



**AN ANALYTICAL STUDY COMPARING COST AND QUALITY OF GENERICS WITH BRANDED DRUGS**

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**ABSTRACT**

There is a long debate in india on whether generic drugs are as effective and safe as the branded drug. A generic drug is identical to a brand name drug in intended use, dosage, strength, effectiveness and safety. An experimental study was conducted on generic and branded drugs by using qualitative and quantitative analysis, and also cost benefit analysis was done to access the price differences in local region. Main aim of the study was to compare the quality and price of generic drug products to their branded products manufactured by the same pharmaceutical company in India. Price-to-patient and price-to-retailers have to be found for branded and generic medicines. Qualitative and quantitative analysis was performed by using various analytical techniques prescribed in the Indian Pharmacopoeia 2018. Results shown that Quality of generic drugs was same as that of branded drugs and having no significant variations. Difference in price-to-patient was not as huge as it is expected for generics but margins for retailer were very high (25-65%) for generic drugs than that of branded drugs. Hence it was seen that generic substitution can be done for specific drugs and also pharmacoeconomic burden can also be reduced for patients.

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**INTRODUCTION**

A generic drug is identical (or bioequivalent) to a brand name drug in intended use, dosage, strength, effectiveness and safety. For a generic drug to be approved, it must meet the same quality standards as the brand name product[8]. Even the generic manufacturing, packaging, and testing must meet the same standards. Many generics are produced in the same manufacturing plant as their branded counterparts[1]. Generic and brand name drugs have identical active ingredients, and generic drugs must meet Indian standards for bioequivalence. Bioequivalent drugs are having the same bioavailability; that is, the same rate and extent of absorption. New drug formulations must meet standards set by WHO. If the generic drug is bioequivalent, it is assumed that it will produce the same effect as the branded drug. This means that new clinical studies are not needed for generic drug formulations[2].

Analytical chemistry studies uses instruments and methods are used to separate, identify, and quantify matter. In practice, separation, identification or quantification may constitute the entire analysis. In this current study spectroscopic evaluation was done for quality of branded and generic drugs by using UV spectroscopy and HPLC[3][7].

Spectroscopy is a general methodology that can be adapted in many ways to extract the information you need. Energies of electronic, vibrational, rotational states, structure and symmetry of molecules, dynamic information[6]. And also drug price should be taken into consideration. There is a big difference in both branded and generic drug pricing. The study mainly focus on pharmacoeconomic studies and quality of both branded and generic drugs.

**Literature Survey**

G.L. Singal, et al.,(2011) conducted a study on “A Comparative Evaluation Of Price And Quality Of Some Branded Versus Branded–Generic Medicines Of The Same Manufacturer In India”. This study aims to compare and evaluate the price and quality of branded and generic equivalents of some commonly used medicines manufactured by the same pharmaceutical company in India and stated that difference in price-to-patient was not as huge as it is expected for generics but margins for retailer were very high for generics. Quality of generics is same as for their branded version. The study highlights the need to modify the drug price policy, regulate the mark-ups in generic supply chain, conduct and widely publicize the quality testing of generics for awareness of all stakeholders.

Jolicoeur LM, Jones-Grizzle AJ, Boyer JG *et al.*, (2018) conducted a review on “Guidelines For Performing A Pharmacoeconomic Analysis”. In this study The fundamentals of pharmacoeconomics are presented. By adhering these

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fundamentals the pharmacist undertaking a pharmacoeconomic evaluation has the greatest likelihood of obtaining valid and useful results.

Abdul Aziz Ramadan, Hasna Mandil et.al.,(2015) conducted a study on “Determination Of Atorvastatin Calcium In Pure And Its Pharmaceutical Formulations Using Iodine In Acetonitrile By Uv-Visible Spectrophotometric Method”. In this study A simple, sensitive and specific spectrophotometric method was developed for the determination of atorvastatin calcium (ATCa) in pure and its pharmaceutical formulations using iodine in acetonitrile. The developed method is applied for the determination of atorvastatin in pure and its commercial tablets without any interference from excipients (at  $\lambda_{max}$  =291 & 360 nm), ezetimibe (EZE), fenofibrate (FEN) and aspirin (ASP) at  $\lambda_{max}$  =360 nm with average recovery of 99.45 to 102.4%. The results obtained agree well with the contents stated on the labels.

Sakala bargavi et.al.,(2013) conducted a study on “UV Spectrophotometric Method for Determination of Glimepiride in Pharmaceutical Dosage Forms”. In this study, a simple, sensitive, accurate and economical spectroscopic method has been developed for the estimation of glimepiride in bulk and in pharmaceutical dosage forms. Results of the analysis were validated for accuracy, precision, LOD were found to be satisfactory. The proposed method is simple, rapid and suitable for the routine quality control analysis

## METHODOLOGY

Highly moving medicines in Guntur region manufactured (branded and generic) versions by the same company were selected. Price-to-patient and price-to-retailers have to be found for branded and generic medicines. Qualitative and quantitative analysis will be performed by using various analytical techniques prescribed in the Indian Pharmacopoeia 2018.

1. The tests performed were determination of percentage purity,
2. High Performance Liquid Chromatography (HPLC), UV spectroscopy, electronic weighing balance, test tubes, volumetric flasks.

## MATERIALS

### Drugs

T. atorvastatin-10mg, T. Metformin-500mg, T. Propranolol-40mg, T. Paracetamol-500mg, T. Pantoprazole-40mg,

### Equipments

UV/VIS spectrophotometer and polystyrene cuvettes, hot plate, 1 10 mL graduated cylinders, 2 100 mL volumetric flask, 6 10 mL volumetric flasks, 1 mL graduated pipet or micropipette, 150 mL beakers, watch glass, mortar and pestle, weighing machine. a pair of 1-cm matched quartz cells was used to measure absorbance of the resulting solution.

## METHODS

Quality and price of medicines were studied to evaluate the two versions of the same therapeutic molecule.

## Medicine Price

Price-to-patient and price-to-retailer (PTR) were analyzed. Maximum retail price (MRP) is the price-to-patient and is always printed on the package in India. Medicines are available to patient at the MRP mentioned on the package of medicine. Details of the five "paired" drug products sold under different trade names with their MRP were checked with the private retail pharmacies.

PTR is the price at which wholesaler sells the product to the retailer and the bill given to retailer by wholesaler mentions the PTR.

## Quality Testing

The test samples were procured from the licensed authorized chemist dealers through valid purchased. Efforts were made to procure these test samples with identical date of manufacture to rule out the possibility of difference in assay because of different dates of manufacturing. The qualitative as well as quantitative analysis was carried out in central drug testing laboratory in chalapathi institute of pharmaceutical sciences, following the methods prescribed in the Indian Pharmacopoeia, (2007) as per the standards laid down in the Drugs and Cosmetics Act 1940 and Rules 1945[4].

Identification test was performed, Identity of the drug molecule was established by performing the identification test through instrumental analysis using HPLC (high pressure liquid chromatography) and UV (ultra violet spectroscopy)[5].

## RESULTS

### Comparative Price and Mark-Up for Branded and Generic Pair of Medicines

Details of different types of medicines including their trade name as sold in the Indian market, strength, dosage form, and the pharmaceutical company that manufactures these products are given in table 1 . Price-to-patient (MRP) and price-to-retailer (PTR) found for all the medicines is tabulated in Table 1.

When compared the percentage of markup for PTR both the generic and branded drugs having high outcomes of margins and presently in branded drugs markup to retailer is on average of 15-60%. Where as in generic drugs margins are very high on average of 10-65%.

MRP to consumers or public domain for generic drugs shown that there is a difference in selling price and actual cost of medicine, overall analysis shows that the generic drugs will be available in lesser costs when compared to that of branded products. A significant difference is seen in margins and upto 30-50% lesser the cost of generic drugs than branded drugs within the same quality.

**Table 1** Comparative Price and Mark-Up for Branded and Generic Pair of Medicines

| Trade name of medicine | Pharmacological name, strength and dosage form | Ptr | Mrp | Price of generic drug to consumer | Mark up(retailer) |
|------------------------|--|-----|-----|-----------------------------------|-------------------|
| Atorva(B)              | Atorvastatin-                                  | 36  | 52  | -                                 | 30.75             |
| Atocop(G)              | 40mg/tab                                       | 30  | 40  | 32                                | 25                |
| EXEEMET(B)             | Metformin-                                     | 20  | 54  | -                                 | 63                |
| Ocamet-500(G)          | 500mg/tab                                      | 14  | 20  | 16                                | 30                |
| Paracip(B)             | Paracetamol-500                                | 36  | 87  | -                                 | 59                |
| Dolo(G)                | mg/tab   | 10  | 10  | 8                                 | 0                 |
| Prolol(B)              | Propranolol-40                                 | 30  | 36  | -                                 | 17                |

|             |               |     |     |    |    |
|-------------|---------------|-----|-----|----|----|
| ProvanoL(G) | mg/tab        | 30  | 35  | 28 | 14 |
| Pantop(B)   | Pantoprazole- | 150 | 175 | -  | 15 |
| Pantocet(G) | 40mg/tab      | 40  | 45  | 36 | 11 |

**Quality of Branded and Branded Generic Pair of Medicines**

Determination of percentage purity: All the five “paired” medicines of branded and branded-generics gave positive identification tests when tested on UV spectroscopy and HPLC.

The different concentrations of 2, 4, 6, 8, 10 µg/mL were scanned and the wavelength of maximum absorption was found and tabulated.

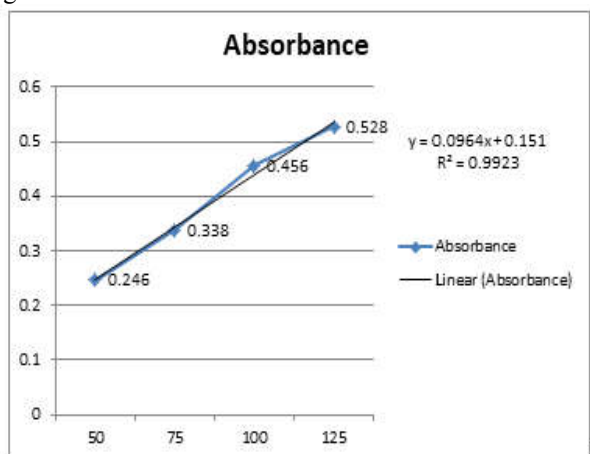
**Paracetamol**

**Branded drug**

**Table 2** Conc. Vs Abs. table for Linearity Study

| Concentration(µg/ml) | Absorbance |
|----------------------|------------|
| 50                   | 0.246      |
| 75                   | 0.338      |
| 100                  | 0.456      |
| 125                  | 0.528      |
| 150                  | 0.672      |

It depicts the absorbance values for different dilutions of paracetamol stock solution. This was graphically represented in figure 1.



**Fig 1** linearity curve of paracetamol.

**Table 3** Evaluation data of percentage purity

| % Recovery | Mean% recovery | SD      |
|------------|----------------|---------|
| 98.63      |                | 0.00577 |
| 98.63      | 98.62          | 0.00543 |
| 98.61      |                | 0.00816 |

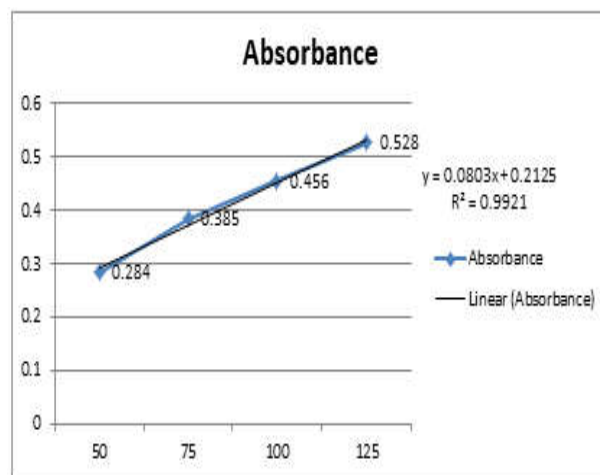
Table 3 describes the recovery of drug in percentages and standard deviation and results shown that mean % recovery was 98.62%

**Generic drug**

**Table 4** Conc. Vs Abs. table for Linearity Study

| Concentration(µg/ml) | Absorbance |
|----------------------|------------|
| 50                   | 0.284      |
| 75                   | 0.385      |
| 100                  | 0.456      |
| 125                  | 0.528      |
| 150                  | 0.689      |

It depicts the absorbance values for different dilutions of paracetamol stock solution. This was graphically represented in figure 2.



**Fig 2** linearity curve of paracetamol

**Table 5** Evaluation data of percentage purity

| % Recovery | Mean % recovery | SD     |
|------------|-----------------|--------|
| 98.00      |                 | 0.0977 |
| 97.85      | 98.50           | 0.0943 |
| 98.05      |                 | 0.0816 |

Table 5 describes the recovery of drug in percentages and standard deviation and results shown that mean % recovery was 98.50%.

Results shown that both the generic and branded drugs meet the standards in IP.

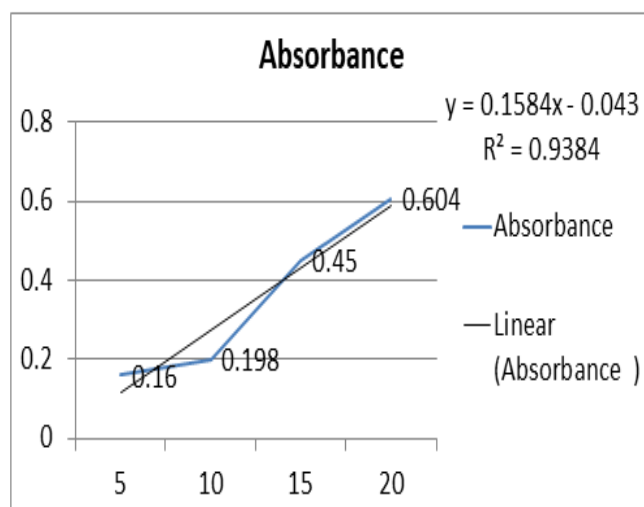
**Atorvastatin**

**Branded**

**Table 6** Conc. Vs Abs. table for Linearity Study

| concentration(µg/ml) | Absorbance |
|----------------------|------------|
| 5                    | 0.160      |
| 10                   | 0.198      |
| 15                   | 0.450      |
| 20                   | 0.604      |
| 25                   | 0.754      |

It depicts the absorbance values for different dilutions of atorvastatin stock solution. This was graphically represented in figure 3.



**Fig 3** linearity curve of atorvastatin

**Table 7** Evaluation data of percentage purity

| % recovery | Mean % recovery | SD   |
|------------|-----------------|------|
| 98.30      |                 | 0.02 |
| 98.45      | 98.70           | 0.05 |
| 99.37      |                 | 0.01 |

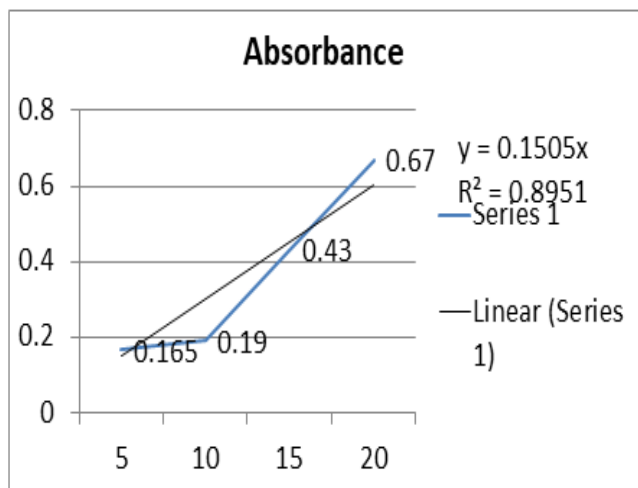
Table 7 describes the recovery of drug in percentages and standard deviation and results shown that mean % recovery was 98.70.

**Generic drug**

**Table 8** Conc. Vs Abs. table for Linearity Study

| concentration( $\mu\text{g/ml}$ ) | Absorbance |
|-----------------------------------|------------|
| 5                                 | 0.165      |
| 10                                | 0.190      |
| 15                                | 0.430      |
| 20                                | 0.670      |
| 25                                | 0.780      |

It depicts the absorbance values for different dilutions of atorvastatin stock solution. This was graphically represented in figure 4.



**Fig 4** linearity curve of atorvastatin

**Table 9** evaluation data of percentage purity.

| % recovery | Mean % recovery | SD   |
|------------|-----------------|------|
| 98.30      |                 | 0.02 |
| 98.45      | 98.70           | 0.05 |
| 99.37      |                 | 0.01 |

Table 9 describes the recovery of drug in percentages and standard deviation and results shown that mean % recovery was 98.70.

Results shown that both the generic and branded drugs meet the standards in IP.

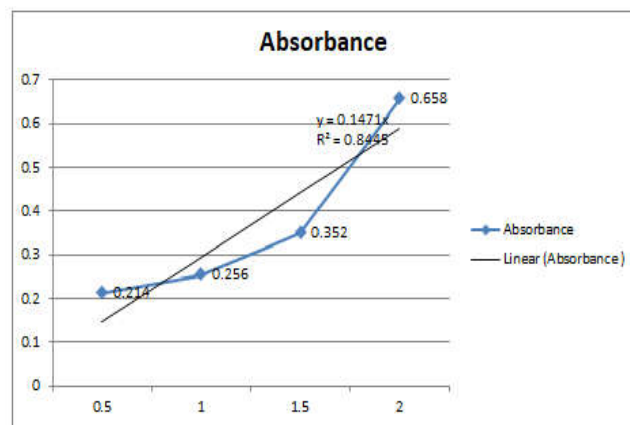
**Metformin**

**Branded**

**Table 10** Conc. Vs Abs. table for Linearity Study

| Concentration ( $\mu\text{g/ml}$ ) | Absorbance |
|------------------------------------|------------|
| 0.5                                | 0.214      |
| 1.0                                | 0.256      |
| 1.5                                | 0.352      |
| 2.0                                | 0.658      |

It depicts the absorbance values for different dilutions of Metformin stock solution. This was graphically represented in figure 5.



**Fig 5** linearity curve of Metformin

**Table 11** evaluation data of percentage purity.

| %recovery | Mean% recovery | SD    |
|-----------|----------------|-------|
| 100.08    | 99.62          | 0.481 |
| 99.56     |                | 0.612 |
| 99.23     |                | 0.681 |

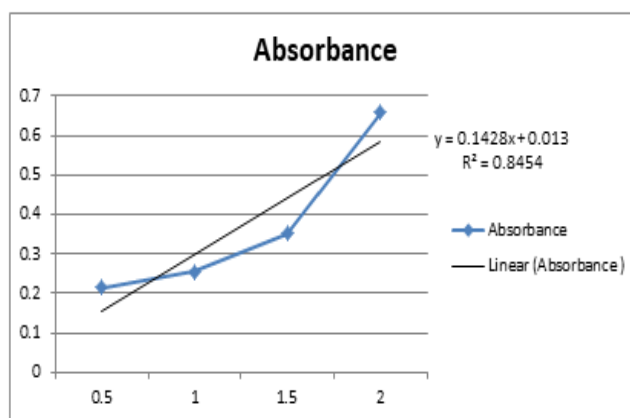
Table 11 describes the recovery of drug in percentages and standard deviation and results shown that mean % recovery was 99.62.

**Generic**

**Table 12** Conc. Vs Abs. table for Linearity Study

| concentration( $\mu\text{g/ml}$ ) | Absorbance |
|-----------------------------------|------------|
| 0.5                               | 0.214      |
| 1.0                               | 0.256      |
| 1.5                               | 0.352      |
| 2.0                               | 0.658      |

It depicts the absorbance values for different dilutions of Metformin stock solution. This was graphically represented in figure 6.



**Fig 6** linearity curve of Metformin

**Table 12** evaluation data of percentage purity.

| %recovery | Mean% recovery | SD    |
|-----------|----------------|-------|
| 100.08    | 99.60          | 0.481 |
| 99.56     |                | 0.612 |
| 99.23     |                | 0.681 |

Table 12 describes the recovery of drug in percentages and standard deviation and results shown that mean % recovery was 99.60.

Results shown that both the generic and branded drugs meet the standards in IP.

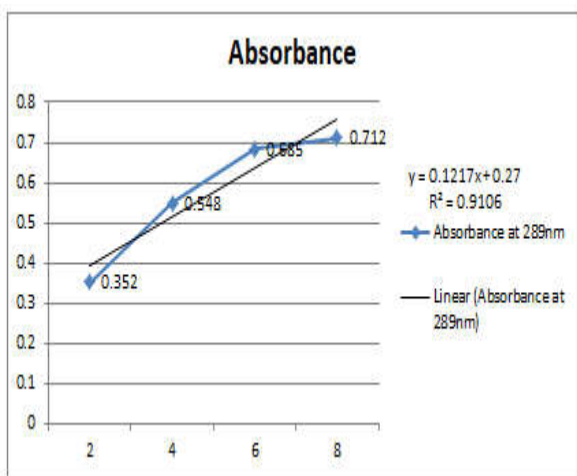
**Propranolol**

**Branded**

**Table 13** Conc. Vs Abs. table for Linearity Study

| Concentration | Absorbance at 289nm |
|---------------|---------------------|
| 2             | 0.352               |
| 4             | 0.548               |
| 6             | 0.685               |
| 8             | 0.712               |

It depicts the absorbance values for different dilutions of propranolol stock solution. This was graphically represented in figure 7.



**Fig 7** linearity curve of propranolol

**Table 14** Evaluation data of percentage purity.

| %recovered | Mean % recovered | SD   |
|------------|------------------|------|
| 96         | 98.19            | 1.7  |
| 99.98      |                  | 0.02 |
| 98.6       |                  | 0.52 |

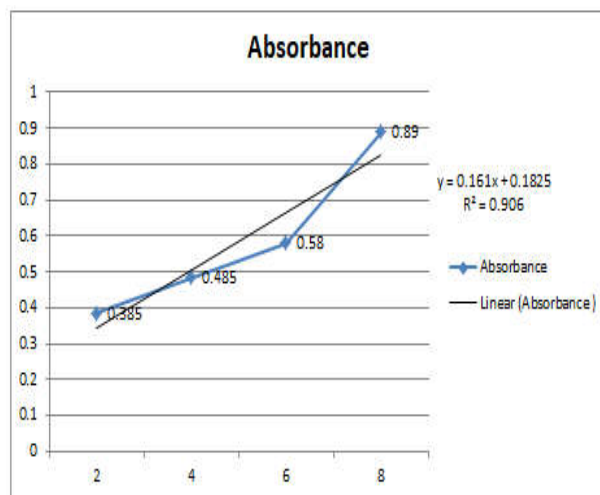
Table 14 describes the recovery of drug in percentages and standard deviation and results shown that mean % recovery was 98.19

**Generic**

**Table 15** Conc. Vs Abs. table for Linearity Study

| Concentration(µg/ml) | Absorbance |
|----------------------|------------|
| 2                    | 0.385      |
| 4                    | 0.485      |
| 6                    | 0.580      |
| 8                    | 0.890      |

It depicts the absorbance values for different dilutions of propranolol stock solution. This was graphically represented in figure 8.



**Fig 8** linearity curve of propranolol

**Table 16** evaluation data of percentage purity

| %recovered | Mean % recovered | SD   |
|------------|------------------|------|
| 96         | 98.19            | 1.7  |
| 99.98      |                  | 0.02 |
| 98.6       |                  | 0.52 |

Table 16 describes the recovery of drug in percentages and standard deviation and results shown that mean % recovery was 98.19.

Results shown that both the generic and branded drugs meet the standards in IP.

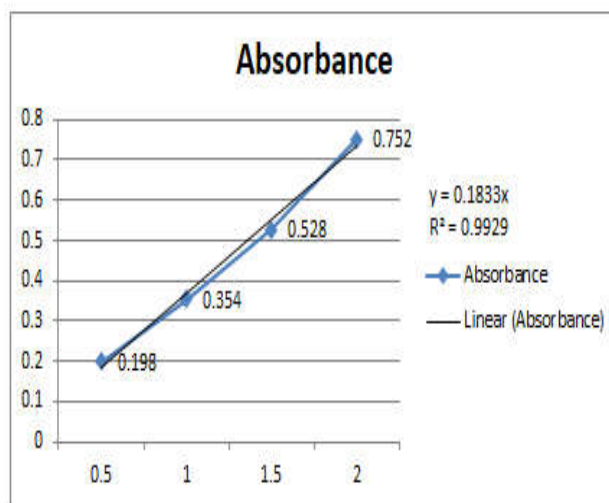
**Pantoprazole**

**Branded**

**Table 17** Conc. Vs Abs. table for Linearity Study

| Concentration(µg/ml) | Absorbance |
|----------------------|------------|
| 0.5                  | 0.198      |
| 1.0                  | 0.354      |
| 1.5                  | 0.528      |
| 2.0                  | 0.752      |
| 2.5                  | 0.986      |

It depicts the absorbance values for different dilutions of Pantoprazole stock solution. This was graphically represented in figure 9.



**Fig 9** linearity curve of Pantoprazole

**Table 18** evaluation data of percentage purity

| %recovered | Mean% recovered | SD     |
|------------|-----------------|--------|
| 100.22     | 100%            | 0.0849 |
| 99.9       |                 | 0.647  |
| 100.1      |                 | 0.597  |

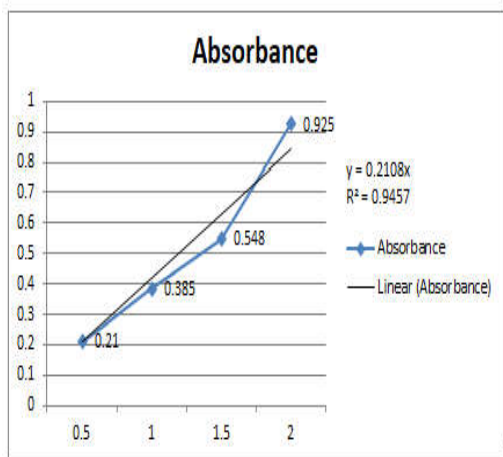
Table 18 describes the recovery of drug in percentages and standard deviation and results shown that mean % recovery was 100

**Generic**

**Table 19** Conc. Vs Abs. table for Linearity Study

| Concentration(µg/ml) | Absorbance |
|----------------------|------------|
| 0.5                  | 0.210      |
| 1.0                  | 0.385      |
| 1.5                  | 0.548      |
| 2.0                  | 0.925      |
| 2.5                  | 1.03       |

It depicts the absorbance values for different dilutions of Pantoprazole stock solution. This was graphically represented in figure 10.



**Fig 10** linearity curve of Pantoprazole

**Table 20** evaluation data of percentage purity

| %recovered | Mean% recovered | SD     |
|------------|-----------------|--------|
| 100.22     | 100%            | 0.0849 |
| 99.9       |                 | 0.647  |
| 100.1      |                 | 0.597  |

Table 20 describes the recovery of drug in percentages and standard deviation and results shown that mean % recovery was 100.

Results shown that both the generic and branded drugs meet the standards in IP.

**DISCUSSION**

An observational and experimental study was conducted on “comparison price and quality of generic versus branded drugs” and main aim is to assess the price and quality of generics versus branded formulation from same company that are manufactured in India,

Based on the results obtained our study reveals that both the generics and branded versions of same drugs were having equal quality of standards as per standards mentioned in ip 2018. Which was similar to study done by Mosab Arafat, et.al.,(2017) conducted a study on “Comparison Between

Generic Drugs And Brand Name Drugs From Bioequivalence And Thermo equivalenceProspective”. Which shown that Quality of generics is same as for their branded version.

In our study we systematically evaluate the price-to-patient and retailer mark-up for the branded and branded-generic versions of the same therapeutic molecule manufactured by the same company. This study has also evaluated the quality of the two versions. Findings of the study revealed that there are huge mark-ups for retailer on generic medicines upto 25-65%.

When compared the percentage of markup for PTR both the generic and branded drugs having high outcomes of margins and presently in branded drugs markup to retailer is on average of 25-50%. Which was similar to work done by G.L. Singal, et.al.,(2011) conducted a study on “A Comparative Evaluation Of Price And Quality Of Some Branded Versus Branded–Generic Medicines Of The Same Manufacturer In India”. Which shown that generic drugs are having huge profits to PTR when compared to branded drugs[1].

Our study also shown that generic drugs are far cheaper than branded drugs of same manufacturer and when compared to price structure generic drugs are available at 30-50% lesser than branded drugs. Which was similar to study conducted by MariaElena Flacco et al.,(2016) conducted a study on “Registered Randomized Trials Comparing Generic and Brand-Name Drugs: A Survey”. Stated that generic substitution drugs are available at 25% cheaper than branded drugs in north india[10].

our study revealed that all the branded and generic drugs which was analysed are having high standards and meet the requirements as per indian pharmacopoeia 2018, results were having standard deviation an average of (SD=0.001 to 1.5) which is in limit range and quality of generic drugs are having same as that of branded drugs. Which was similar to study conducted by Mubarak Nasser, Al Ameri et.al., (2011) conducted an experimental study on “The Differences Between The Branded And Generic Medicines Using Solid Dosage Forms: In-Vitro Dissolution Testing”. Stated that A total of 13 branded medicines and 24 generic counterparts were obtained locally and internationally were

collected. Most medicines in this study complied with the pharmacopeial limits.

**CONCLUSION**

Findings of our present study indicate that both the branded and generic versions of medicines had identical quality and they fulfilled all the criteria prescribed by the statutory standards. Hence, the general notion and doubt regarding the quality of the branded-generic version of medicines needs to be erased conducting more such studies and publishing them widely [9].

Our study concluded that price of generic drugs were far cheaper than branded counter parts and generic drugs are substantially having high margins for retailer than public domain.

Suitable changes in the drug price policy may be made to have lower prices for branded versions. Transparency in fixing the MRP by the manufacturer and clear guidelines for mark-ups at least for generics is required in pharmaceutical trade[4]. The government must take up generic promotional schemes, general awareness programs on quality of generics to build

confidence among prescribers, pharmacists, and consumers. Availability of generics or branded drugs in the market with lower price tag and assured quality is essential to make the medicines affordable.

#### **Future Prospectives**

By using the basis of this study one can educate patients regarding usage of generic and branded drugs.

Further observational studies can be performed by assessing the usage of drugs by patients those who switch from branded drugs to generic drugs and can easily assess the disease progression.

#### **Limitations**

Price structure may vary from region to region which accuracy may not be obtained

Quality control studies was performed and some deviations can be seen in spectroscopy evaluations those which are minor.

#### **Benefits**

By conducting this study we can easily come to a conclusion that generic substitution of branded drugs are having same quality and percentage purity and can be prescribed and can be used. Economic burden on patient can be minimized.

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