Journal of Medical Pharmaceutical And Allied Sciences

www.jmpas.com
ISSN 2320-7418

RESEARCH ARTICLE

COMPARATIVE PHARMACEUTICAL STUDY OF SOME BRANDED AND GENERIC TABLET FORMULATIONS

Manoj Gajanan Bajait*, Roshan Ghatmale, Bhagyashree mundhey

Sandip Institute of Pharmaceutical Sciences, Nashik, Maharastra

Correspondence

Manoj Gajanan Bajait

Sandip Institute of Pharmaceutical Sciences, P.O. Mahiravani, Trimbak Road Nashik, Maharastra, India.

✉ **bajitmanoj@gmail.com**

Keywords

Branded medicine, Generic drug Active Pharmaceutical Ingredient

Received

10/10/2019

Reviewed

15/10/2019

Revised/ Accepted

18/10/2019

ABSTRACT

A branded medicine is the original medicine developed by the pharmaceutical company so that branded medicines are also known as inventor drugs. During the research, the company spends a huge amount of money so that the company files the patent of the drug to recover the money spent during research. The generic drugs are the drug that contains the same chemical substance as a drug that was patented by the branded drug. A generic drug is allowed to sell after the expiry of the patent which files by the inventor company. The generic drug contains the same active pharmaceutical ingredient as of the branded product. The present study aimed to compare the generic and branded tablet formulation which are frequently prescribed, sell or purchased (over the counter) in terms of the pharmaceutical parameters

INTRODUCTION

In 2008, the government of India started "jan Aushadhi" the program contemplates making unbranded quality medicine available to the patient at affordable price through retail store.

The MCI (Medical Council of India) in October 2016 has recommended that every physician prescribed drug with generic drug name.

MATERIALS AND METHODS

Tablet is a most convenient and widely accepted dosage form due to some benefits like ease of use, patient compliance, unit dose dispensing, easy to store and handle. Considering this we have chosen some frequently prescribed or sold tablet formulation over the counter of following category

Over The Counter Tablets Formulations

1. Anti-allergic
2. Analgesic
3. Antacid

Prescribed Tablet Formulations

1. Antibiotic
2. Antihypertensive
3. Anti-diabetic

Requirements

Chemical

Distilled water, Phosphate Buffer (pH 6.8), Phosphate Buffer (pH 7.2)

Equipment

1. Digital Weighing Balance (WENSAR)
2. Hardness Tester (MONTANSO, PFIZER)
3. Friability Tester (VEEGO)
4. Disintegration Apparatus (VEEGO)
5. UV- Spectrometer (SHIMADZU).

Method of Evaluation

Evaluation of tablets is most important aspect to check quality of product as per IP. Generally, evaluation is done by testing some common parameters like.

1 Weight Variations
2 Hardness
3 Friability
4 Disintegration
5 Percent content

1. **Weight Variation Test**

These test is carried out to ensure that the tablet contain the perfect amount of the drug. The 10 tablet are weigh individually using analytical balance then the average weight was calculated after that individual tablet weight was compare with average weight and percentage weight variation is calculated by using following formula(4).

$$PD = \frac{W_{avg} - W_{ind}}{W_{avg}} \times 100$$

Figure 2. Digital Weighing Balance

Hardness Test

The hardness test is used to determine the structural integrity and braking point of the tablet and to find out the changes during the storage condition, transportation, packaging and handling before usage. The hardness test is performed using Monsanto or Pfizer type hardness tester (5).

Figure 3. Hardness Tester

Friability test

The 6 tablets from each formulation were weighed and tested at a speed of 25 rpm for 4 min, the tablet dust was remove after 4 min and the tablet was weighed and the percent friability was find out using equation. Friability percentage was calculated using the following equation (6).

$$\% \text{ Friability} = \frac{W1 - W2}{W1} \times 100$$

Figure 4.Friability Tester

Disintegration Test

The disintegration test is used to know how the drug disintegrates into the solution. These tests are performed to know that the drug will disintegrate in a specified period of time or not when placed in the liquid medium under prescribed experimental condition. (7)

Figure 5. Disintegrating Apparatus

Percent Content

A. Levocetirizine Dihydrochloride

The 20 tablets are taken each tablet contain 5 mg of Levocetirizine were weighed and

crushed to powder, the average weight was calculated. The Powder equivalent to 10 mg of Levocetirizine was transferred in volumetric flask (100ML). A 50 ml Methanol was added and Sonicated for 15 minutes. The solution was further diluted and filtered using Whatmann filter paper no. 41, first 5 ml of filtrate was discarded. The solution was further diluted to obtained 10µg/ml solution with water and the concentration is found out using spectrophotometer (9).

B. Diclofenac Sodium

The twenty tablets are taken each contain 5 mg of Diclofenac sodium weigh and crush. The average weight was calculated. Powder equivalent to 10 mg of Diclofenac sodium was transferred in volumetric flask (100 Ml). A 50 ml of Distilled water was added and sonicated for 15 minutes, the solution was further diluted up to the mark with Distil water and filtered using Whatmann filter paper no. 41, and examined under UV at 376nm using Distilled water as blank (10).

C. Ranitidine Hydrochloride

Weigh and powder 20 tablet. Weigh a quantity of 25mg Ranitidine hydrochloride Dissolved and volume was made to 25 ml with methanol. The solution was further diluted with distilled water up to 100mL. The solution was filtered using whatman filter paper no.41, this solution was further diluted to obtain 10 µg/mL solution with water, Measure the Absorbance of resultant solution at maximum at about 200 to 400nm. Calculate percent content at specific absorbance 313nm (11).

D. Anhydrous cefixime

Twenty tablets of anhydrous cefixime was weigh and crushed to powder and average weight was calculated. Powder equivalent to 50 mg of anhydrous cefixime was transferred in of volumetric flask (50Ml) and diluted up to the mark with 0.1N HCL. The solution was sonicated for 45 minutes and filter using Whatman filter paper no. 41, the solution was further diluted to obtain 12µg/ml solution with 0.1N HCL and UV analysis was done at 283nm using 0.1N HCL as blank (12).

E. Amlodipine Besylate

Twenty tablets of Amlodipine Besylate were weighed crushed to powder and average weight was calculated. Powder equivalent to 5 mg of Amlodipine Besylate was transferred in 100 ml of volumetric flask. The solution was filtered using Whatmann filter paper no. 41, this solution was further diluted to obtain 10µg/mL solution with water and examine under UV at 283nm using water as blank (13).

F. Metformin Hydrochloride

Twenty tablets of Metformin Hydrochloride was weigh crushed to powder and average weight was calculated. Powder equivalent to 100 mg of Metformin Hydrochloride was

transferred in volumetric flask (100 Ml). A 50 ml of Water was added and then solution was further diluted up to the mark with water. The solution was filtered using whatman filter paper no. 41, the solution was further diluted to obtain 100µg/ml solution with water and examine under UV at 570nm using water as blank (14).

RESULTS

Anti-allergic Drugs: Levocetirizine Dihydrochloride Tablet IP

Selected Levocetirizine Dihydrochloride Branded (L. Hist) and Generic (Okacet) tablets was evaluated for the Weight variation, Hardness, Friability, Disintegration, and Percent Content. All the test results were found to be within the standard acceptable limit and very little or no significant difference between generic and branded tablets note. (Table-1, Figure.7)

Analgesic: Diclofenac Tablet IP

The entire test for generic (Reactine) and branded (Voveran) found to comply with stander range and there is no significant difference was observed between generic and branded formulation. (Table no-2, Figure No-8)

Antacids Drugs: Ranitidine Tablet IP

All the tests for generic (Pantakind) and branded (Pan 40) Tablet found to comply with the standard range and there was no significant difference was observed between the generic and branded tablet formulation. (Table-3, Figure-9)

Antibiotic Drugs: Anhydrous Cefixime

All the tests for generic (Zifi200) and branded (Miliximm200) Tablet was found to complies with the standard range. (Table-4, Figure-12)

Antihypertensive Drugs Amlodipine Tablet IP

All the tests for generic (Amlodep-5) and branded (Amlovas-5) Tablet were found to comply with the standard range and there is no significant difference was observed between the branded and generic tablet formulation.(Table-5, Figure No.13)

Anti-diabetics Drugs: Metformin Tablet IP

All the tests for generic (Okamet) and branded (Glyciphage) Tablet were found to comply with the standard range and there is no significant difference was observed between them.(Table-6, Figure-14)

DISCUSSION

Globally, the generic drug formulations are accepted as equivalent to the branded formulation. The Indian government also started campaigning for the same but the general population has some misconception. We attempt to evaluate physical or pharmaceutical differences between branded and generic drugs. We evaluated all the

generic and branded tablets for physical parameters like Weight Variation, Hardness, Friability, Disintegration, and Percent content. It was found that the generic and branded tablets from anti-allergic, analgesic, antacid, antibiotics, anti-hypertensive and anti-diabetic category is equivalent; there was a little variation in the category for the parametric test which is not significant and may not affect the efficacy of the drug. Although generic drugs are cheaper than the branded, they are equivalent in terms of physical pharmaceutical aspects.

Our study results showed that all the selected generic formulation have low cost than the branded formulation. Hence in terms of cost-effective generic drugs may be preferred over branded.

CONCLUSION

1. With very few exceptions the generic formulations are generally cheaper than brand and present study results showed that there is no significant pharmaceutical difference between them.
2. The patient with chronic disease is in trouble due to long-time heavy prescription cost containing branded drugs. The present study indicates that the generic the drug is cheaper in cost and equivalent with branded drug hence reduce the cost of prescription even OTC and increases patient survival.
3. Hence, considering the above pharmaceutical similarity and per capita income of the people generic drugs are a good choice instead of a branded one.
4. Present the study demonstrates pharmaceutical similarity, bioavailability and other evaluation parameters need to study for future prospect.

REFERENCES

1. www.fda.gov/drug/resourcesforyou/consumer/questionsanswers/ucm100100.htm.

2. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4355878.

3. Anand K. and Amareshwar P.; journal of chemical& Pharmaceutical Sciences; Quality Evaluation and Comparative Study on Tablet Formulations of Different Pharmaceutical Companies; 2(1), 2012, Page24-31.

4. https://www.google.com/search?tbm=isch&sa=1&ei=taXIz0Jsio9QO2jby4BA&q=weighing+balance

5. https://www.google.com/search?tbm=isch&sa=1&ei=6QKbXLrE5P5rQHjoq7YDA&q=disintegration+tes

6. https://www.google.com/search?tbm=isch&q=pfizer+hardness+tester&chips=q:pfizer+hardness+tester

7. https://www.google.com/search?q=uv+spectrometer&source=lnms&tbm=isch

8. https://www.google.com/search?tbm=isch &sa=1&ei=AwObXNSIHIGyAOw3Ksw&q= Dislution+tes

9. Nitin Kumar Patel, Pradeep Chouhan, Suresh Kumar Paswan, Prakash Kumar Soni. Development and validation of a UV spectrophotometric method for simultaneous estimation of combination of Montelukast sodium in presence of Levocetirizine Dihydrochloride, 2014; 6(3):313-321

10. Safila Naveed, Fatima Qamar. UV spectrophotometric assay of Diclofenac sodium available brands, 2014; 1(3):92-96

11. Kanakapura Basavaia, Paregowda Nagegowd, Veeraiah Ramakrishn. Determination of Drug Content of Pharmaceuticals Containing Ranitidine by Titrimetry and Spectrophotometry in Non-Aqueous Medium, 2005:207-2014

12. Md. Ahasan Ullah Nayon, Jeb-Un Nesa, Md. Shah Amran. Development and validation of UV Spectrometric Method for the Determination of Cefixime trihydrate in Bulk and Pharmaceutical Formulation; 2015: 3(22):1-5

13. Manisha Masiha, Bhilasha Mitta, Nandy Bc. Spectrophotometric simultaneous estimation of amlodipine besylate and losartan potassium tablet dosage form 2014: 7:6163

14. Naveed S, Qamar F, Sarwer G, Percentage Assay of Metformin in Different Medium Using UV-Spectrophotometer; World Research Journal of Organic Chemistry; 2014:012-01

15. Indian Pharmacopoeia, published by govt. of India, Ministry of Health and Family Welfare, New Delhi. Vol.2, 2014.

EXPERIMENTAL TABLE AND FIGURE

Table-1.Evaluation test of L.Hist and Okacet.

S.N	Evaluation Tests	Branded Drug (L. Hist)	Generic Drug (okacet)	Standard Drug Range	Status
1.	Weight Variation (% Deviation)	0.2±2.66	0.5±1.09	Less than 5	Complies
2.	Hardness (kg/cm2)	3±0.4	2.8±0.6	2.5 – 5 kg/cm^3	Complies
3.	Friability (% w/w)	0.8403	0.4721	Less than 1%	Complies
4.	Disintegration (min)	14±1	10±2	Within 15 minute	Complies
5.	Percent Content (%)	98.10	97.87	NLT 95% NMT 101%	Complies

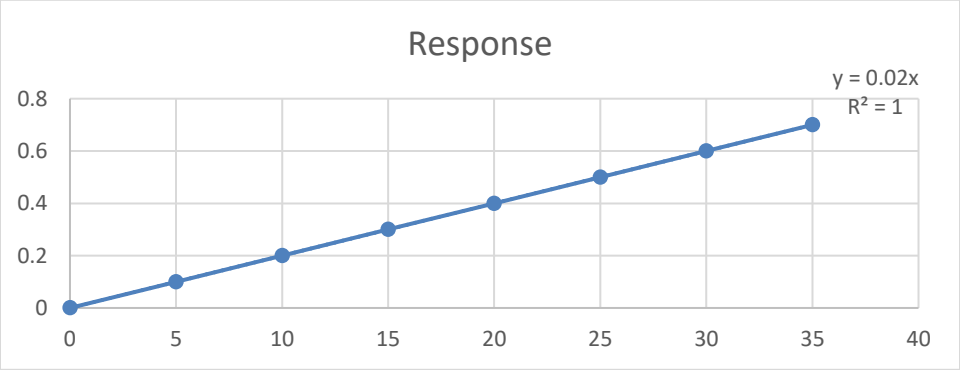

Figure.7: Standard Calibration curve of Levocetirizine Dihydrochloride.

Table no-2: Evaluation test of Voveran and Reactine

S.N.	Evaluation Tests	Branded Drug (Voveran)	Generic Drug (Reactine)	Standard Range	Status
1.	Weight Variation (%)	0.1±1.2	0.2±1.7	10	Complies
2.	Hardness (kg/c`m2)	3.2±0.4	3.4±0.4	2.5-5	Complies
3.	Friability (% w/w)	0.8620	0.09078	It should less than 1%	Complies
4.	Disintegration (min)	26±1	24±1	30	Complies
5.	Percent Content (%)	99.144	98.44	100±2%	Complies

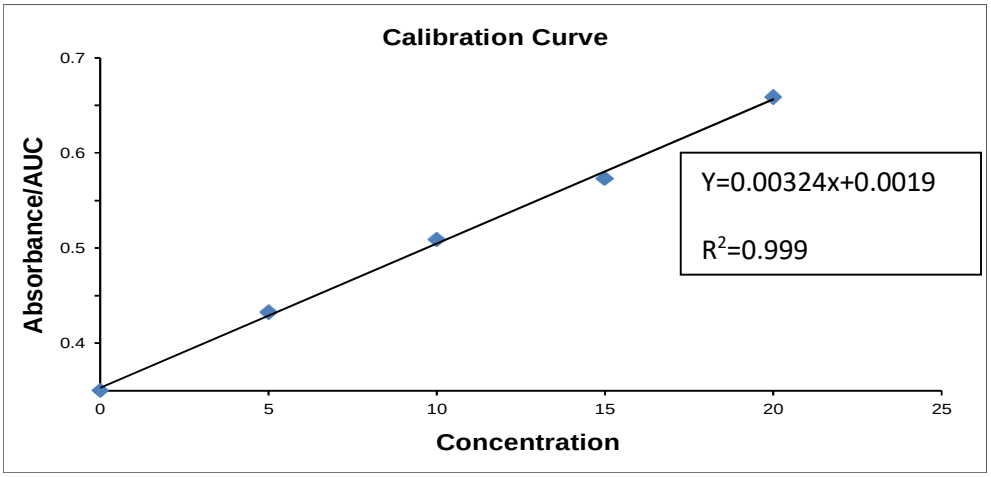

Figure No-8: Standard Calibration Curve of Diclofenac

Table-3. Evaluation test of Pan40 and Pantakind

S.N.	Evaluation Tests	Branded Drug (Pan 40)	Generic Drug (Pantakind)	Standard Range	Status
1.	Weight Variation (%)	0.2±1.2	0.5±2	5	Complies
2.	Hardness (kg/cm2)	2.8±0.8	2.6±1	2.5 to 5	Complies
3.	Friability (% w/w)	0.2090	0.9287	It should less than 1%	Complies
4.	Disintegration (min)	23±1	22±1	30	Complies
5.	Percent Content (%)	96.19	97.09	98±2	Complies

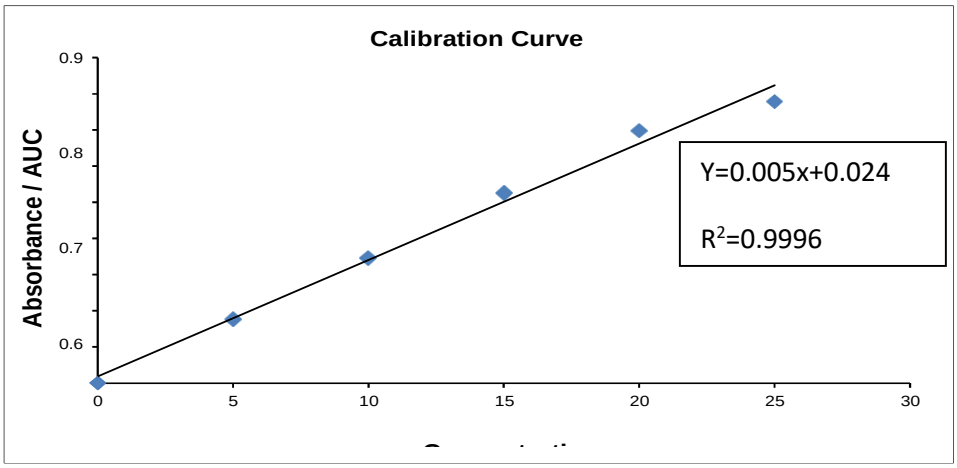

Figure 9: Standard Calibration curve of ranitidine

Table-4. Evaluation test of Zifi200 and Milixim200

S.N.	Evaluation Tests	Branded Drugs (Zifi200)	Generic drugs (Milixim200)	Standard Range	Status
1.	Weight Variation (%)	0.2±2.24	0.097±1.7	5	Complies
2.	Hardness (kg/cm2)	1.8±4	2.4±0.4	2.5 to 5	Complies
3.	Friability (% w/w)	0.0877	0.7680	It should less than 1%	Complies
4.	Disintegration (min)	4±1	5±1	Within 15 minutes	Complies
5.	Percent Content (%)	98.91	97.63	NMT 101% NLT 95%	Complies

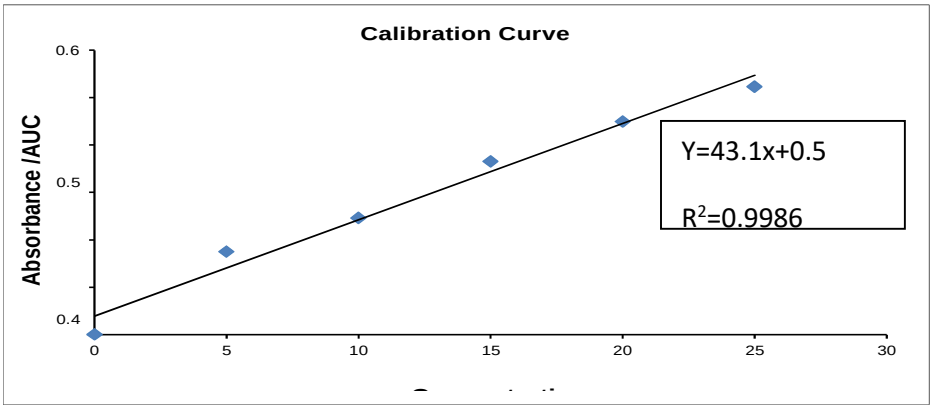

Figure-12. Calibration Curve of Cefixim

Table-5. Evaluation test of Amlovas-5 and Amlodep-5.

S.N.	Evaluation Tests	Branded Drug (Amlovas-5)	Generic Drug (Amlodep-5)	Standard Range	status
1.	Weight Variation (%)	0.3±2	0±1.3	±5%	Complies
2.	Hardness (kg/cm2)	4.0±0.115	3.56±0.20	2.5-5	Complies
3.	Friability (% w/w)	0.65	0.63	It should less than 1%	Complies
4.	Disintegration (sec)	24sec	10 sec	Within 15 minutes	Complies
5.	Percent Content (%)	96.34	99.53	100±5%	Complies

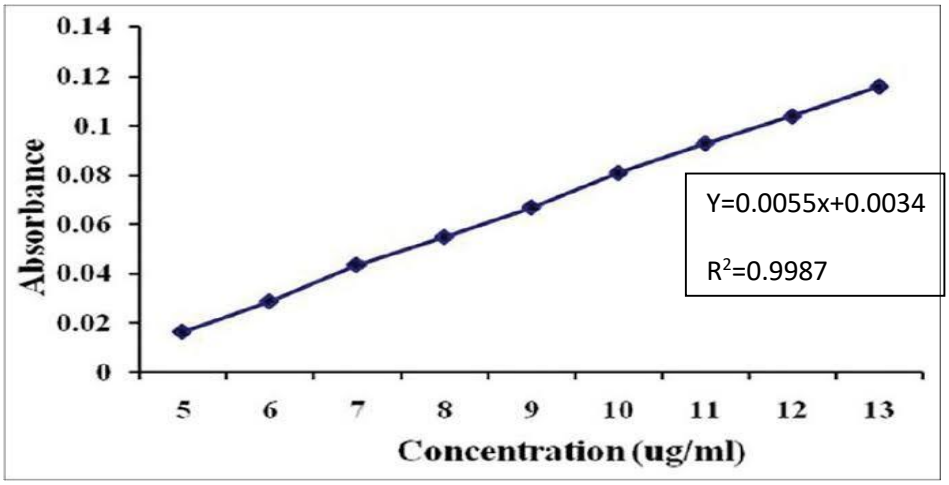

Figure No.13 Standard Calibration curve of Amlodipine Besylate

Table-6 Evaluation test of Glyciphage and Okamet-500

S.N.	Evaluation Tests	Branded Drugs (Glyciphage)	Generic drugs (Okamet)	Standard Range	status
1.	Weight Variation (%)	0.8193±0.1170	2.010±0.1153	±5	Complies
2.	Hardness (kg/cm2)	3.2±1	2.8±1	2.5-5	Complies
3.	Friability (% w/w)	0.1794%	0.1151%	It should less than 1%	Complies
4.	Disintegration (min)	13 minutes	14 minutes	Within 15 minutes	Complies
5	Percent Content (%)	100.08	95.25	100±5	Complies

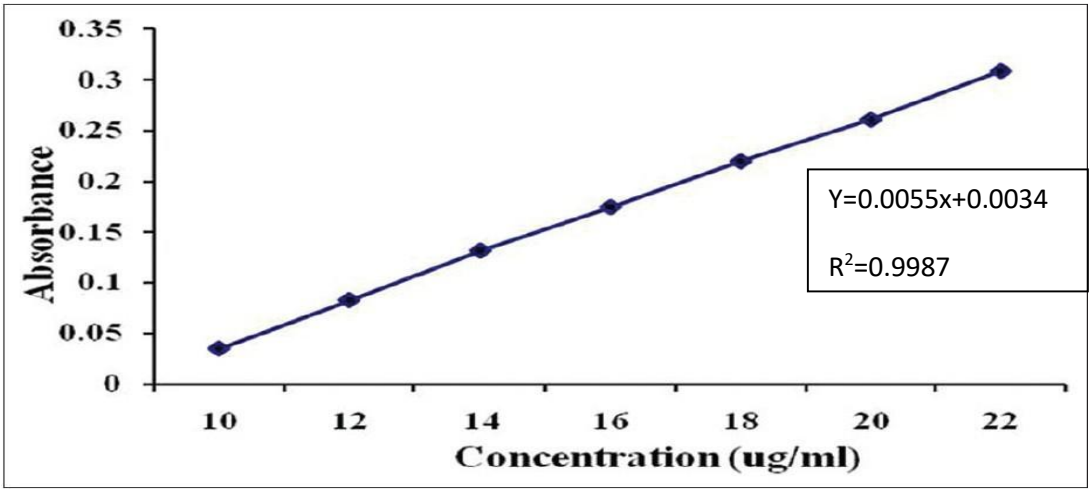

Figure-14: Standard Calibration curve of Metformin