

## COMPARING BRANDED DRUGS TO THEIR GENERIC EQUIVALENTS BY SPECTROPHOTOMETRIC METHODS

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### ABSTRACT

For the purposes of drug approval, the interchangeability of a generic drug and the corresponding brand-name drug is based on the criterion of "essential similarity," in drug content, type of active principle and therapeutic effectiveness as the original drug. Simple, accurate, precise, sensitive UV and Visible spectrophotometric methods were used to compare drug content in generic drugs with their branded equivalents. Simvastatin, furosemide, Clopidogrel bisulphate, Losartan potassium and paracetamol were estimated for their drug content in generic and branded dosage forms. The amount of difference was expected and acceptable and the difference between generic to branded comparison was about the same as the brand to brand comparisons.

**Keywords:** Clopidogrel bisulphate, furosemide, Losartan potassium, paracetamol, Simvastatin.

### INTRODUCTION

Brand-name drug<sup>1</sup> is a drug that has a trade name and is protected by a patent (can be produced and sold only by the company holding the patent). When the patent protection for a brand-name drug expires generic<sup>2</sup> versions of the drug can be offered for sale if the FDA agrees; "generic drugs are usually cheaper than brand-name drugs.

A generic drug is comparable to brand/reference listed drug product in dosage form, strength, route of administration, quality and performance characteristics, and intended use. A generic drug must contain the same active ingredients as the original formulation. According to the U.S. Food and Drug Administration (FDA)<sup>3-5</sup>, generic drugs are identical or within an acceptable bioequivalent range to the brand-name counterpart with respect to pharmacokinetic and Pharmacodynamic properties. Generic drugs are usually sold for significantly lower prices than their branded equivalents. Some of the reasons for the relatively low price of generic medicines are-competition increases among producers when drugs no longer are protected

by patents. Generic manufacturers do not incur the cost of drug discovery. Generic manufacturers also do not bear the burden of proving the safety and efficacy of the drugs through clinical trials, since these trials have already been conducted by the brand name company. Generic drugs can be produced without patent infringement for drugs where:

- 1) The patent has expired.
- 2) The generic company certifies the brand company's patents are either invalid, unenforceable or will not be infringed.
- 3) For drugs which have never held patents.
- 4) In countries where the drug does not have current patent protection.

Our present work aims to estimate the drug content in both generic and branded tablets by conducting simple spectrophotometric methods<sup>6-9</sup>.

### MATERIALS AND METHODS INSTRUMENTATION

The present work was carried out on Elico SL164 UV- visible spectrophotometer having

double beam detector configuration. The absorption spectra of reference and test solution were carried out in a 1 cm quartz cell over the range of 200-800nm.

#### **Drug solution**

A stock solution of 1 mg/ml was prepared and diluted to 100µg/ml with respective solvents for all the five generic and branded dosage forms.

#### **Chemicals**

2-propanol, conc.H<sub>2</sub>SO<sub>4</sub>, methanol, 0.1N NaOH, 0.1N HCl, 1N HCl, NaNO<sub>2</sub>, freshly prepared ammonium sulphamate.

### **PROCEDURE**

#### **SIMVASTATIN**

##### **Method I**

Aliquots of working standard solution of Simvastatin 1-6ml (100µg/ml) were transferred into a series of 10ml volumetric flask. The volumetric flasks are made up to the volume with 2-propanol. Then the absorbance of the samples is measured spectrophotometrically at 240nm against a reagent blank

##### **Method II**

Aliquots of working standard solution of Simvastatin 1-6ml (100µg/ml) were transferred into a series of 10ml volumetric flask. The volumetric flasks are made up to the volume with conc.H<sub>2</sub>SO<sub>4</sub>. Then the absorbance of the samples is measured spectrophotometrically at 415nm against a reagent blank

#### **2. FUROSEMIDE**

##### **Method I**

Aliquots of working standard solution of furosemide 1-6ml (100 µg/ml) were transferred into a series of 10 ml calibrated test tubes. The volume was made up to 10ml with methanol. Similarly, 3ml of 100µg/ml solutions of generic as well as branded tablets were taken in another two test tubes and made up to 10 ml with methanol. These were measured spectrophotometrically at 226nm against blank.

##### **Method II**

Aliquots of working standard solution of furosemide 1-6ml (100 µg/ml) were transferred into a series of 10 ml calibrated test tubes. The volume was made upto 10ml with 0.1N NaOH. Similarly, 3ml of 100µg/ml solutions of generic as well as branded tablets were taken in another two test tubes and made upto 10 ml with 0.1N NaOH. These were measured spectrophotometrically at 209nm against blank.

#### **3. CLOPIDOGREL BISULPHATE**

##### **Method I**

Aliquots of working standard solution of clopidogrel bisulphate 1-6ml (100 µg/ml) were transferred into a series of 10 ml calibrated test tubes. The volume was made up to 10ml with 0.1N hydrochloric acid. Similarly, 3ml of 100µg/ml solutions of generic as well as branded tablets were taken in another two test tubes and made up to 10 ml with 0.1N hydrochloric acid. These were measured spectrophotometrically at 222nm against blank.

##### **Method II**

Aliquots of working standard solution of clopidogrel bisulphate 1-6ml (100 µg/ml) were transferred into a series of 10 ml calibrated test tubes. The volume was made up to 10ml with 0.1N hydrochloric acid and water. Similarly, 3ml of 100µg/ml solutions of generic as well as branded tablets were taken in another two test tubes and made up to 10 ml with 0.1N hydrochloric acid and water. These were measured spectrophotometrically at 222nm against blank

#### **4. LOSARTAN POTASSIUM**

##### **Method I**

Aliquots of working standard solution of Losartan potassium 1-6ml (100 µg/ml) were transferred into a series of 10 ml calibrated test tubes. The volume was made up to 10ml with 0.1N hydrochloric acid. Similarly, 3ml of 100µg/ml solutions of generic as well as branded tablets were taken in another two test tubes and made up to 10 ml with 0.1N hydrochloric acid. These were measured spectrophotometrically at 395nm against blank.

##### **Method II**

Aliquots of working standard solution of Losartan potassium 1-6ml (100 µg/ml) were transferred into a series of 10 ml calibrated test tubes. The volume was made up to 10ml with water. Similarly, 3ml of 100µg/ml solutions of generic as well as branded tablets were taken in another two test tubes and made upto 10 ml with water. These were measured spectrophotometrically at 395nm against blank.

#### **5. PARACETAMOL**

##### **Method I**

Aliquots of working standard solution of paracetamol 1-6ml (100 µg/ml) were transferred into a series of 10 ml calibrated test tubes. The volume was made up to 10ml with 0.1N hydrochloric acid. Similarly, 3ml of

100µg/ml solutions of generic as well as branded tablets were taken in another two test tubes and made up to 10 ml with 0.1N hydrochloric acid. These were measured spectrophotometrically at 240nm against blank.

### Method II

Aliquots of working standard solution of paracetamol 1-5ml (100 µg/ml) were transferred into a series of 10 ml calibrated test tubes. Into the series of test tubes take 1,2,3,4 and 5ml of above solution of paracetamol (100µg/ml). To each test tube add 1ml of 1N HCl and 1ml of NaNO<sub>2</sub> and allow to stand for 5mins. To neutralize the nitrous acid add 1ml of freshly prepared ammonium sulphate. Shake vigorously and keep aside for 5mins. Then add 1ml of NaOH solution. Make up the volume up to 10ml and measure the absorbance at 430nm against the reagent blank.

### RESULTS AND DISCUSSION

The drug content in both generic and branded dosage forms are estimated using simple spectrophotometric methods and result were shown in table no.1. Above all five drugs the drug content in both generic and branded were same. Discussing the values; we cannot

clearly say that branded dosage forms are rich in drug content while generics are not and vice versa. In some drugs, generics are superior to brand and branded are superior to generic in drug content in some others. So, it's not right to underestimate generic dosage forms.

### CONCLUSION

From the above information, it clearly indicates that there is no difference in drug content in both the generic and branded dosage forms. Generic versions of a drug have different colors, flavors, or combinations of inactive ingredients than the original medications but the active ingredients were proved to be same. Of course the generic drugs cost less, it doesn't mean that they are of less quality.

So there's no truth in the myths that generic drugs are manufactured in poorer-quality facilities or are inferior in quality to brand-name drugs. The FDA applies the same standards for all drug manufacturing facilities, and many companies manufacture both brand-name and generic drugs.

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Table 1:

S.No	Drug	Labelled amount	Method-I		Method-II	
			Generic (mg/tab)	Branded (mg/tab)	Generic (mg/tab)	Branded (mg/tab)
1.	simvastatin	10mg/tab	8.91	9.57	8.91	9.24
2.	Furosemide	100mg/tab	96.6	106.6	93.3	96.6
3.	Clopidogrel bisulphate	75mg/tab	73	76.6	76.6	80
4.	Losartan potassium	50mg/tab	46.7	43.3	40	43.3
5.	Paracetamol	500 mg/tab	520	500	510	480

### REFERENCES

1. Generic Drugs, Center for Drug Evaluation and Research, U.S. Food and Drug Administration
2. www.medterms.com: definition of generic drug
3. Food & Drug Administration, Generic Drugs: Questions and Answers. Food and Drug Administration. January 12, 2010. Retrieved 2010-02-03.
4. Guidance for Industry: 180-Day Generic Drug Exclusivity under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (PDF). FDA, Center for Drug Evaluation and Research (CDER). June 1998. Retrieved August 24, 2009.
5. Authorized Generics. Generic Pharmaceutical Association (GPhA). 2008. Archived from the original on 2008-05-29. Retrieved 2008-06-16.
6. Merck index, Maryadele J.O.Neil Edu. In: 13th Ed. Published by Merck Research lab., NJ, USA.2001, 148.

7. Darkes MJ, Poole RM and Goa KL. Ezetimibe. *Am J Cardio Vasc Drugs*. 2003;3(1): 67-76.
8. Furosemide. The American Society of Health-System Pharmacists. <http://www.drugs.com/monograph/furosemide.html>. Retrieved 3 April 2011.
9. Rossi S. Australian Medicines Handbook 2004 (5th ed.). Adelaide, S.A.: Australian Medicines Handbook Pty Ltd. ISBN 0-9578521-4-2. <http://www.amh.net.au/>.
10. Chan FK, Ching JY and Hung LC. Clopidogrel versus aspirin and esomeprazole to prevent recurrent ulcer bleeding. *N Engl J Med*. 2008;352(3):238-44.doi:10.1056/NEJMoa042087. PMID 15659723.