Chemical and Microbial Analysis of Post Marketed Antibiotics

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ABSTRACT

The present study was conducted to monitor the comparative quality study of post marketed antibiotics. Eleven groups of antibiotics of five companies each were tested. The samples were collected from market and DTL (Drug Testing Lab). Antibiotics were analyzed on properties, potency and anti-microbial activity according to USP (United States Pharmacopeia) and BP (British Pharmacopeia). After the assay work it was found that our government certified all companies that are producing good antibiotics but some uncertified and new companies are not in good result. Further study can be done on it. Considering the overall tests, government certified all companies that are producing safe quality products and that also have good market value, so effective measures should be taken by the authority to ensure the quality of all certified medicines.

Key words: antibiotics, physical properties, potency, quality of products, certified medicines.

INTRODUCTION

Antibiotics are especially useful for treating infections caused by bacteria. In addition, some antibiotics are effective against infections caused by fungi and protozoa, and a few are useful in treating cancer. Antibiotics are also used to treat infectious diseases in animals. Farmers sometimes add small amounts of antibiotics to livestock feed. The antibiotics support the animals' growth for reasons that are not entirely understood. Antibiotics are not effective against colds, influenza, or other viral diseases. In addition, the effectiveness of antibiotics is limited because both pathogenic microbes and cancer cells can become resistant to them.

Antibiotics are selectively toxic—that is, they damage some types of cells without harming others. Medically useful antibiotics attack infectious microbes or cancer cells without excessively hurting human cells. Antibiotics fight different types of illnesses in a variety of ways. Antibiotics fight microbes and cancer cells by interfering with normal cell functions. In most cases, this interference occurs in one of three ways: (1) prevention of cell wall formation, (2) disruption of the cell membrane (covering), and (3) disruption of chemical processes. Many antibiotics are regarded among the safest drugs when properly used. But antibiotics can sometimes cause unpleasant or dangerous side effects. The three main dangers are (1) allergic reactions, (2) destruction of helpful microbes, and (3) damage to organs and tissues.

Production of antibiotics involves several steps. First, cultures of antibiotic-producing microbes are grown in flasks and then transferred to huge fermentation vats. The microbes multiply rapidly in the vats because the environment is controlled to stimulate their growth. After fermentation, the antibiotic substance is extracted from the culture and purified. Some natural antibiotic substances are modified chemically to produce semi synthetic antibiotics. Many such drugs are more effective than the natural antibiotics from which they were developed. Drug companies conduct special tests on antibiotics during and after production to ensure their quality. Finally, manufacturers make the purified antibiotic substances into pills, liquids, and ointments for medical use.

Marketed drugs are the medicinal substances, which are made available to the market by pharmaceutical manufacturing or distributors, which people seek out or are given with the intention of preventing or treating illness, alleviating symptoms or improving health. Human health, more specifically patient's life depends on the quality of marketed drugs. "Quality is never an accident; it is always the result of intelligent efforts". The quality of drugs means the quality of treatment that ensures the well-being of the patients. According to WHO book on good practice for the...
manufacture and control of drugs, the manufacturer must assume responsibility for the quality of the drugs, which they produce.

Modern medicines for human use are required to meet exacting standards which relate to their quality, safety and efficacy. The evaluation of safety and efficacy and their maintenance in practice is dependent upon the existence of adequate methods for quality control of the product. The standard of purity must, therefore, be strictly defined in such a way as to ensure that successive batches are consistent in composition, irrespective of whether they come from the same or different manufacturers.

This thesis work was designed to find out the current status of the quality of marketed medicines. Some brands of medicines were taken for this study and analyzed for quality parameters. But we have a few opportunities to perform this type of research work. For lack of time, brands chosen were not enough to show the overall quality of marketed tablets. So it is necessary to work with more brands and strictly with official compendia. So this is the field in which more and more research work is necessary.

MATERIALS AND METHODS

Collection of sample for analysis

The reference samples were collected from local market and national market. The samples of marketed antibiotics of different companies were collected at maximum retail prices (NIRP) from different regions of Khulna and Dhaka city for the analytical studies. The samples were properly checked for their batch number and shelf life, name of manufacturer, manufacturing license number, and DAR number. No samples were taken whose expiry date had already been expired. The samples were then coded with ethics for analysis.

<table>
<thead>
<tr>
<th>Specification for different test</th>
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<td>Test</td>
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General Appearance

The general appearance of a tablet or capsule, its visual identity and overall “elegance” is essential for consumer acceptance, for control of batch-to-batch uniformity and general tablet uniformity and for monitoring trouble free manufacturing. The control of the general appearance of a tablet involves the measurement of a number of attributes such as a tablet’s size, shape, color, presence or absence of an odor, test, surface texture, physical flows and consistency, and legibility of any identifying markings.

Working procedure: The tablets were destriped or deblistered carefully. The tablets were observed visually with care at day light on a white surface. For packaging control, the outer pack and blister/strips were also checked, especially cuts, and ruptures, imprinting problems and the quality of packaging materials (paper/aluminium).

Thickness test of tablet

Thicknesses of 5 tablets of each sample were measured with a slide calipers. The average thickness of the tablets was determined and then thickness variation was calculated. In this way the thickness variation of different brands of tablets was determined.

Weight variation test of tablets

The weight variation is routinely measured to help ensured that a tablet contains proper amount of drug.
**Procedure:**

5 tablets were taken and weighed individually by an analytical balance. The average weight of the tablets was calculated. Then % of weight variation is calculated by using the following formula.

\[
% \text{ of weight variation} = \left( \frac{\text{individual weight} - \text{average weight}}{\text{average weight}} \right) \times 100
\]

In the case of capsule the capsule weight of the powder in shell were measured. The formula was:

**Individual Weight or Powder Weight = Capsule weight – Blank Shell Wight.**

In this way the weight variation for different brands of tablets were measured and the observed value for each sample was recorded.

**Note:**

1. Not more than two tablets should fall outside the limit.
2. No tablet should differ by more than two times the allowed % limit.

**Friability:**

Tablet friability results in weight loss of tablets in the container owing to partial powdering, chipping, or fragmentation of the tablets on attrition or wear (Gupta, 1940). Tablet friability often reflects lack of cohesiveness and compression of the dry granulation from which the tablets are made.

**Procedure:**

Four tablets were taken and weighed by an analytical balance. Then the tablets were put in a friabilator and the machine is allowed to rotate at 25 rpm for four minutes. After that the tablets were weighed again. The percent friability was calculated by the following formula:

\[
% \text{ of friability} = \left( \frac{\text{initial weight} - \text{final weight}}{\text{initial weight}} \right) \times 100
\]

In this way % friability was determined for different brands of tablets.

**Disintegration**

The process by which a tablet is broken down into smaller particles or granules is known as disintegration. Disintegration time is the length of time required for causing disintegration of tablet. This test not only evaluates the quality but also the bioavailability and effectiveness of tablet.

**Procedure:**

The equipment consists of 6 glass tubes that are 3 inches long, open at the top and held against a 10-mesh screen at the bottom and of the basket rack assembly. The basket rack is positioned in a 1-liter beaker of medium (water) at 37°C ± 0.5°C, such that the tablets remain 2.5 cm below the surface of the liquid on their upward movement and descend 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 the tablets up and down through a distance of 5 to 6 cm at a frequency of 28 to 32 cycles per minute. There are also six perforated plastic discs, which may be used on top of the tablets to impart an abrasive action to the tablets if necessary. The disks are useful for tablets that float. The disintegration time of each tablet was determined and the average disintegration time was calculated.
Potency determination

Indication:

Potency of tablet is expressed as grams or milligrams of micrograms (for some potent drugs) of drugs per tablet and is given as the label strength of the product. Official compendia of other standards provide an acceptable potency range around the label potency. For highly potent, low dose drugs such as Cefixime, this range is usually not less than 90% and not more than 110% of the labeled amount. For most other larger dose drugs in tablet from the official potency range that is permitted is not less than 95% and not more than 105% of the label amount while some have limit (90% to 120%) like Cefuroxim. In general official potency analytical methods require that a composite sample of the tablets be taken, ground up, mixed, and analyzed to produce an average potency value. In composite assays, individual discrepancies can be masked by use of the blended sample.

Measuring powder amount:

To make the chemical assay, it is needed to take a specific amount of powder of tablets. This amount depends on the average weight, equivalent weight and claim of the medicine in mg. The formula is:

\[
\text{The working weight} = \frac{\text{Average weight} \times \text{Equivalent weight}}{\text{Claim (mg)}}
\]

Preparation of test solution

*Ceftizime:

Take working amount of powder

- Add 2ml methanol
- Dissolve in phosphate buffer (pH 7.2) until limit 50ml
- Filter this mixture
- Take 3ml from this filtrate
- Dissolve in phosphate buffer (pH 7.2) until limit 100ml

*Amoxicillin:

Take working amount of powder

- Dissolve in distilled $\text{H}_2\text{O}$ until limit 100ml
- Filter the mixture
- Take 10ml filtrate
- Dissolve in distilled $\text{H}_2\text{O}$ until limit 100ml

*Ciprofloxacin:

Take working amount of powder

- Dissolve in N/10 HCl until limit 100ml
- Filter the mixture
- Take 2ml from this filtrate
Dissolve in N/10 HCl until limit 100ml

*Flucloxacin:*

Take working amount of powder
Dissolve on 40% methanol until limit 50ml
Filter the mixture
Take 5ml of this mixture
Dissolve in 40% methanol until limit 50ml

*Cefuroxime:*

Take working amount of powder
Dissolve in distilled H₂O until limit 100ml
Filter the mixture
Take 2ml of this filtrate
Dissolve in distilled H₂O until limit 100ml

*Levofloxacillin:*

Take working amount of powder
Dissolve it in N/10 HCl until limit 100ml
Filter the mixture
Take 2ml of this filtrate
Dissolve it in N/10 HCl until limit 100ml

*Renetidine:*

Take working amount of powder
Dissolve it in methanol until limit 100ml
Filter the mixture
Take 1ml from this filtrate
Dissolve it in methanol until limit 50ml

*Riboflavine:*

Take working amount of powder
Add 2ml GAA with it
Heat for 30min
Cool
Dissolve in distilled H₂O until limit 100ml
Filter the mixture
Take 10ml of this mixture
Add 3.5ml NaCOOCH₃
Dissolve in distilled H₂O until limit 50ml

*Metronidazole:

Take working amount of powder
Dissolve in N/10 HCl until limit 250ml
Filter the mixture
Take 3ml of this filtrate
Dissolve in N/10 HCl until limit 250ml

*Cephradine:

Take working amount of powder
Dissolve it in Distilled H₂O until limit 100ml
Filter the mixture
Take 5ml of this filtrate
Dissolve it in buffer solution (pH 4.4) until limit 100ml

*Tetracycline:

Take working amount of powder
Dissolve in N/100 HCl until limit 100ml
Filter the mixture
Take 10ml of this filtrate
Add distilled H₂O until limit 75ml
Add 5ml 5M NaOH
Add N/10 HCl until 100ml limit

Calculation of potency

Spectrophotometry involves the use of a spectrophotometer. A spectrophotometer is a photometer (a device for measuring light intensity) that can measure intensity as a function of the color (or more specifically the wavelength) of light. Important features of spectrophotometers are spectral bandwidth and linear range of absorption measurement. The prepared samples with their specific reagents were taken for spectrophotometer reading. The readings, and measured weights were used to calculate the potency.
The potency was calculated by the following equation:

Potency of sample = \frac{\text{Spectrophotometer reading of Sample} \times \text{Standard Weight} \times \text{Standard%} \times \text{Average weight}}{\text{Standard reading} \times \text{Sample weight} \times 100}

Or

\frac{\text{Sample Reading} \times \text{Dilution} \times \text{Average weight}}{\text{Value} \times \text{Sample weight} \times \text{dilution} \times 100}

In this way disintegration times for different brands were determined and recorded.

Microbial analysis of post marketed antibiotics

The most commonly used method for testing the antibiotic susceptibility of aerobic and facultative bacteria is the disk diffusion method. However, some anaerobic bacteria do not grow well enough in anaerobic jars for performance of disk diffusion tests. A modification of the broth-disk method of Schneierson allowed us to determine antibiotic susceptibility in a completely anaerobic environment.

Commercial antibiotic disks were added anaerobically to tubes of pre reduced brain heart infusion broth to achieve a concentration of each antibiotic approximating that attainable in blood. The tubes were then inoculated and incubated for 18 h. Resistance or susceptibility to each antibiotic was determined according to the amount of growth in each tube as compared with a control culture without the antibiotic.

Test of Antimicrobial activity by disc diffusion method:

Principle

In this method-measured amount of the test samples are dissolved in definite volumes of solvent to give solutions of known concentration (µg/ml). Then sterile Matricel (BBL, Cocksville, USA) filter paper discs are impregnated with known amount of test substances using micropipette and dried. Standard antibiotic discs and discs on which the solvent used to dissolve the samples is adsorbed and dried are used as positive and negative control, respectively.

These discs are then placed in petridishes (120 mm in diameter) containing a suitable agar medium seeded with the test organisms using sterile transfer loop for antimicrobial screening. The plates are then kept at 4°C for facilitating maximum diffusion. The test material diffuses from the discs to the surrounding medium. The plates are then kept in an incubator (37°C) for 12-18 hour to allow the growth of the microorganisms.

If the test material has any anti-microbial activity, it will inhibit the growth of microorganism giving a clear, distinct zone called zone of inhibition. The antibacterial activity of the test agent is determined by measuring the diameter of the zone of inhibition in term of millimeter.

The experiments are carried out three times and the mean of the reading are recorded.

Culture media

A mixture of nutrients used in the laboratory to support growth and multiplication of a culture (a population of microorganisms) is called culture medium (Pelczar,1986). The nutritional requirements of bacteria vary widely; there are great differences in the chemical compositions own in a medium containing only inorganic compounds, whereas others require a medium containing organic compounds (amino acids, sugars, purines, or pyrimidines, vitamins, or coenzymes).

In addition to specific nutrients, each kind of organism also requires specific physical conditions for growth. For example, some bacteria cannot grow below 40°C, some cannot grow above 20°C and some require a temperature close to that of the human body (i.e., 37°C). Light may be another important physical condition. The successful cultivation of bacteria requires an awareness of all of these factors (Pelczar et al., 1986).

Each kind of microorganism grows in a characteristic manner. On solid media, microbes grow as colonies-distinct, compact masses of cells that are macroscopically visible. Colonies are characterized by their size, shape, texture, consistency, color, and other notable features (Pelczar, 1986).

The following media are used normally to demonstrate the antibacterial activity and to make subculture of the test organisms.
a) Nutrient agar media  
b) Nutrient broth media  
c) Mueller-Hinton agar media  
d) Tryptic soya broth (TSB)

Among these, the first one is most frequently used which was also used for the present anti-microbial screening. Composition of Nutrient agar media (Mast Diagnostics, Mast Group Ltd., Merseyside, U).

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Amounts (gram/liter)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peptone A</td>
<td>6.0</td>
</tr>
<tr>
<td>Yeast extract</td>
<td>2.0</td>
</tr>
<tr>
<td>Beef extract</td>
<td>1.0</td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>5.0</td>
</tr>
<tr>
<td>Agar A</td>
<td>14</td>
</tr>
<tr>
<td>pH</td>
<td>7.3(approx)</td>
</tr>
</tbody>
</table>

**Preparation of media**

Nutrient agar media was prepared by adding water to a dehydrated product that contains all the ingredients. Practically all media are available commercially in powdered form (Pelczar, 1986).

Media of the nutrient agar type was prepared by compounding the required individual ingredients or, more conveniently, by adding water to a dehydrated product which contains all the ingredients. Practically all media are available commercially in powdered form. The following steps were involved in the preparation of bacteriological media:

Definite amounts of nutrient agar were accurately weighed.

It was taken in a volumetric flask containing distilled water (half of the required volume).

A clear medium was obtained by thoroughly dissolving agar over a water bath with occasional shaking.

Then the final volume was adjusted.

The medium was then transferred in 16 ml and 5 ml volume respectively, to prepare plates and slants, in a number of test tubes.

The test tubes were then plugged with cotton and sterilized in an autoclave at a temperature of 121 °C and pressure of 15-lbs/sq inch for 20 minutes.

**Sterilization of different equipments and media**

Media, petridishes and other glassware were sterilized by autoclaving at a temperature of 121 °C and a pressure of 15-lbs/sq inch for 15 minutes. Blank discs kept in a covered petridishes; loop and forceps were subjected to dry heat sterilization at 160 °C for 1 hour. Later they were kept in a laminar hood under LTV light for 30 minutes. W light was switched on before one working hour in a laminar hood to avoid accidental contamination.

**Preparation of disc:**

Three types of discs were used for antibacterial screening:

a) Sample discs  
b) Standard discs and  
c) Blank discs
Sample discs

20 sterile filter paper discs (5 mm in diameter) were taken in a blank petridish. 10µl of the test sample solution was applied on the discs (500µg/disc) with the help of a micropipette in an aseptic condition under the laminar air flow. These discs were left for several hours (4-6) in aseptic condition under the laminar air flow for complete removal of solvent as the solvent (ethanol) has some antimicrobial activity.

Standard discs

These were used as positive control to ensure the activity of standard antibiotic against the test organisms as well as for comparison of the response produced by the known antimicrobial agent with that produced by test samples. In this investigation Kanamycin (30 pg/disc) standard discs was used as the reference.

Blank discs

These were used as negative control. They ensure that the residual solvents (left over the discs even after air drying) and the filter paper were not active themselves.

Application of discs

Sample impregnated discs, standard antibiotic discs (Kanamycin discs) and negative control discs (blank discs) were placed gently on the 16 discrete solidified agar plates, freshly seeded with the test organisms with the help of a sterile forceps to assure complete contact with medium surface. The spatial arrangement of the discs was such that the discs were no closer than 15mm to the edge of the plate and far enough apart to prevent overlapping the zones of inhibition. The plates were then inverted and kept in refrigeration for about 4 hours at 4°C. This was sufficient time for the material to diffuse into a considerable area of the medium. Finally the plates were incubated upside down at 37°C for 12-18 hours.

Determination of zone of inhibition

After proper incubation, the antibacterial activity of the test agent was determined by measuring the diameter of zone of inhibition in term of millimeter with a digital slide calipers.

RESULT AND DISCUSSION

General Appearance of Antibiotics

The general appearance of all antibiotics has thoroughly analyzed and the results are shown in the following table:

<table>
<thead>
<tr>
<th>Group Name</th>
<th>Sample No</th>
<th>Shape</th>
<th>Color</th>
<th>Appearance</th>
<th>Surface Texture</th>
<th>Identifying Marks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cefixime</td>
<td>Cefixime 1 to 5</td>
<td>Oval</td>
<td>White, Green</td>
<td>Shiny</td>
<td>Smooth</td>
<td>One side cut mark and another side company monogram</td>
</tr>
<tr>
<td>Amoxicillin</td>
<td>Amoxicillin 1 to 5</td>
<td>Oval, Round</td>
<td>White</td>
<td>Shiny</td>
<td>Smooth</td>
<td></td>
</tr>
<tr>
<td>Ciprofloxacin</td>
<td>Ciprofloxacin 1 to 5</td>
<td>Oval</td>
<td>White</td>
<td>Shiny</td>
<td>Smooth</td>
<td></td>
</tr>
<tr>
<td>Flucloxacillin</td>
<td>Flucloxacillin 1 to 5</td>
<td>Oval</td>
<td>White</td>
<td>Shiny</td>
<td>Smooth</td>
<td></td>
</tr>
<tr>
<td>Cefuroxime</td>
<td>Cefuroxime 1 to 5</td>
<td>Oval</td>
<td>Yellow, Orange, White</td>
<td>Shiny</td>
<td>Smooth</td>
<td></td>
</tr>
<tr>
<td>Levofloxacine</td>
<td>Levofloxacine 1 to 5</td>
<td>Oval</td>
<td>Cream, White, Green</td>
<td>Shiny</td>
<td>Smooth</td>
<td></td>
</tr>
</tbody>
</table>
Weight Variation:

Weight variation test is done according to BP/USP procedure. Tablets were coated and uncoated. There were some capsules also. For capsule the average weight was taken from powder inside capsule. The weight variation test is a satisfactory method of determining the drug content uniformity of tablets. Weight variation may result from:

* Poor granulation flow properties, resulting in uneven die fill.
* A wide variation in granules particle size which results in a variation in die fill density as a function of particle size distribution at different points in the production run.
* Differences in lower punch length which results in different size die cavities. Improper incorporation of glidant, granulation flow promoters.
* Tablet machine in mechanically poor condition or dirty which prevent free punch movement.

<table>
<thead>
<tr>
<th>Group Name</th>
<th>Number Of Tablets Taken</th>
<th>Average Weight (mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cefixime</td>
<td>5</td>
<td>About 675.3</td>
</tr>
<tr>
<td>Amoxicillin</td>
<td>5</td>
<td>About 582.6</td>
</tr>
<tr>
<td>Ciprofloxacin</td>
<td>5</td>
<td>About 687.6</td>
</tr>
<tr>
<td>Flucloxacin</td>
<td>5</td>
<td>About 555.9</td>
</tr>
<tr>
<td>Cefuroxime</td>
<td>5</td>
<td>About 517.8</td>
</tr>
<tr>
<td>Levofloxacin</td>
<td>5</td>
<td>About 688.8</td>
</tr>
<tr>
<td>Renetidine</td>
<td>5</td>
<td>About 162.4</td>
</tr>
<tr>
<td>Riboflavin</td>
<td>5</td>
<td>About 2.6</td>
</tr>
<tr>
<td>Metronidazole</td>
<td>5</td>
<td>About 259.2</td>
</tr>
<tr>
<td>Cephradine</td>
<td>5</td>
<td>About 532.5</td>
</tr>
<tr>
<td>Tetracycline</td>
<td>5</td>
<td>About 579.4</td>
</tr>
</tbody>
</table>

Allowed range of variation tablets: ±10% (w/w) must.

According to the USP specification at least two third tablets must be within the weight limit ±10% (w/w) to comply with the specification. It is observed from the above that all brands complied with the specification.

When the weight variation is within the specifications the tablets are thought to contain uniform active ingredient to give desired therapeutic response. But when the weight variation is out of the specification the tablets are thought to contain less or more active ingredient to give ineffective therapeutic response or toxic effect respectively.

Potency determination

In 1st graph, Cefixime, Cefuroxime and Flucloxacin are presented. Cefixime has potency of 90% to 110% whereas Cefuroxime and Flucloxacin have potency of 90% to 120%. So, Cefixime 5, Cefuroxime 5 and Flucloxacin 3 failed.
According to figure 4.2, Amoxicillin4 failed in potency test. Levofloxacin, Amoxicillin and Riboflavin have limit of 90% to 110%.

Renetidine, Cephradine and Metronidazol all have potency of 90% to 110%. Here, Cephradine 5 and Renetidine 5 failed.
From the results obtained in this study, it is clear that most of the brands were found standard with respect to their standard range of the tests. For the greatest interest of the Public health those brands should be standard quality.

**Microbial Analysis of Antibiotics**

According to the procedure most antibiotics are able to inhibit specific microbial growth. As it related with potency, the antibiotics that failed in potency test did not give good inhibitory zone.

The main areas on which the activity can focus on are:

1. National Health Policies: Emphasizing primary and preventive health care as well as educating the public to understand the quality, limits and dangers of drugs.
2. Companies' Responsibility: They should not obstruct Government policies designed to safe guard the patients, and should promote the better health of the population by providing quality drugs.
3. Consumers' awareness: Security rights and right to get safety from the unwanted effects caused by a drug.
4. Drug Administration: The drug administration is the main agency responsible for giving effect to the drug policy and regulations thereby providing the quality drugs. This can be achieved by continuous supervision of the manufacturing plants in different parts of Bangladesh. Those who do not follow the rules and regulations, punishment should be strict in accordance with the Drug Control Ordinance, 1982, Ordinance no. VIII (section 15, 16).

**CONCLUSION**

It was not possible to do all the tests broadly and the companies' names are not published. Physical appearance, potency and microbial tests were done broadly for antibiotics. With this calculation it can be said that maximum companies of our country are able to supply a good quality product. Only some local companies which do not get government certification are not so good. But the results of herbal medicines are not satisfactory. However, a huge samples size is lacking in this research work. For shortage of time it was not possible to collect more samples.

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 and drugs which require high technology for manufacturing. About 92.8% drugs are manufactured by the National companies and the rest of the drugs are manufactured by multinational companies. Although overall quality of the drug products in our country is satisfactory but some spurious and substandard drugs are also supplied by some of the pharmaceutical companies.

From the above result it is assumed that although most of the brands meet with specification, few brands do not satisfy the specification. So the Drug Control Authority should take proper measure to control quality of marketed drug in any situation. Sub-standard drugs cause not only wastage of money but also are responsible for health hazards which are sometimes so acute that may cause death. So the drug control authority should strengthen their visiting team to visit frequently the manufacturing plant and establish more effective analytical measures to analyze the marketed.

The drug control authority of a country should consider all of the quality parameters so that manufacturers are bound to ensure their quality. The present study although performed on a limited scale, yet on the basis of professional judgment, the data reported in this project paper can help the Drug Control Authority to get an idea about the quality
status of the marketed tablets preparations in Bangladesh. We are hopeful that the results of this work will awake the
drug control authority to take appropriate steps to ensure quality medicine thereby assuring good health.

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