quality status of potassium Losartan preparation.

Chapter two

Literature review

Title 1. Ranitidine for Hypercalcemia: An Unproven yet Common Practice (prepared by Susan B. LeGrand, dr.Dona Leskuski,Ivan Zama, MD)

Although primary hyperparathyroidism is the most common cause of hypercalcemia, cancer is the most common cause requiring inpatient intervention. An estimated 10% to 20% of all patients with cancer have hypercalcemia at some point in their disease trajectory, particularly in advanced disease. Aggressive saline hydration and varying doses of furosemide continue to be the standard of care for emergency management. However, a review of the evidence for the use of furosemide in the medical management of hypercalcemia yields only case reports published before the introduction of bisphosphonates, in contrast to multiple randomized, controlled trials supporting the use of bisphosphonates. The use of furosemide in the management of hypercalcemia should no longer be recommended.

Title 2. Phencyclidine intoxication is prepared by (L. J. Sioris, E. P. Krenzelok)

The history, symptoms, diagnosis and treatment of phencyclidine hydrochloride (PCP) intoxication and the pharmacology of PCP are reviewed. Intoxication with low to moderate doses of PCP (5-20 mg) resembles an acute, confusional state generally lasting four to six hours. High doses (>20 mg) may cause serious neurologic and cardiovascular complications and the patient is often comatose for several days. Treatment involves supportive psychological and medical measures. Evacuation of the stomach with activated charcoal and a saline cathartic may be indicated and succinylcholine chloride may ease intubation. Diazepam and chlorpromazine may be used to control the combative patient and the 'PCP psychosis' patient, respectively. Antihypertensive agents are not usually needed, but diazoxide and hydralazine hydrochloride have been used to treat hypertensive crises. Diazepam and phenytoin have been used to treat seizures. Ion-trapping by continuous gastric suctioning and by urine acidification with ammonium chloride may increase clearance of PCP. Forced diuresis with furosemide in conjunction with acidification may further increase PCP clearance. Use of physostigmine is based on conjecture.

Title 3. Clinical Characteristics in Children (prepared by Craig A. Friesen, MD, Charles C. Roberts, MD)

hirty-five cases of cholelithiasis diagnosed at a children's hospital over a 7.5-year period are reviewed and compared to 693 cases of pediatric gallstones reported in the literature. Symptomatology and associated medical history are more important in diagnosing cholelithiasis than are laboratory tests. Hemolytic disease is the most common associated condition in our series (46%) as well as in the literature (30%), but the frequency of the various associated conditions varies with age. Isolated gallstone disease does occur, particularly in the young infant. Jaundice is the most common symptom in children less than 1 year of age, being present in greater than 90 percent of symptomatic patients previously reported. Overall, the most common symptom in our series is vomiting (60%). Right upper quadrant pain in the absence of vomiting does not appear to be significant.

Title 4. Diuretics with carbonic anhydrase inhibitory action prepared by
(Maurizio & Claudia T Suburban) Pages 681-691 | Published online: 14 Mar 2013.

Carbonic anhydrases (CAs, EC 4.2.1.1) are wide-spread zinc enzymes, present in archaeon- and eubacteria, algae, green plants and animals. Within these organisms CAs are encoded by three distinct, evolutionarily unrelated gene families: the α-CA, the β-CA and the γ-CA families, respectively. These enzymes are very efficient catalysts for the reversible hydration of CO_2 to bicarbonate; the α-CAs possess high versatility, being able to catalyze other hydrolytic processes. It is not known whether other reactions catalyzed by CAs (than the hydration of CO_2/dehydration of HCO^-) may have physiological relevance in systems where these enzymes are present.

Title 5. Ranitidine -induced bullous pemphigoid is prepared by (Lee JJ,Downham MD)

Journal of Drugs in Dermatology : JDD[01 Jun 2006.

Bullous pemphigoid (BP) is an acquired autoimmune disease characterized by subepidermal vesicles and bullae. The etiology for BP is mostly idiopathic with the highest occurrence in elderly patients; however, it is now well-accepted that BP has been triggered by or associated with drug therapy. We present a case of furosemide-induced bullous pemphigoid and review the literature of drug-induced bullous pemphigoid (DIBP).

Chapter Three

Materials and methods

3.1 Materials:

Name of the glass were	Manufacturer/source
Measuring cylinder	India
Beaker	Gilin brand,china
Pipette	Germany
Funnel	China

3.1.1 Collection of sample:

Sample from three pharmaceuticals company were randomly selected, one of sample patent sample. Sample were collected from retail medicine shop of Bangladesh. The samples were properly cheeked for their physical appearance name of the manufacturer, batch number, manufacturing date, expiry date, manufacturing license number, D.A.R and maximum retail price at the time of purchase.

3.1.2 Status of the sample

The status of purchased furosemide market preparation were as follows:

Three different brands of various manufacturers and patent of tablet were purchased for the analytical studies.

3.1.3 Coding of tablet

Sample code	Product name	Company name	Tablest (Mg)
R-01	Xantid	Aci	150mg
R-02	Ranid	Ziska	150 mg
R-03	Ranitidine	Albion	150mg

3.1.4 Apparatus used in this study

Table 3.1:Name of glasswere

Table 3.2: Name of the instrument

Si.no	Name of the instrument	Manufacturer
01	Analytical balance	China
02	Hardness tester	India
03	Friability tester	Avis
04	Disintegration tester	India
05	Dissolution test apparatus	China
06	Uv – visible spectrophotometer	England

3.2 Methods

Microspheres were prepared by water-in-oil emulsion technique, using glutaraldehyde as a cross-linking agent. The effect of independent variables like stirring speed and polymer-to-drug ratio on dependent variables, i.e. percentage mucoadhesion, percentage drug loading, particle size and swelling index, was examined using a 3(2); factorial design

3.2.1 preparation of reagents

Preparation of 0.1 normal hydrochloric acid.

8.3ml of HCL was added to distilled water in a 1000ml volumetric flask and dilute to 1000ml with distilled water

3.2.2 weight variation test of tablets

The weight variation test is measured to help ensured that a tablet contains proper amount of drug.

Procedure:

Different aliquots (0.4- 8.0µg/ml) of RNH were transferred in to a series of 10 ml calibrated flasks by means of a micro burette. Then, 1 ml of 5M HCl was added followed by 1ml of CAS solution. The contents were shaken well and were set aside for 15 minutes with occasional shaking. Then, 1.0 ml of malachite green was added to each flask, and the volume was adjusted up to the mark with distilled water and mixed well. The absorbance of each solution was measured at 615 nm against the corresponding reagent blank. The absorbance corresponds to the bleached color, which in turn corresponds to the drug solution, was obtained by subtracting the absorbance of the blank by that of the test solution.

3.2.3 Hardness procedure:

Hardness of furosemide tablets were measured by following way:

- The tablet is placed between two platens.
- Two platen moves to apply sufficient force to the tablet.
- The mechanism should be free of any bending displacement as the load is applied.
- Rate and uniformity of loading.
- A calibrated load cell measure the force applied.
- Result are expressed in newton or kilo pound (KP).

3.2.4 Friability test of tablets

Friability is the condition of being friable, describes the tendency of a solid substance to break into smaller pieces under duress or contact, especially by rubbing. The opposite of friable is indurate.

Procedure

10 tablets were taken and weighted by an analytical balance. then the tablets were put in friabilator and the machine is allowed rotate at 25 R.P.M for 4 minute and then tablet were taken again. then the % of friability was calculated by the following formula.

% of friability =(initial weight – final weight/initial weight)*100

3.2.5 disintegration time test of tablets

Disintegration is when one thing splits into parts or just ceases to exist. When something is destroyed, broken up into pieces, or falls apart on its own, that's disintegration. breaking of tablets into smaller particle is known as disintegration and time taken for breaking of tablets in a suitable medium is called disintegration time (DT).

Procedure

Disintegration apparatus contain 6 glass tube that are 3inche long.to test for disintegration time at first one tablet is placed in each tube and the basket rack is positioned in a 1000 ml beaker of 0.1 normal hydrochloric acid. then the tablet remains 2.5 cm below the surface of the liquid on their upward movement descent not closer than 2.5 cm from the bottom of the beaker. A standard motor driven device is used to move the basket assembly containing tablet up and down through a distance of 5 to 6 cm at a frequency of 28 to 32 cycles per minute perforated plastic discs may also be used in the test.

3.2.6 Dissolution rate test of tablets:

Dissolution testing is an important tool for characterizing the performance of oral solid dosage forms. Its significance is based on the fact that for a drug to be effective, it must first be released from the product and dissolve in the gastrointestinal fluids before absorption into the bloodstream can happen. In other words, the rate and extent of drug absorption are determined by its dissolution from the dosage form.

Chapter four

Data presentation

4.1 Weight variation of Ranitidine

Weight variation test of three different brand of ranitidine are shown below:

Table 4.1: Data of weight variation test:

Sample code	Total no. of tablet taken	Average weight of tablet
R-01	10	0.3614 mg
R-02	10	0. 3216mg
R -03	10	0.3029 mg

4.2 Hardness test of Ranitidine

Hardness test of 3 different brand of ranitidine are shown below.

Table 4.2: Data of hardness

Si. No	Sample code	Average hardness
01	R-01	8.788kg/cm2
02	R-02	9.804kg/cm2
03	R-03	9.194kg/cm2

4.3 Friability test of Ranitidine

Friability test of 3 different brand of ranitidine are shown below:

Table 4.3: Data of friability test:

Marketed sample	Total no. of tablet taken	Total initial weight (mg)	Total final weight (mg)	Observed friability (%)
R-01	10	0.320	0.321	0.31
R-02	10	2770	2.775	0.18
R-o3	10	0.3610	0.3616	0.16

4.4 Disintegration test of ranitidine

Disintegration test of 3 different brand of furosemide are shown below:

Table 4.4 Data of disintegration test

Si.no	Marketed sample	Average time
01	R- 01	453sec
02	R- 02	927sec
03	R- 03	1640sec

Chapter five

Result and discussion

5.1 weight variation test of ranitidine tablets

The weight variation test is measured to help ensured that a tablet contains proper amount of drug.

20 tablet were taken and weight individually by an analytical balance. average weight of the tablet was calculated weight variation is calculated by using the following formula:

% of weight variation=(individual weight – average weight) *100

Weight variation for 3 different brands of tablet were measured and observed value for each sample was recorded.

5.2 Hardness test of Ranitidine tablets

The hardness of 3 different brand of ranitidine tablets were determined according to the procedure

5.2.1 USP specification for hardness test

USP specification of oral tablet normally has a hardness of 3 to 11 kg.it is observed from the above result that two brand complied with the specification but the one has low hardness value. three sample of furosemide tablet (5 tablets of each brand) were measured and observed results are shown in table. BP/USP specification of hardness not more than 7 kg/cm2.it was seen from result none of the marketed furosemide sample exceeded the specification and therefore it can be said that all the sample complied with the specification for hardness.

5.3 Friabilty test of tablet

Three different brand of ranitidine tablets were measured according to the procedur

5.3.1 USP/BP Specification for friability of tablets.

Allowed range =1.0% (w/w)

Friability of tablets is mportant to determine the loss of weight during packaging and shipment.if the friability is higher (more than 1.0% w/w),the loss of active ingredient during packaging and transportation will be excessive,and the remaining active ingredient in the tablet will result in the tablet will result in deficient therapeutic effect.

5.4 BP/USP Specification of disintrgrtion time

Uncoated Tablets:
Not more than 30 minute for uncoated tablets. Place 1 tablet in each of the six tubes of the basket and operate the apparatus,using water maintained at 37 ± 2 as the immersion fluid unless otherwise specified in the individual monograph At the end of the time limit specified in the monograph, lift the basket from the fluid, and observe the tablets: all of the tablets have disintegrated completely. If 1 or 2 tablets fail to disintegrate completely, repeat the test on 12 additional tablets: not less than 16 of the total of 18 tablets tested disintegrate completely.

5.5 Dissolution rate of tablets:

Chapter six
Conclusion

At present about 95% of the essential drugs are being produced in our country. Now only 5% drugs are imported which include different types of vaccines are drugs which require high technology for manufacturing. about 90% drugs are manufactured by the national companies and the rest of the drugs are manufactured by multinational companies although overall quality of the drug product in our country is satisfactory but some spurious and substandard drugs are also supplied by some of the pharmaceutical companies.
There is no alternative to quality medicine for good health. After the implementation of national drug policy in 1982, no doubt the quality of medicine is improved, but not as expected. This project work was designed to evaluate the current status of the marketed furosemide dosage from because very often we found in various news media about the spurious and substandard drug in Bangladesh.

Sub-standard drugs cause not only wastage of money but also are responsible for health hazards which are sometimes so acute that they.