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A Comparative Evaluation of Cost and *In-Vitro* Study between Branded and Generic Medicine

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Abstract

To compare and evaluate the price and quality of "branded" and branded-generic equivalents of some commonly used medicines manufactured by the different pharmaceutical company in India. Materials and Methods: Two commonly used medicines: TELMISARTAN and ONDANSETRON manufactured in branded and branded-generic versions by the different company were selected. Price-to-patient and price-to-retailers were found for two "pair" of medicines. Both quantitative and qualitative analysis were performed following the methods prescribed in the Indian Pharmacopoeia on two "pair" of medicines. The tests performed were identification test, dissolution studies. Result & Conclusion Price-to-patient (MRP) for two branded medicines were in the range of 58-23% but for their branded-generics version manufactured by the same companies (PTR) was in the range of 160-16%. Retailer mark-ups for two "pair" of medicines for branded versus branded-generic: telmisartan and ondansetron were 38% versus 160%, 44% versus 16% respectively. Both versions of two medicines were within their permissible range for all the quantitative and qualitative parameters as prescribed in Indian Pharmacopoeia.

Keywords: Branded Medicines; Branded-Generic; Generics; Mark-ups; Medicine price; India; Quality Testing; *In-Vitro*; Telmisartan; Ondasetron

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Introduction

Branded and Generic Medicines

Generic drugs

According to FDA "a drug product that is comparable to branded product is dosage form strength route of administration, quality and performance, characteristics, and intended use. It is a copy of branded drug whose patent has expired which has no longer exclusive rights to produce and distribute medicines [1].

Branded drugs

It is the original product that has been developed by pharmaceutical company. It has sole right to manufacture and distribution for a period of time (patent). A brand name drug is a small medicine that's discovered developed and marketed, by pharmaceutical company. One's a new drug is discovered, the company files for a patent to protect against other companies making copies and selling the drugs [2-5]. At this point the drug has two names - a generic name and a brand name to make it stand out in the market place.

Brand name medicine is originally discovered and developed by a pharmaceutical company. Brand name medicine is approved by FDA by submitting a New Drug Application along with data regarding proof of characteristics of dosage form, manufacturing, chemistry, stability, efficacy, safety, labelling and packaging. After approval by FDA only, the innovatory company can exclusively market this brand name medicine for a period of patent protection (about 20years or as specified). Brand name medicine is generally sold at high cost to cover expense in research and development of drug [6-9].

View of Professionals Doctors

Doctors generally not prescribed the generic because they are not completely satisfied about safe and effectiveness as compared to branded medicines. They have no any commission from manufacturer for prescribing generics like commission on branded. Doctors are also differ in their belief towards and experience with different medications, medical history, preference may also influence doctor's decision. When the doctor prescribed generic medicines they do not give patient health result as compared to branded medicines [10-15].

Pharmacist

They get minimum profits on sale of generics drugs as compared to branded medicines. There is also an availability issue of generic drug in Indian market. Less demand of generics by consumers due to less quality and result. Patient strictly follow the prescription which mostly contain branded medicines. The pharmacist can dispense any brand of the drugs when the prescriber writes the generic name on a prescription.

When patents or other periods of exclusivity on brand-name drugs are near expiration, manufacturers can apply to the FDA to sell generic versions by separate name called branded generic. If drug is manufacture and sold by its original name is called pure generics [16-19]. For both, submission of Abbreviated New Drug Application with data regarding bioequivalence study as a proof that the generic version deliver the same amount of active ingredients into a patient's bloodstream in the same amount of time as the innovator drug. All other data require are same as innovator drug product except preclinical and clinical data regarding safety and efficacy of medicine. Generic and branded drugs may be identical in formulations but differ in certain other characteristics such as shape, release mechanisms, packaging, excipients, expiration date/time and minor aspects of labelling and storage conditions. Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act allowed for the approval of generic copies of many approved drug after the patent had expired.

In India, 90% of branded generics share in the ~1-lakh-crore market.[4] India is the largest provider of generic drugs by exporting in more than 200 countries with the 20 per cent of global exports of generics in terms of volume. With flourish of generic market, now battle for better drugs is going on in India [20-22].

Materials and Methods

Materials

Telmisartan and Ondansetron were purchased from the Lincorn Pharmaceuticals was received as a gift sample. All other chemicals were of analytical grade were issued from Shankersinh Vaghela Bapu Institute of Pharmacy.

Methods

Selection of Drug

The drug Telmisartan and ondasetron were randomly picked for market research.

Market Cost Evaluation

Comparative evaluation of cost between branded and branded. Price-to-patient (MRP) for two branded medicines their branded-generics version manufactured by the same companies (PTR) was in the range. Retailer mark-ups for two "pair" of medicines for branded versus branded-generic: telmisartan and ondansetron.

Melting point determination [23-25]

The capillary method used as the standard technique for melting point determination. This method used by placing the drug into a capillary tube and bind them with the end of a thermometer for measuring degree of the melting point. Then fix them with a stand in such a way that the end tip of thermometer and capillary tube should be dipped into 100 ml liquid paraffin oil and heat it until drug start to melt.

Uniformity of weight

10 tablets of each branded and generic were weighed individually using a digital electronic balance and the average weight was calculated from the total weight.

Friability test

Friability test is performed to check the % of weight loss during transportation.

Friability of the tablets was determined using Roche friabilator at 25rpm/min for 4min.

10 tablets were weighed and loss in weight(%) was calculated by the following equation,

Friability=(w1-w2)/w1*100%

Where,W1= weight of 10 tablets

W2= weight after friability

Wetting time / Swelling index

The wetting time of the tablets was measured using a simple procedure (**Figure 1**). Two circular tissue paper were placed in petridish. Six milliliters of water containing Eosin Y ,a water soluble dye, was added to the petri-dish. A tablet was carefully placed on the surface of tissue paper. The time required for water to reach the upper surface of the tablets was noted as the wetting

Figure 1 Wetting Time

time (**Table 5**).

Disintegration time

It was performed by using USP DT apparatus. This apparatus contain a basket rack having six-open ended glass tubes held in a vertical position. A number ten-mesh stainless steel wire screen is attached to the bottom. To check for disintegration time, one tablet from each formulation was individually added into the basket of disintegration apparatus and temperature was set at 37°C. Finally the time required for complete disintegration was recorded (**Table 6**).

Dissolution test

Dissolution testing (**Figure 2**) measures the extent and rate of solution formation from a dosage form. It is important for its bioavailability and therapeutic effectiveness. In vitro dissolution studies were carried out by using the tablet dissolution tester. After reaching the bath temperature and basket temperature at 37.5 degree celcius, a tablet was placed in the basket and the paddle made to rotate at 50rpm.Aliquots of 5ml were collected at different temperature and the drug concentration was analysed by UV spectrophotometer (**Figure 3**).

%Purity

%Purity of a substance can be calculated by dividing the mass of the pure chemical by total mass of the sample and then multiplying this number by 100 (**Table 7**).

Result

Market Cost Evaluation

Price-to-patient (MRP) for two branded medicines was in the range of 58-23% but for their branded-generics version manufactured by the same companies (PTR) was in the range of 160-16% (**Table 1**). Retailer mark-ups for two "pair" of medicines for branded versus branded-generic: telmisartan and ondansetron were 38% versus 160%, 44% versus 16% respectively.

Melting point determination

Data of Uniformity of weight (Table 2)

Tablets were passed the weight variation test, according to official guidelines since the percentage deviation was under±7.5%. The uniformity of the weight implies proper tooling of the tablet punching machine (**Table 3**).

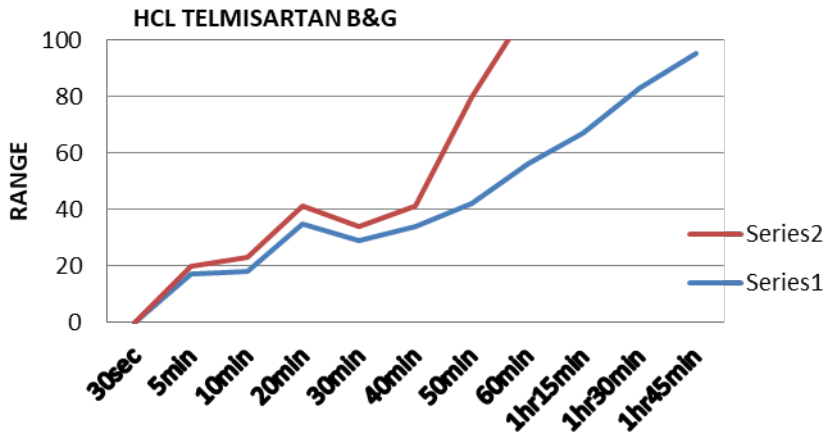

Figure 2 Comparison of Branded and Generic Medicine of Telisartan

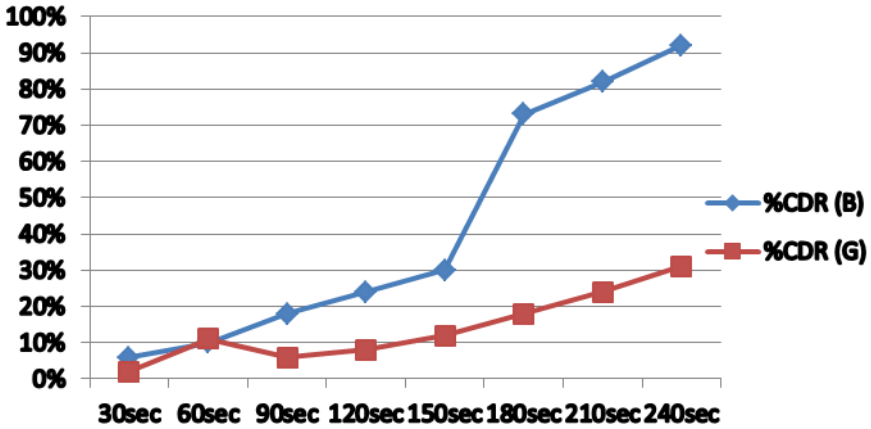

Figure 3 Comparison of Branded and Generic Medicine of Ondansetron

Table 1: Market Cost Evaluation

Trade Name	Pharmacological name, strength, dose	Manufacturer	PTR	MRP	Mark-up Retailer
TELMIRIDE B **TELMIZEM GB**	Telmisartan 40mg/tab	UNISON	26 10	36 15	38 50
ONDET-MD **VOMIKIND-MD**	Ondansetron 4mg/tab	INTAS	36 30.49	52 40	44 31

Table 2: Melting Point of Pure Drugs

	Reference	Pure
Telmisartan	183	180
Ondasetron	180	177

Table 3: Weight Uniformity

Drug	Branded	Generic
Telmisartan	180mg	240mg
Ondasetron	0.12mg	0.10mg

Table 4: Friability

	Weight before test (mg)	Weight after test (mg)	Percentage weight loss
Telmisartan(B)	102.1	101.9	0.19%
Telmisartan(G)	102.5	102.2	0.29%
Ondasetron(B)	103.9	103.6	0.28%
Ondasetron(G)	101.5	101.2	0.29%

Table 5: Wetting Time

Drug	Branded	Generic
Ondasetron	11	18

Table 6: DT

Disintegration time data

	Branded	Generic
Telmisartan	29sec	30sec
Ondasetron	21sec	23sec

Table 7: % Purity of Medicine

%Purity –

SR NO	Trade Name	Starting point	Ending point	% purity
1	**Telmiride 40**	0	0.5	99%
2	**Telmizem 40**	0	1	96%
3	**Ondet MD**	0	0.5	99%
4	**Vomikind MD**	0	0.5	99%

Data of friability test

Tablets of each batch were evaluated for percentage friability and the data's were shown below (**Table 4**).

The average friability of all the formulations lies in the range of 0.19% - 0.29% which was less than 1% as per official requirement of IP indicating a good mechanical resistance of tablets.

Wetting time

For Oldasetron as it is mouth dissolving.

Conclusion

The idea and evaluate the price and quality of "branded" and brandedgeneric equivalents of some commonly used medicines manufactured by the different pharmaceutical company in India is to provide an acceptable and practical approach for the objectives of finding.

After performing a comparative evaluation of cost and in vitro study between branded and branded. Price-to-patient (MRP) for two branded medicines were in the range of 58-23% but for their branded-generics version manufactured by the same companies (PTR) was in the range of 160-16%. Retailer mark-ups for two "pair" of medicines for branded versus branded-generic: telmisartan and ondansetron were 38% versus 160%, 44% versus 16% respectively. Both versions of two medicines were within their permissible range for all the quantitative and qualitative parameters as prescribed in IndianPharmacopoeia.

Pre-compression parameters.

Friability of tablets was less than 1%.

Weight variation test result showed that the weight of tablets tested was within the range ±7.5%.

Disintegration time of the tablets of optimized formulation BRANDED AND GENERIC was

Wetting time for ondasetron of optimized formulation is done 11 (b)-18 (g) sec.

Drug content uniformity study results showed that the drug Febuxostat was uniformly distributed throughout the formulation.

Finally, we conclude that, among prepared formulations, the prepared BRANDED AND GENERIC SHOW immense difference in market price and in testing of both.

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Conflict of Interest

The authors have no conflicts of interest regarding this investigation.

References

1 Sateesh KV, Karthik N (2015) Lovastatin fast dissolving tablets: Formulation and in vitro evaluation. Appl Sci Report. 11: 76-82.

2 Rakesh KB, Pradip KG (2012) Design and development of ondansetron orally disintegrating tablets and its optimization using design of experiment. Int J Pharm Sci Res. 3: 840-887.

3 Dahiwal SS, Bhokare SG (2017) *In vitro* evaluation of marketed brands of paracetamol tablets in India using quality control tests. Int J Pharm Res. 10: 182-192.

4 Menaka M, Pandey VP, Anton SA (2014) Colloidal dispersions as a potential nasal drug delivery system for ondansetron hydrochloride-*in vitro* and *in vivo* properties. Asian J Pharm Clin Res. 7: 72-85.

5 Maria ER, Maria GV (2014) Biopharmaceutical relevance of dissolution profile comparison: proposal of a combined approach. Dissolution Technologies 2: 32-43.

6 Wubayehu K, Ayenew A (2013) Comparative quality evaluation of some metronidazole tablets and metronidazole benzoate oral suspensions available in retail outlets of Addis Ababa, Ethiopia. Int J Pharm Sci Res. 4: 1384-1391.

7 Abdullah AR, Tariqul I, Sazaul MS, Faruk H (2018) Comparative study on quality analysis on marketed diclofenac sodium tablets of different brands available in Bangladesh. Res J Life Sci Bioinform Pharm Chem Sci. 4: 362-373.

8 Esimone CO, Okoye FBC, Onah BU, Nworu CS, Omeje EO (2008) In vitro bioequivalence study of nine brands of artesunate tablets marketed in Nigeria. J Vector Borne Dis. 45: 60-75.

9 Anupam R (2016) Oro dispersible tablets: a review. Asian J Pharm ClinRes. 9: 19-26.

10 Neelima RT, Lalitha KCT, Mallikarjun RB, Brahma RDR (2012) Comparitive in vitro evaluation of different commercially available brands of pantoprazole tablets. Int J Pharm Sci Res. 3: 1108-1111.

11 Akira F, Norio YF, Taku N, Takenori N, Manabu S et al. (2008) Comparative in vivo bioequivalence and in vitro dissolutionof two valproic acid sustained-release formulations. Drug DesDevel Ther. 2: 139-144.

12 Sravanthi M, Srinivasa RB. (2017) Design and evaluation of ondansetron fast disintegrating tablets using natural polymers and modified starches as super disintegrants for the enhancement of dissolution. J Young Pharm. 9: 519-524.

13 Shahtalebi MA, Tabbakhian M, Koosha S (2015) Formulation andevaluation of orally disintegrating tablet of ondansetron usingnatural superdisintegrant. J Herb Med Pharma col. 4: 102-119.

14 Ashwini D, Darshak KP (2015) Formulation and evaluation of oral disintegrating tablets of ondansetron hydrochloride by sublimation technique. Int J Biopharm. 5: 163-170.

15 Dhaval MR, Shwetha SKK, Shashank NN, Arpit SP, ShabarayaAR. (2013) Effect of natural super disintegrants on the fast dissolving tablet of carvedilol by sublimation method. Am J Pharm Tech Res. 3: 259-270.

16 Sudhakararao GV, Sujana K, Pedababu T (2014) Development and validation of uv spectrophotometric method for the estimationofondansetron in bulk and pharmaceutical formulation. W JPharm Res. 3: 2222-2234.

17 Harshal P, Chhaya V, Pravin J, Kavita M (2014) Development andevaluation of or dispersible tablets using a naturapolysaccharide isolated from cassia tora seeds. Integr Med Res. 3: 91-98.

18 Farzana H, Sharja N, Hasib AH, Shamima N (2017) Comparative bioequivalence study of different brands of valsartan tablets marketed in Bangladesh by dissolution modelling and quality control tests. W J Pharm Pharm Sci. 6: 112-121.

19 Rakshita AS, Shashank NN, Shwetha S, Kamath K (2019) Study of postcompression parameters of various marketed paracetamol tablets in India. Pharma Tutor. 7: 35-42.

20 Ronald P, Shashank NN, Shwetha SKK, Shabaraya AR (2014) Formulation and evaluation of fast dissolving tablets offlunarizine hydrochloride by sublimation method using sodium starch glycolate as superdisintegrant. Int J Pharm Tech Res. 6: 1085-1095.

21 Oby D, Sharifa S, Shohag H (2018) In vitro comparative quality evaluation of different brands of esomeprazole tablets available in selected community pharmacies in Dhaka, Bangladesh. MCRes Notes 11: 1-5.

22 Promit D, Sajan D, Rumana A, Sumaiya H, Raushanara A, et al. (2017) Comparative in vitro equivalence evaluation of some spironolactone generic tablets, commercially available in Bangladesh drug market. Indo Am J Pharm Res. 7: 544-551.

23 Shwetha SKK, Shashank NN, Srinivas H, Shabaraya AR (2013) Designand evaluation of fast dissolving tablet of caffeine by usingnatural superdisintegrant. Inventi Rapid: Pharm Tech. 77: 1-4.

24 Shashank NN, Shwetha SKK, Arpit SP, Srinivas H, Shabaraya AR (2013) Formulation and evaluation of fast dissolving tablet of caffeine by sublimation method. Inventi Rapid: Pharm Tech. 9: 1-4.

25 Mohammad S, Mohammad S, Bijja S, Ashraf Bv (2014) Evaluation of tablets by friability apparatus. Int J Res Pharm Chem. 4: 837-840.